

Conflict of Interest in Research Policy

Scope

This policy applies to all Mayo Clinic employees who perform internally or externally funded research involving humans, animals, bio specimens and all other research requiring IRB, IACUC, OSPA or departmental approval. Also applies to all members of the Mayo Clinic Community Accountable Care Organization, LLC Governing Board (ACO Board) as well as ACO Corporate Officers.

Purpose

To identify and manage conflicts of interest between an investigator's research project obligations and his/her private interests or obligations.

Policy

- All individuals listed on a protocol or grant, regardless of title or position, who may be responsible for design, conduct, or reporting of research must complete a "Financial eDisclosure" form in order to disclose all financial interests that would reasonable 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, his/her spouse or domestic partner and dependent children.
- Disclosures submitted through Research-related financial eDisclosure processes pertain to all institutional responsibilities including, research, education, clinical practice, leadership, purchasing and administrative activities.
- Federal regulations require institutions to have policies and procedures in place to ensure that investigators disclose any financial interests in relationship to PHS/NIH-funded research projects.
- Mayo Clinic extends this requirement for disclosure to all research projects regardless of funding source to ensure that financial interests are identified and managed.
- 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 Institutional Review Board 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.
- This disclosure and management policy is consistent with 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.

Related Procedure(s)

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

[Management of Financial Interest](#)

[Review Criteria and Determination](#)

Related Document(s)

[Determination matrix](#)

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.

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.

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.

PD/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.

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 assure 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. 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). As used in this subpart, 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](#)

Approved by

Conflict of Interest Review Board

Mayo Clinic Board of Governors 12/2013

Owner

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

Contact

[Monica Sveen-Ziebell](#), Administrator

Revision History

Date	Synopsis of Change
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.