

Conflict of Interest in Research Policy

Scope

Applies to all Mayo Clinic Personnel who perform internally or externally funded Research involving humans, animals, biospecimens and all other Research requiring Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Office of Sponsored Projects Administration (OSPA), or departmental approval.

Purpose

To identify and manage conflicts of interest between an Investigator's Research project obligations and their private interests or obligations.

Policy

- Federal regulations require Institutions to have policies and procedures in place to ensure that Investigators disclose any Financial Interests in relationship to Research projects funded by the United States Department of Health and Human Services (HHS), Public Health Service (PHS), and National Institutes of Health (NIH)
- Mayo Clinic extends this requirement for disclosure to all Research projects regardless of funding source to ensure that Financial Interests are identified and managed.
- All individuals listed on a protocol or grant, regardless of title or position, who are responsible for the designing, conducting, or reporting of Research, must complete a "Financial eDisclosure" form in order to disclose all Financial Interests that would reasonably appear to be related to their Institutional Responsibilities.
 - Generally, this includes all individuals listed on a grant budget, Research protocol or other Research activity. It always includes the Principal Investigator, Co-Investigators and Key scientific Personnel.
 - In some cases, it may include other Research personnel (such as technologists or Research fellows) if they are responsible for the design, conduct, or reporting of the activity funded by the Research project. For the purposes of disclosure, the term "Investigator" includes the Investigator, their spouse or domestic partner and dependent children.
- All Financial Interests, including equity, consulting, and/or royalties must be disclosed from the first dollar or from contractual rights to receive funds. * Federal Regulations further clarify what constitutes a Significant Financial Interest and a Financial Conflict of Interest with respect to PHS/NIH-funded research.
- Externally reimbursed or sponsored travel must be disclosed when aggregated per entity (organization) meets or exceeds \$5,000 (see COI Policy in Research Addendum for PHS-NIH Funded Research)

- All foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold of \$5,000 must be disclosed.
- Disclosures submitted through Research-related financial eDisclosure processes pertain to all Institutional Responsibilities, including Research, education, clinical practice, leadership, purchasing and administrative activities.
- Disclosures must be made prior to the submission of a proposal for funding, prior to approval of a Research protocol by IRB, and prior to activation of a Research project by IACUC.
- All financial disclosures must be updated during the period of the award on an annual basis either through Progress Reports filed with IRB or IACUC or through grant renewal applications filed with the Office of Sponsored Projects Administration.
- During the course of a Research project, any new Financial Interests as defined by federal regulations and Mayo Clinic Conflict of Interest Policy must be reported to the Conflict of Interest Review Board within 30 days and Managed, reduced or eliminated and reported to the PHS/NIH Awarding Component within 60 days of identification.
- With respect to human subjects Research, the IRB has the final authority to approve the management plan developed by the Conflict of Interest Review Board and to approve whether or not the Research itself can move forward.
- Administrative actions or management strategies to satisfactorily manage, reduce, or eliminate Financial Interests, Significant Financial Interests or Financial Conflicts of Interest must be approved by the Conflict of Interest Review Board prior to expenditure of an award, submission of a protocol to the IRB or activation of a Research effort within IACUC.

Policy Notes

Financial interests may result in a conflict of interest related to a staff member's institutional responsibilities that include, but are not limited to research, education, clinical practice, purchasing, leadership, and administrative activities. These interests include any of the following for the staff member, his/her spouse, domestic partner or dependent children:

- Holders of equity, including stock, stock options or warrants, in publicly traded or privately held companies (This excludes investments in mutual funds over which staff members have no direct oversight)
- Recipients of consulting income, honoraria, salary (excluding that from Mayo Clinic), gifts or other
- Emoluments or other in-kind compensation per year
- Recipients of license fees*, equity, royalties or contractual rights to receive royalties either through Mayo Clinic or from an external entity

- Recipients of unrestricted research or education grants
- Service as an officer, director or in any other fiduciary role for a commercial entity.

*Paid-up license agreements that do not include future sales-based royalties are not considered a financial interest.

Potential conflicts of interest involving members of the Board of Governors will be managed pursuant to the Trustee Conflict of Interest Policy.

Related Procedures

[Disclosure of Financial Interests and Related Research](#)

[Management of Financial Interest](#)

[Review Criteria and Determination](#)

Related Documents

[Determination Matrix](#)

[Conflicts of Interest in Research Policy Addendum for PHS/NIH-funded Research](#)

Definitions

Financial Conflict of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS/NIH-funded Research.

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.

Health and Human Services (HHS): The United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution: Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS/NIH Research funding.

Institutional Responsibilities: An Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on Financial Conflicts of Interest, which may include for example: activities such as Research, Research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

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 funded by the PHS/NIH, or proposed for such funding, which may include, for example, collaborators or consultants. For the purposes of disclosure, "Investigator" includes the Investigator, his/her spouse or domestic partner and dependent children.

Manage: Taking action to address a Financial Conflict of Interest, which can include reducing or eliminating the Financial Conflict of Interest, to ensure, to the extent possible, that the design, conduct, and reporting of Research will be free from bias.

Project Director (PD)/Principal Investigator (PI): A Project Director or Principal Investigator of a PHS/NIH-funded Research project; the PD/PI is included in the definitions of Senior/Key Personnel and Investigator under this subpart.

Public Health Service (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 (PHS Act): The statute codified at 42 U.S.C. 201 et seq.

Rebuttable Presumption: A Rebuttable Presumption is an assumption of fact accepted until disproved. All presumptions can be characterized as rebuttable. It is an assumption that is made in the law that will stand as a fact unless someone comes forward to contest it and prove otherwise. As applied to human subjects Research, the Rebuttable Presumption means that the Institution will presume, in order to ensure that all potentially problematic circumstances are reviewed, that a financially interested individual and/or institution may not conduct the human subjects Research in question.

This rule is not intended to be absolute; a financially interested individual and/or institution may rebut the presumption by demonstrating facts that, in the opinion of the Conflict of Interest Review Board, constitute compelling circumstances for the financially interested individual to conduct the Research in question. The individual and/or Institution would then be allowed to conduct the Research under conditions specified by the Conflict of Interest Review Board and approved by the Institutional Review Board.

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 any such activity for which Research funding is available from a PHS/NIH Awarding Component through a grant or cooperative agreement, whether authorized under the PHS/NIH Act or other statutory authority, such as a Research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or Research resources award.

Senior/Key Personnel: The PD/PI and any other person identified as Senior/Key Personnel by the institution in the grant application, progress report, or any other report submitted to the PHS/NIH by the Institution under this subpart.

Significant Financial Interest: A Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse or domestic partner and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

- With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve 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 income, 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;

- 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 twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator’s spouse or domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of fees related to such rights and interests.

Small Business Innovation Research (SBIR) Program: The extramural Research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97–219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102–564

References

[Conflict of Interest Review Board website](#)

[Conflict of Interest Training](#)

[Link to eDisclosure System](#)

[Travel Disclosure for PHS/NIH-funded Research](#)

Public Health Service (PHS) regulations, “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors,” [42CFR, Part 50, Subpart F](#) and [45 CFR, Part 94](#), effective August 24, 2012.

Owner

[Monica Sveen-Ziebell](#), on behalf of the Conflict of Interest Review Board

Contact

[Monica Sveen-Ziebell](#), Administrator

Revision History

Date	Synopsis of Change
02/05/2024	Outside two-year review. Adding language reflecting longstanding expectations for disclosure of financial interests, including reimbursed or sponsored travel, language specific to foreign financial interests. Added link to addendum document as related document. Added policy note on paid-up licenses. Added policy note on management of Board of Governors members. Approved by COIRB on 12/18/2023. Approved by Board of Governors 2/5/2024.

05/05/2023	Outside two-year review. Updated scope to remove ACO, added PHS/NIH funded research policy addendum in related documents section. Approved by COIRB Exec on 4/21/23.
05/27/2020	<p>Aligned Scope and Purpose sections to Policy Office requirements; changed staff/employee throughout policy to "Personnel" and added "Personnel" to Definitions section; Moved regulatory information to Reference section; added Disclosure of Financial Interest, and Review Criteria and Deamination to Related Procedures and Determination Matrix to Related Documents; and made minor non-substantive changes for clarity and to make the policy more internally consistent.</p> <p>Conflict of Interest Review Board: 08/12/2019</p> <p>Mayo Clinic Board of Governors: 05/18/2020</p>
05/13/2019	Minor Revision - Initial ACO acronym changed to Accountable Care Organization.
05/06/2019	Revised - Added ACO statement to Scope as required by CMS and checked document into the Policy and Procedure Management System.
08/02/2016	Created separate policies by subject versus one Conflict of Interest Policy.
12/2013	<p>Approval for need to establish document:</p> <p>Conflict of Interest Review Board</p> <p>Mayo Clinic Board of Governors 12/2013</p>