

Harvard Medical School/Harvard School of Dental Medicine Policy on Financial Conflicts of Interest in Sponsored Research

Harvard University Faculty of Medicine may from time to time apply for and/or receive funding through various outside grant awards for their Research, for example grants from government awarding agencies, research foundations, and private companies. The following requirements apply to Sponsored Research, including at the time an application for funding is made to an awarding agency, for example the National Institutes of Health (NIH). These requirements are in addition to the rules set forth in the Faculty of Medicine Policy on Conflicts of Interest and Commitment (Faculty COI Policy) and apply to all Investigators, as defined below, in a Research project for which an application for funding has been made through and/or granted to Harvard Medical School (HMS).¹ In the event certain Research would not be permitted to proceed pursuant to the Research Rules and other prohibitions outlined in the Faculty COI Policy, nothing in this policy alters that conclusion. As such, the requirements outlined in this policy apply to Investigators who are planning to conduct or are conducting Sponsored Research (applied for and/or received through HMS) that is not otherwise prohibited by the Faculty COI Policy or other applicable requirements.

- 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 Faculty COI Policy.
 - A. **Designated Official.** The Designated Official will be the Dean for Faculty and Research Integrity.
 - B. **Financial Conflict of Interest (FCOI).** A Significant Financial Interest or Travel that could directly and significantly affect the design, conduct, or reporting of Research.
 - C. **Institution.** HMS in its capacity as an entity applying for or receiving PHS research funding.
 - D. **Institutional Responsibilities.** An Investigator's professional responsibilities on behalf of HMS. 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 HMS.
 - 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)). The PHS, through its funding agencies, implements and enforces the Department of Health and Human Services' (DHHS) Rule entitled "Responsibility of Applicants for Promoting

¹ As a point of clarification, this policy does not apply to Sponsored Research awards that come through the Harvard affiliated institutions or through any other school at Harvard University (e.g., the School of Public Health). This policy is limited to Sponsored Research that is applied for and received through HMS.

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.

G. 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 Investigators’ Institutional Responsibilities. The Office of the Dean 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 HMS in the grant application, progress report, or any other report submitted to the PHS by HMS.

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 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: salary, royalties or any 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; 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.

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 HMS, 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 HMS.** All Investigators conducting Research for which a funding application has been made to an external funding agency or entity through HMS must disclose the information required herein and by the Faculty COI Policy on an annual basis in accordance with the process established by the Office of the Dean. Additionally, at a minimum and no later than the time of application, 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) received in the preceding 12 months. 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:* Only PHS-funded Investigators are required to disclose Travel. A \$5000 de minimis applies to travel reporting.² 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 HMS:* Investigators must provide in a timely manner any information related to their disclosed Reviewable Interests that HMS, in its discretion, deems relevant to its review and FCOI assessment.

III. **Review by HMS.** 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 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 HMS

² The \$5000 de minimis means that an investigator does not have to report travel if the investigator receives less than \$5000 in aggregate from the entity (including the travel). On other words, an investigator only has to report travel if a reasonable estimate for that travel exceeds \$5000, the investigator earns more than \$5000 from the entity sponsoring or reimbursing the travel, or the combination of the two exceed \$5000.

Financial Interest Review Committee, a Faculty committee comprised of representatives across the HMS departments that apply for and/or receive grant funding through HMS.

A. *Relatedness Standard*: An Investigator's Reviewable Interest is related to Sponsored Research when HMS 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. HMS 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 HMS 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, HMS, through its Designated Official and with the advice and counsel of the Financial Interest Review Committee, 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*: HMS reserves the right to impose any requirements it sees fit on any disclosed interest, even those that are not prohibited by the Faculty 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. HMS 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, HMS is required to report to the PHS awarding agency the existence of an FCOI and submit an FCOI report.

B. *Timing of Report*: HMS 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.

C. *Annual FCOI Reports*: For any FCOI previously reported by HMS with regard to an ongoing PHS funded research project, HMS shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists. HMS shall provide annual FCOI reports to the PHS Awarding Component for the duration of

the project period (including extensions with or without funds) in the time and manner specifically specified by the PHS Awarding Component.

- VI. **Subrecipient.** When proposed HMS Research is to be funded by PHS and carried out through a subrecipient, HMS 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 HMS is able to meet its reporting obligations to the PHS awarding agency.
- VII. **Public Accessibility.** For PHS-funded Research, HMS will ensure public accessibility of information concerning the FCOIs currently held by Senior/Key Personnel subject to this policy. Unless and until HMS establishes a mechanism of making such information available through a publicly accessible website, HMS will, upon receipt of a complete written request for information in accordance with the process and requirements outlined at <http://hms.harvard.edu/content/integrity-academic-medicine> 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.

The information that HMS makes public will include the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

- VIII. **New Interests that Arise During an On-Going Sponsored Research Project.** To the extent a new Reviewable Interest is disclosed to HMS 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 HMS identifies a Reviewable Interest that was not previously reviewed in a timely manner by HMS in accordance with this policy, HMS 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. HMS 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 HMS's 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.**

For PHS-funded Research, 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; HMS's failure to review or manage such an FCOI; or Investigator failure to comply with an FCOI management plan, HMS will:

A. Within 60 days of identifying the SFI: HMS shall implement on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest;

B. Retrospective Review: HMS shall, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigators activities and the PHS-funded research projects to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research. HMS shall document the retrospective review, which shall include, at a minimum, the following key elements:

- i. Project number;
- ii. Project title
- iii. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- iv. Name of the Investigator with the FCOI;
- v. Name of the entity with which the Investigator has a financial conflict of interest;
- vi. Reason(s) for the retrospective review;
- vii. Detailed methodology used for the retrospective review (e.g. methodology of the review process, composition of the review panel, documents reviewed);
- viii. Findings of the review; and
- ix. Conclusions of the review.

C. *Mitigation.* If bias is found during the retrospective review of PHS-funded Research, HMS 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 HMS'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.

D. *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 HMS, 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, Investigators must complete all required conflicts of interest training prior to engaging in Research at or under the auspices of HMS, 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:
- HMS 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 HMS; or
 - HMS finds that an Investigator is not in compliance with this policy or an imposed management plan.
- XI. **Record Retention.** HMS will maintain records relating to all Investigator disclosures of financial interests, and its review of, and response to, such disclosures (whether or not a disclosure resulted in a determination of a financial conflict of interest) and all actions taken in pursuant to this policy or any retrospective review, for a minimum of three years from the date the final expenditures report is submitted to the PHS. Records will be maintained by the Office for Professional Standards and Integrity.
- XII. **Noncompliance and Sanctions.** In the event an Investigator fails to comply with this policy or an FCOI management plan imposed hereunder, the Office of the Dean may impose a wide variety of sanctions, including but not limited to restricting or conditioning the Investigator's ability to apply for grants through HMS, as well as imposing one or more of the sanctions outlined in the HMS 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 PHS-funded Research, HMS shall promptly notify the PHS awarding agency of the corrective action taken or to be taken.