

Endocrine Society Policy on Financial Conflicts of Interest in Sponsored Research

The Endocrine Society (ES) is dedicated to maintaining public trust in the integrity of our research-related activities. The identification and responsible management of financial conflicts of interest (FCOI) are crucial both for safeguarding research objectivity and for compliance with federal regulations and ES policies.

The Endocrine Society seeks to ensure the integrity of its research and to comply with the federal Public Health Service's (PHS) requirements for institutions that seek research funding. The PHS has implemented 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") to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest. The FCOI Regulations are applicable to institutions that apply for or receive PHS grants or cooperative agreements for research and to each investigator (as defined below) planning to participate in or participating in such research. This policy (the "FCOI Policy") is implemented to fulfill ES obligation under the FCOI Regulations to maintain an up-to-date, written, enforced policy and process on investigator conflicts of interest.

The following Conflict of Interest requirements apply to all Sponsored Research applications submitted to agencies within the Public Health Service (PHS), such as the National Institutes of Health (NIH). They may also apply to other sponsors that have adopted the PHS rules. The PHS Conflict of Interest policies must be met in addition to the Endocrine Society's Policy on Conflicts of Interest (ES COI Policy). As a result, the requirements outlined in the PHS policy apply to Investigators who are planning to conduct, or are conducting, Sponsored Research that is not otherwise prohibited by the ES COI Policy or other applicable requirements.

The PHS Conflict of Interest (COI) policies apply to Investigators (as defined below) involved in a Sponsored Research project that is part of PHS application for funding that has either been submitted by, or awarded to, ES. Presented below is a summary of the PHS policies on COI:

I. Definitions

The following definitions apply specifically in the context of this policy on Sponsored Research. Unless otherwise noted, capitalized terms used in this policy that are not defined herein will be given the meaning ascribed to them in the COI Policy.

A. Designated Officials. The Designated Officials will be the Signing Official and the Chair of the Endocrine Society Conflict of Interest Advisory Group.

B. Family. The "Family" of a Faculty member includes his or her spouse or domestic partner, and dependent children.

C. Financial Conflict of Interest (FCOI). A Significant Financial Interest or Travel that could directly and significantly affect the design, conduct, or reporting of Research.

D. Institutional Responsibilities. An Investigator's professional responsibilities on behalf of ES. These may include, for example, activities such as research, research consultation, teaching, and professional practice.

E. Investigator. The project director (PD) or principal investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Research supported by a grant awarded to ES.

F. 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). As used in this policy, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, institutional infrastructure award, institutional training grant, program project, or research resources award.

G. Reviewable Interest. Any Significant Financial Interest (SFI) belonging to an Investigator or an Investigator's Family, and any Travel, to the extent that it relates to the Investigators' Institutional Responsibilities. The Endocrine Society Conflict of Interest Advisory Group may in the future determine additional interests to constitute Reviewable Interests.

H. Senior/Key Personnel. The PD or PI and any other person identified as senior/key personnel by ES in the grant application, progress report, or any other report submitted to the PHS by ES.

I. Significant Financial Interest (SFI). A financial interest consisting of one or more of the following interests:

1. With regard to any publicly traded entity, when the value of any remuneration (salary and any payment for services that are not otherwise identified as salary, for example consulting fees, honoraria, paid authorship) received from the entity in the twelve (12) months preceding disclosure of the interest aggregated with the value of any equity in the entity (for example, stock, stock options, or other ownership interests as determined through reference to public prices or other reasonable measure of fair market value) in the entity as of the date of the disclosure exceeds \$5,000.
2. With respect to any non-publicly traded entity, when the aggregated value of any remuneration received from the entity in the twelve (12) months preceding disclosure of the interest exceeds \$5,000, or any equity in the entity; or
3. Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.

Exclusions: The term Significant Financial Interest does not include the following types of financial interests: 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 or 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.

J. Travel. Any travel that is reimbursed (i.e., the Investigator is made whole for the financial outlay required) or sponsored (i.e., the costs are paid on behalf of the Investigator such that the exact monetary value may not be readily available) other than by ES, a Federal state or local government agency, an institution or 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.

II. Investigator Disclosure to ES

All Covered Persons, including Investigators conducting Research for which a funding application has been made to an external funding agency or entity through ES, must disclose the information required herein and by the Endocrine Society on an annual basis in accordance with the process established by the ES COI Policy. At a minimum and no later than the time of application for funding, Investigators planning to participate in PHS-funded Research are required to disclose all Reviewable Interests (namely, (i) any Significant Financial Interests (SFIs) belonging to the Investigator or the Investigator's Family, and (ii) any Travel, to the extent the Investigator determines that the Reviewable Interest relates to the Investigators' Institutional Responsibilities). Investigators must update their disclosures annually during the period of the PHS award, as well as within 30 days of discovering or acquiring a new Reviewable Interest.

A. Travel Disclosures [For PHS-funded Research Only]: The following information must be provided in connection with any Travel disclosure in the context of PHS-funded Research:

1. The purpose of the trip;
2. The identity of the sponsor/organizer of the trip;
3. The destination of the trip; and 4. The duration of the trip.

B. Additional Information Requested by ES: Investigators must provide in a timely manner any information related to their disclosed Reviewable Interests that ES, in its discretion, deems relevant to its review and FCOI assessment.

III. Review by ES

Prior to expenditure of any funds under a Sponsored Research award, the Designated Official must reasonably determine whether any Reviewable Interest disclosed by any Investigator is related to the Sponsored Research; if so, whether it can reasonably be determined that the Reviewable Interest constitutes a Financial Conflict of Interest (FCOI); and if a FCOI is determined to exist, how the FCOI will be managed.

A. Relatedness Standard: An Investigator's Reviewable Interest is related to Sponsored Research when ES reasonably determines that the Reviewable Interest could be affected by the Sponsored Research; or is in an entity whose financial interest could be affected by the Sponsored Research. ES will be informed by the relevant Investigator in the determination of whether a Reviewable Interest is related to the Sponsored Research.

B. FCOI Standard: An FCOI exists if ES reasonably determines that the Reviewable Interest related to the Sponsored Research could directly and significantly affect the design, conduct or reporting of the Sponsored Research.

IV. Management of Identified FCOIs

A. Management Techniques: For any identified FCOI, ES, through its Designated Officials and with the advice and counsel of the Conflict of Interest Advisory Group, will take appropriate action to manage the conflict in order to reduce the potential for it to compromise the safety or validity of the Research. Research in which an Investigator is found to have an FCOI will not be permitted to proceed until the Investigator has agreed to implement an acceptable management plan.

B. Disclosed Interests That are Not FCOIs: ES reserves the right to impose any requirements it sees fit on any disclosed interest, even those that are not prohibited by the ES COI Policy, do not constitute Reviewable Interests and/or do not constitute an FCOI requiring management in accordance with this policy and/or applicable regulations.

C. Compliance with Management Plans: Investigators have an on-going obligation to adhere to an imposed management plan and failure to do so may be grounds for sanctions under this policy. ES will monitor Investigator compliance with an imposed management plan on an ongoing basis until the completion of the Sponsored Research project.

V. Reporting FCOIs to PHS

A. Content of Report: For all PHS awards, prior to expenditure of any funds under the award, ES is required to report to the PHS awarding agency the existence of an FCOI and submit an FCOI report.

B. Timing of Report: ES is responsible for submitting FCOI reports to PHS initially (prior to expenditure of funds), annually during the award period, and within 60 days of any subsequently identified FCOI.

VI. Subrecipient or Subcontractor

When proposed ES Research is to be funded by PHS and carried out through a subrecipient, ES 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 ES is able to meet its reporting obligations to the PHS awarding agency.

VII. Public Accessibility [For PHS-funded Research only]

For PHS-funded Research, ES will ensure public accessibility of information concerning the FCOIs currently held by Senior/Key Personnel subject to this policy. Unless and until ES determines otherwise, ES will, upon receipt of a complete written request for information in accordance with the process and requirements outlined in section XIII, provide a written response within five (5) business days regarding any SFI disclosed and still held by the Senior/Key Personnel that has been determined to relate to the PHS funded research and constitute an FCOI pursuant to this policy.

VIII. New Interests that Arise During an On-Going Sponsored Research Project

To the extent a new Reviewable Interest is disclosed to ES in the course of an on-going Sponsored Research project (i.e., an Investigator who is new to participating in the Research discloses a Reviewable Interest or an existing Investigator discloses a new Reviewable Interest), or ES identifies a Reviewable Interest that was not previously reviewed in a timely manner by ES in accordance with this policy, ES will, within 60 days from the date of the disclosure: (i) determine if the Reviewable Interest relates to the Investigator's Research; (ii) if it relates, determine if it qualifies as an FCOI; and (iii) if it is an FCOI, implement on at least an interim basis a management plan in accordance with this policy. ES may, depending on the circumstances of the SFI, conclude that additional interim measures are necessary with regard to the Investigator's participation in the Research between the date of disclosure or identification and the completion of ES review (including, where warranted for PHS-funded Research, a retrospective review as discussed below).

IX. Retrospective Review, Identification of Bias and Mitigation Reporting of PHS-Funded Research

A. Retrospective Review: In the event of failure to meet PHS regulations, including failure by the Investigator to disclose timely a Reviewable Interest that is determined to constitute an FCOI; ES's failure to review or manage such an FCOI; or Investigator failure to comply with an FCOI management plan, ES will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded Research project to determine any bias in the design, conduct or reporting of Research during the time period of the noncompliance. ES will document the retrospective review in accordance with its policies and procedures and applicable PHS regulations.

B. Mitigation. If bias is found during the retrospective review, ES will notify the PHS awarding agency promptly, if applicable, develop and implement a mitigation plan, and submit the PHS required mitigation report, which will include at least the elements documented in the retrospective review and a description of the impact of the bias on the Research project and ES's plan of action or actions taken to eliminate or mitigate the effect of the bias. Any FCOI report submitted to the PHS awarding agency with respect to such Research will be updated as necessary in light of the results of the retrospective review.

C. Disclosure for PHS-Funded Drug/Device Research: In any case in which the Department of Health and Human Services (HHS) 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 has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by ES, the Investigator will be required to disclose the FCOI in each public

presentation of the results of the research and to request an addendum to previously published presentations.

X. Training [For PHS-funded Research only]

For PHS-funded Research, Investigators must complete all required conflicts of interest training prior to engaging in Research at or under the auspices of ES, and at least every four years following the initial training. Additionally, Investigators will be required to receive training immediately in any of the following circumstances:

- ES revises its policy or procedures governing FCOI in PHS-funded Research in any manner that affects the requirements applicable to Investigators;
- An Investigator is new to ES;
- ES finds that an Investigator is not in compliance with this policy or an imposed management plan.

XI. Record Retention

ES will retain documentation related to its FCOI review and management process to the extent required by law and any other applicable ES record retention policies, but in no case will records be maintained for less than three years. Records will be maintained by the Endocrine Society.

XII. Noncompliance and Sanctions

In the event an Investigator fails to comply with this policy or an FCOI management plan imposed hereunder, the Conflict of Interest Advisory Group may impose a wide variety of sanctions, including but not limited to restricting or conditioning the Investigator's ability to apply for grants through ES, as well as imposing one or more of the sanctions outlined in the ES COI Policy. Additionally, if the failure of an Investigator to comply with this policy or an FCOI management plan appears to have biased the design, conduct or reporting of the PHS Research, ES shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

XIII. Public Accessibility Process

This FCOI Policy will be posted on an Endocrine Society publicly accessible website, as required by the FCOI Regulations. Prior to expending any funds under a PHS-funded grant or cooperative agreement, ES 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.

ES will make available the following information:

- Name of senior/key personnel with the financial conflict of interest;
- The individual's title and role in the research project;
- The name of the entity in which the financial interest is held;
- The nature of the financial interest;
- The approximate value of the financial interest (by ranges).

The Endocrine Society may be asked to provide records related to this FCOI Policy, including disclosure forms, to the Department of Health and Human Services or other federal agencies or entities. ES will provide the requested information and make any other disclosures necessary to comply with this FCOI Policy or as required by law. Such records may be requested and provided whether or not the disclosure resulted in a determination that an FCOI existed.