



New England College of Optometry Policy on Financial Conflicts of Interest For Public Health Service Sponsored Research

Preamble:

New England College of Optometry and New England Eye Institute, Inc. (collectively "NECO") strongly believe that it is vital that all research be conducted with the highest scientific and ethical standards. Research and the resulting interactions among government, research institutions, and the private sector have become increasingly complex. The ensuing increased public expectation to strengthen transparency and accountability has led the Department of Health and Human Services (HHS) to propose a more rigorous and transparent approach to investigator disclosures, management of financial conflicts, and federal oversight. In response to the major issues addressed by HHS, NECO has enacted this policy to reflect

- Lower financial disclosure thresholds
- New mandatory conflict of interest training
- New public accessibility requirements
- Increased transparency for travel reimbursements

Policy:

NECO's Investigators may from time to time apply for and/or receive funding through the Public Health Service (PHS) and its various funding agencies for their Research. The following requirements apply to research that is supported by the PHS, including at the time an application for funding is made to an awarding agency. This policy is intended to ensure that the PHS-funded Research conducted by NECO Investigators is free from bias; and, has been developed to meet the requirements of HHS Rule entitled "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors" and codified at 42 C.F.R. Parts 50 and 94.

- I. **Definitions.** The following definitions apply specifically in the context of this policy:
 - A. **Designated Official.** The Designated Official is NECO's Chief Financial Officer.
 - B. **Family.** Spouse 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 NECO. 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 NECO.

F. PHS. The Public Health Service, including the various agencies that are designated as components through which research grants are issued (for example, the National Institutes of Health (NIH)).

G. Research. A systematic investigation, study or experiment designed to develop or contribute to general 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).

H. Reviewable Interest. Any Significant Financial Interest (SFI) belonging to an Investigator or an Investigator's Family, and any Travel, to the extent either relates to the Investigator's Institutional Responsibilities.

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

J. 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 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. With respect to any 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.

- K. **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 NECO, 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.
- II. **Investigator Disclosure to NECO.** All NECO Investigators conducting or planning to conduct Research for which a funding application will be made to the PHS, must disclose no later than the time of application for funding 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:* The following information must be provided in connection with any Travel disclosure provided 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 NECO:* Investigators must provide in a timely manner any information related to their disclosed Reviewable Interests that NECO, in its discretion, deems relevant to its review and FCOI assessment.

III. **Review by NECO.** Prior to expenditure of any funds under a PHS award, the Designated Official must reasonably determine whether any Reviewable Interest disclosed by any Investigator is related to the Research; if so, whether it can reasonably be determined that the Reviewable Interest constitutes a Financial Conflict of Interest (FCOI); and if an FCOI is determined to exist, how the FCOI will be managed. The determinations of the Designated Official will be informed by the recommendations of the Research Financial Conflict of Interest Committee (RFCOIC), composed of the Vice President of Academic Affairs, Director of Research and Vice President Business Development.

A. *Relatedness Standard:* An Investigator's Reviewable Interest is related to the PHS-funded Research when NECO reasonably determines that the Reviewable Interest could be affected by the Research; or is in an entity whose financial interest could be affected by the Research. NECO may involve the relevant Investigator in the determination of whether a Reviewable Interest is related to the Research.

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

IV. **Management of Identified FCOI's.**

A. *Management Techniques:* For any identified FCOI, NECO, through its DO and with the advice and counsel of the RFCOIC, 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 FCOI's:* NECO reserves the right to impose any requirements it sees fit on any interest belonging to a NECO Investigator of which it becomes aware, even those that 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. NECO will monitor Investigator compliance with an imposed management plan on an ongoing basis until the completion of the PHS-funded Research project.

V. **Reporting FCOI's to PHS.**

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

B. *Timing of Report.* NECO 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.** When proposed Research is to be funded by PHS and carried out through a subrecipient, NECO will incorporate as part of a written agreement with the subrecipient terms that establish 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 NECO is able to meet its reporting obligations to the PHS awarding agency.
- VII. **Public Accessibility.** NECO will ensure public accessibility of information concerning the FCOI's currently held by Senior/Key Personnel subject to this policy. NECO will provide a written response within five (5) business days of receipt by the Designated Official of a complete written request for information regarding any SFI disclosed and still held by Senior/Key Personnel that has been determined to relate to the PHS-funded research and constitute an FCOI pursuant to this policy. Individuals seeking to make such requests should mail them to the attention of New England College of Optometry, ATT: Chief Financial Officer, 424 Beacon Street, Boston, MA 02115.
- VIII. **New Interests that Arise During an On-Going Research Project.** To the extent a new Reviewable Interest is disclosed to NECO in the course of an on-going PHS-funded 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 NECO identifies a Reviewable Interest that was not previously reviewed in a timely manner by NECO in accordance with this policy, NECO 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. NECO 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 NECO's review (including, where warranted, 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; NECO's failure to review or manage such an FCOI; or Investigator failure to comply with an FCOI management plan, NECO 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. NECO 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 of PHS-funded Research, NECO 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 NECO'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 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 NECO, 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**. NECO Investigators who plan to conduct PHS-funded Research must complete all required conflicts of interest training prior to engaging in such Research at or under the auspices of NECO, 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:

- NECO 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 NECO;
- NECO finds that an Investigator is not in compliance with this policy or an imposed management plan.

- XI. **Record Retention.** NECO will retain documentation related to its FCOI review and management process, and all actions required by this policy for at least three years from the date the final expenditures report is submitted to the PHS, or as otherwise required by law.
- XII. **Noncompliance and Sanctions.** In the event an Investigator fails to comply with this policy or an FCOI management plan imposed hereunder, NECO may impose a variety of sanctions as recommended by the RFCOIC, including but not limited to:
- Restricting or conditioning the Investigator's ability to apply for grants through NECO;
 - Ineligibility of the faculty member to supervise graduate students in research activities;
 - The inclusion in the Investigator's file of a letter from NECO administration calling into question the individual's good standing as an NECO faculty member;
 - Formal admonition;
 - Dismissal; or
 - Any other restriction, limitation or punishment recommended by the RFCOIC.
 - Additionally, for PHS-funded Research, 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 Research, NECO shall promptly notify the PHS awarding agency of the corrective action taken or to be taken.