

Financial Conflicts of Interest Related to Research Funded under the Public Health Service

Policy Statement

Individuals serving the Foundation of the Massachusetts Eye and Ear Infirmary, Inc. and its subsidiaries, including Massachusetts Eye and Ear Infirmary, Massachusetts Eye and Ear Associates, Inc., and Schepens Eye Research Institute, Inc. (collectively, Mass. Eye and Ear) serve the public trust and, therefore, must act in the interest of furthering Mass. Eye and Ear's charitable purpose. Decisions must be made in the interest of protecting and advancing (i) the mission and integrity of Mass. Eye and Ear and (ii) the clinical care, research, and teaching conducted at Mass. Eye and Ear.

Mass. Eye and Ear recognizes that those who serve Mass. Eye and Ear may have diverse financial and professional interests. As those individuals extend their professional and personal relationships outside Mass. Eye and Ear, potential or actual conflicts may arise both in their relationship to Mass. Eye and Ear and to the clinical care, research, and teaching they conduct.

This policy identifies and addresses the real or apparent conflicts of interest presented by the intersection of research activities and personal financial interests, and defines the requirements of research personnel who engage in Public Health Service (PHS)-funded research to ensure that those activities are conducted objectively and without consideration of personal financial gain.

Purpose

As set forth in this policy, Mass. Eye and Ear complies with Title 42 Code of Federal Regulations Part 50, (42 CFR 50) Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought*, which was established to ensure that the design, conduct, and reporting of Research will not be biased by a conflicting financial interest of an Investigator.

This Policy:

- applies to all Investigators, as defined in A.
- defines and identifies potential financial Conflicts of Interest in PHS-funded research;
- identifies personnel who must complete the disclosure process;
- sets forth the process for disclosure and completion of related forms;
- sets forth the process for reviewing disclosures made;
- sets forth the process for managing identified financial Conflicts of Interests; and
- provides guidance regarding sanctions for failure to abide by the Policy.

A. Definitions

Conflict of Interest in Research is an interest, commonly but not solely financial in nature, related to the design, conduct, analysis, reporting, or support of Research that creates or may be reasonably expected to create a bias stemming from that interest.

Family of an Investigator includes his or her spouse or domestic partner, and dependent children.

Financial Interest means anything of monetary value, including but not limited to salary or other payments for services (e.g. consulting fees or honoraria), equity interests (e.g. stocks, stock options, or other ownership interests), and royalties from intellectual property rights (e.g. patents or copyrights) held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable.

Financial Interest does not include:

1. Salary, royalties, or other remuneration from Mass. Eye and Ear;
2. Income from the authorship of academic or scholarly works;
3. Income from seminars, lectures, or teaching engagements sponsored by U.S. federal, state, or local governmental agencies; U.S. institutions of higher education; or U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, or medical centers;
4. Income from service on advisory committees or review panels for U.S. federal, state, or local governmental agencies; U.S. institutions of higher education; or U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, or medical centers; and
5. Equity interest or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, Financial Interest also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities, including travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. Financial Interest excludes travel reimbursed or sponsored by U.S. federal, state, or local governmental agencies, U.S. institutions of higher education, or U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, or medical centers.

Financial Conflict of Interest (fCOI) exists when the Institutional Official reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of the Research.

Institutional Official means the individual at Mass. Eye and Ear who is responsible for the solicitation and review of disclosures of significant financial interests, including those of the Investigator's Family, related to the Investigator's institutional responsibilities. For the

purposes of this policy, the Institutional Official is designated as the Vice President for Research and Academic Affairs or his/her designee.

Institutional Responsibilities means the Investigator's responsibilities associated with his/her Mass. Eye and Ear appointment or position, such as research, teaching, clinical activities, administration, and institutional (internal and/or external) professional committee service.

Investigator means any person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS. Anyone who leads, manages, or makes a substantive contribution to a significant research-related activity including proposal development, conduct of research procedures, and/or analysis or reporting of results should be included in this definition. In addition to the Principal Investigator, Investigators may be, for example, collaborators, co-investigators, consultants or fellows. Senior/Key Personnel should be considered as Investigators.

Management Plan means actions taken by Mass. Eye and Ear to address a fCOI, which can include reducing or eliminating the fCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PHS is the Public Health Service of the U.S. Department of Health and Human Services, and any components of PHS to which the authority of the PHS may be delegated, including the National Institutes of Health, Center for Disease Control (CDC), and Food and Drug Administration (FDA).

Principal Investigator (PI) is the individual responsible for directing the project or program being supported by a grant. He/she is responsible for the conduct of research and/or other activities described in a proposal for an award. In the context of this document, PI also means Program Director, Project Director, etc.

Research means a systematic investigation 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, and product development.

Senior/Key Personnel means the Principal Investigator and any other person identified as Senior/Key Personnel in a grant application, progress report, or any other report submitted to the PHS by Mass. Eye and Ear.

Significant Financial Interest (SFI) means a Financial Interest with an outside entity that reasonably appears to be related to the Investigator's Institutional Responsibilities, and

1. if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the twelve-month period preceding the disclosure, plus the value of any equity interest as of the date of disclosure, exceeds \$5,000; or

2. if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the twelve-month period preceding the disclosure exceeds \$5,000 or
3. if with a non-publicly traded entity, is an equity interest of any value as of the date of disclosure; or
4. is income related to intellectual property rights and interest not reimbursed through Mass. Eye and Ear.

B. Process for Disclosure of SFI by Investigators

1. **Annual Disclosure.** All Investigators must disclose their SFI to Mass. Eye and Ear prior to initiating PHS-funded Research and on an annual basis thereafter during the period of the award. This disclosure shall be made through the Financial Disclosure process that is described on the Mass. Eye and Ear intranet. For Investigators who are also Harvard Medical School (HMS) faculty, Mass. Eye and Ear accepts the annual Outside Activity Report required by HMS as the required disclosure under this policy.
2. **Ad hoc Disclosures.** In addition to the annual disclosure, all Investigators must disclose any newly acquired SFI or any changes to a previously disclosed SFI through the same process within thirty (30) days of acquiring or changing the SFI.
3. **Financial Disclosure Certification.** Prior to submitting a grant application to a PHS agency, each Investigator shall complete and submit to the Pre-award Office in Research Administration a Financial Disclosure Certification (FDC) form certifying that the Investigator's SFIs have been properly disclosed and are up-to-date. The PI must ensure that all Investigators (as defined above) are named on the project, have completed the disclosure process and have signed/submitted an FDC form. The Office of Research Administration will not permit the submission of any application until completed FDC forms are received for all Investigators named in the application.

Travel Disclosure. Investigators must disclose reimbursed or sponsored travel related to their institutional responsibilities and that, when aggregated with any other remunerations from the same entity over the previous 12 months is \geq \$5,000. Disclosures must be made within 30 days of such travel. Such disclosures must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Institutional Official will determine whether additional information is needed to decide whether the travel constitutes an fCOI with the Investigator's Research.

4. Investigators who conduct Research at Mass. Eye and Ear but who are not employed by Mass. Eye and Ear must also disclose any SFIs. It shall be the responsibility of the Principal Investigator to ensure that these individuals make the required disclosures, either using Mass. Eye and Ear's process or, if acceptable to the Institutional Official, through the policy of the individuals' own institutions.
5. If Mass. Eye and Ear carries out PHS-funded Research through a subrecipient, Mass. Eye and Ear will incorporate, as part of a written agreement with the subrecipient, terms that establish whether Mass. Eye and Ear's or the subrecipient's policy on the PHS financial conflict of interest requirements will apply to the subrecipient's Investigators.

If the subrecipient's policy will apply, the subrecipient will certify as part of the agreement that its policy complies with 42 CFR 50, Subpart F. In addition, the agreement shall specify time period(s) for the subrecipient to report all identified fCOIs and related management plan to Mass. Eye and Ear to enable Mass. Eye and Ear to provide timely reports to the relevant PHS agency. Alternatively, if Mass. Eye and Ear's policy will apply, the agreement shall specify time period(s) for the subrecipient to submit all subrecipient Investigators' disclosures of SFIs. Such time periods shall be sufficient to enable Mass. Eye and Ear to comply with timely review, management, and reporting obligations under the PHS regulations.

6. The SFIs of all Investigators on a Research project must be disclosed to Mass. Eye and Ear and fCOIs managed, reduced, or eliminated before any Research may be started. Annual review will be performed throughout the life of the project.

C. Process for Reviewing Disclosures and Managing fCOIs

1. At the time of application to a PHS funding agency, the Director of Pre-award and Regulatory Compliance, or designee, shall collect the required FDC form from each Investigator identified on the project prior to signing and submitting the application.
2. At or before the time of award funding, the Institutional Official, or designee, shall review SFIs made by each Investigator as it relates to the grant application, and document this review on the Significant Financial Disclosure Review form. If a perceived fCOI is found, the IO, or designee, will consult with the Investigator and the Chief of the Department to whom the Investigator reports (the "Chief") to determine whether the disclosure is related to the research project and whether a fCOI exists. If so, the Institutional Official and the Chief shall determine the appropriate action for the management, reduction, or elimination of the fCOI pursuant to the guidelines set forth below. The Institutional Official may consult with the Office of General Counsel to assist in the determination and/or management of an fCOI. If the Institutional Official determines that there is an fCOI that can be managed, he/she must require and approve a written Management Plan before the Investigator may perform the related Research.
3. The Institutional Official and the Chief shall be responsible for ensuring that the fCOI is managed consistent with the Management Plan.

The Institutional Official, or designee, shall report to the appropriate PHS agency the existence of any Investigator's fCOI and shall ensure that the fCOI is managed, reduced, or eliminated as set forth in the Management Plan before any awarded funds are spent for the related project and annually throughout the duration of that project as long as the fCOI exists.

4. In the course of on-going Research, if an Investigator new to the Research discloses an fCOI or an existing Investigator discloses a new or changed fCOI, the Institutional Official will implement a Management Plan within 60 days of the submission of the Disclosure Form.

D. Guidelines for the Management of fCOIs

The following are potential solutions that could be set forth in the Management Plan for the management, reduction, or elimination of fCOI:

1. Disclosure of the fCOI to all personnel participating in the Research, including trainees.
2. Public disclosure of the fCOI in publications, presentations, and, in the case of Human Subjects Research, in the informed consent document.
3. Objective review by non-interested colleagues of any manuscripts or other information made available to the public based on the results of the proposed Research project.
4. Designation of an alternate Investigator (peer or superior) who has no fCOI in the Research.
5. Disqualification of the Investigator from participating in part or all of the proposed Research.
6. Reduction or divestiture of the fCOI held by the Investigator and restrictions on re-investment after the project is completed for an appropriate period of time to provide for publication and critique of the project.
7. Severance of other relationships with the sponsor or competitor that create the actual or potential fCOI.
8. Prohibition from conducting the proposed Research.

E. Reporting to PHS

In the event that any reported conflict or non-compliance requires reporting to PHS, the Institutional Official, or designee, will report in accordance with PHS regulations.

F. Retrospective Review

If the Institutional Official, or designee, determines that an fCOI was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose an SFI that is determined to be an fCOI, or failure by an Investigator to materially comply with a management plan for an fCOI, the Institutional Official will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the Research project to determine whether the Research conducted during the period of non-compliance was biased in the design, conduct, or reporting of the Research. In addition, within 60 days of identification of that fCOI, the Institutional Official will implement a Management Plan.

Documentation of the retrospective review shall include detailed methodology used for the retrospective review, and findings and conclusions of the review. The Institutional Official will update any previously submitted reports to PHS specifying the actions that will be taken to manage the fCOI going forward. If bias is found, the report will include a mitigation

report in accordance with PHS regulations, including 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.

G. Sanctions for Failure to Abide by this Policy

Investigators who fail to abide by this Policy are subject to Mass. Eye and Ear's progressive disciplinary process. Non-employees who fail to abide by this Policy or any related procedure are subject to sanctions up to and including termination of the business relationship. Additional sanctions may be set forth in a related procedure.

H. Training

Each Investigator must complete training on the PHS regulations and this Policy prior to engaging in Research funded by a PHS agency, and at least every four (4) years thereafter. Investigators must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this Policy or with a Management Plan related to his or her activities.

At the time of training, each Investigator shall provide acknowledgement that he/she has read and understands this Policy.

I. Record Retention

The Institutional Official will retain all related forms, Management Plans, and documents for a period of three (3) years from the date when the final expenditure report for the PHS-funded grant is submitted to the PHS agency.

J. Public Disclosure

Mass. Eye and Ear will make this Policy available to the general public by posting it on the Mass. Eye and Ear external website.

Mass. Eye and Ear is required by federal regulation to make certain information about fCOIs related to PHS-funded Research by Senior/Key Personnel available to the public. Mass. Eye and Ear will do so by responding to any request for information concerning any fCOI that meets the following criteria:

1. The SFI was disclosed and is still held by the Investigator;
2. A determination has been made that the SFI is related to the PHS-funded Research; and
3. A determination has been made that the SFI is a fCOI.

The information to be made available shall be consistent with the requirements of the PHS policy. Please address all inquires to Alan K. Long, Ph.D., Vice President for Research & Academic Affairs, Massachusetts Eye and Ear, 243 Charles Street, Boston, MA 02114.

K. Mass. Eye and Ear Responsibilities

Mass. Eye and Ear will certify in each application for PHS funding that this policy regarding Conflicts of Interest Related to Research Funded under the Public Health Service exists and that, prior to any expenditure of funds, Mass. Eye and Ear will report the existence of an fCOI to the appropriate agency and ensure that it is managed, reduced, or eliminated.

L. Confidentiality

To the extent permitted by law, all forms related to this policy and process as well as any Management Plans, and related information will be confidential. However, Mass. Eye and Ear may make such information available to any PHS agency funding research of the Investigator. If Mass. Eye and Ear is requested to provide information contained in these forms or Management Plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

M. Implementing Procedures and Documentation

The Institutional Official shall have responsibility for developing procedures and documentation as necessary for implementing this Policy. Modifications to the Forms and operational process, as necessary from time to time, may be made by the Institutional Official, or designee.

N. Regulatory Authority

This policy implements the requirements of Title 42 Code of Federal Regulations Part 50, (42 CFR 50) Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought*.

Approved by the Conflict of Interest Committee 8/13/12

Reviewed and approved by the Conflict of Interest Committee: 6/13/16