



*Conflict of Interest in  
Research Policy  
Addendum for PHS/NIH-  
funded Research*

## *Regulations Regarding Conflicts of Interest in PHS/NIH-funded Research (42 CFR Part 50, Subpart F-“Promoting Objectivity in Research”)*

### **A. Purpose**

These regulations promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from investigator Financial Conflicts of Interest.

### **B. Applicability**

These regulations are applicable to each institution that is applying for, or that receives, PHS/NIH research funding by means of a grant or cooperative agreement and to each investigator who is planning to participate in, or is participating in, such research. These regulations do not apply to Small Business Innovation Research (SBIR) Program Phase I applications.

Mayo Clinic Conflict of Interest policies regarding PHS/NIH-funded research comply with federal regulations entitled, “Promoting Objectivity in Research for which PHS/NIH Funding is Sought” ([42 CFR Part 50, Subpart E](#)).

### **C. PHS/NIH Definition for 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 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 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 income related to
- such rights and interests

The term significant financial interest **does not** include the following types of financial interests: salary, royalties\*, or 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; any ownership interest in the institution held by the investigator, if the institution is a commercial or for-profit organization; 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.

\*Note: Mayo Clinic does consider royalties paid through the institution as a financial interest.

#### **D. Institutional Responsibilities**

Mayo Clinic will maintain an up-to-date, written, enforced policy on Financial Conflicts of Interest that complies with these regulations, and make such policy available via a publicly accessible website.

Mayo Clinic will also inform each investigator of the institution's policy on Financial Conflicts of Interest, the investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each investigator to complete training regarding the same prior to engaging in research related to any PHS/NIH-funded grant and at least every four years, and immediately when any of the following circumstances apply:

1. The institution revises its Financial Conflict of Interest policies or procedures in any manner that affects the requirements of investigators;
2. An investigator is new to an institution; or
3. An institution finds that an investigator is not in compliance with the institution's Financial Conflict of Interest policy or management plan.

#### **E. Investigator Requirements**

- Each investigator who is planning to participate in the PHS/NIH-funded research must disclose to the institution's designated official(s) the investigator's significant financial interests\* and those of the investigator's spouse and dependent children no later than the time of application for PHS/NIH-funded research.
- Each investigator who is participating in the PHS/NIH-funded research must submit an updated disclosure of significant financial interests\* at least annually, in accordance with the specific time period prescribed by the institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the institution, or in a subsequent disclosure of significant financial interests\* (e.g., any Financial Conflict of Interest identified on a PHS/NIH-funded project that was transferred from another institution) and shall include updated information regarding any previously disclosed significant financial interest\* (e.g., the updated value of a previously disclosed equity interest).
- Each investigator who is participating in the PHS/NIH-funded research must submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

\*Note: Mayo Clinic requires disclosure of all financial interests from the first dollar.

## F. Disclosure/Documentation for PHS/NIH Grant Awards

1. Whenever, in the course of an ongoing PHS/NIH-funded research project, a new investigator participating in the research project discloses an SFI or an existing investigator discloses a new SFI to Mayo Clinic, the designated official(s) of Mayo Clinic shall, within 60 days: Review the SFI disclosure; determine whether it is related to PHS/NIH-funded research; determine whether an FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI. Depending on the nature of the SFI, Mayo Clinic may determine that additional interim measures are necessary with regard to the investigator's participation in the PHS/NIH-funded research project between the date of disclosure and the completion of Mayo Clinic's review.
2. Whenever Mayo Clinic identifies a significant financial interest that was not disclosed timely by an investigator or, for whatever reason, was not previously reviewed by Mayo Clinic during an ongoing PHS/NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to PHS/NIH-funded research; determine whether a Financial Conflict of Interest exists; and, if so:
  - a. 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 going forward;
  - b. In addition, whenever a Financial Conflict of Interest is not identified or managed in a timely manner including failure by the investigator to disclose a significant financial interest that is determined by Mayo Clinic to constitute a Financial Conflict of Interest; failure by Mayo Clinic to review or manage such a Financial Conflict of Interest; or failure by the investigator to comply with a Financial Conflict of Interest management plan, Mayo Clinic will, within 120 days of their determination of noncompliance, complete a retrospective review of the investigator's activities and the PHS/NIH-funded research project to determine whether any PHS/NIH-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
  - c. Mayo Clinic will document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:
    - Project number;
    - Project title;
    - PD/PI or contact PD/PI if a multiple PD/PI model is used;
    - Name of the investigator with the FCOI;
    - Name of the entity with which the Investigator has a financial conflict of interest;
    - Reason(s) for the retrospective review;
    - Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
    - Findings of the review; and
    - Conclusions of the review.
  - d. Based on the results of the retrospective review, if appropriate, Mayo Clinic will update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.
3. If the failure of an Investigator to comply with Mayo Clinic's conflict of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, Mayo Clinic will promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to Mayo Clinic for further action, which may

include directions to Mayo Clinic on how to maintain appropriate objectivity in the PHS-funded research project. PHS may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator.

In any case in which the HHS determines that an NIH-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 a conflicting interest that was not managed or reported as required by the regulation, Mayo Clinic will require the investigator(s) involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

### **G. Reports to PHS/NIH after Grant Award**

Prior to expenditure of any PHS/NIH funds under an award, Mayo Clinic will report to the PHS/NIH Awarding Component the existence of a Financial Conflict of Interest and assure that the interest has been managed, reduced or eliminated in accordance with Section 50.604 (g)(c); and, for any interest that Mayo Clinic identifies as conflicting subsequent to Mayo Clinic's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification.

#### Elements of an FCOI Report

- Grant number;
- PD/PI or contact PD/PI;
- Name of Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria);
- Value of the financial interest \$0-4,999; \$5K-9,999; \$10K-19,999; amts between \$20K-100K by increments of \$20K; amts above \$100K by increments of \$50K or a statement that a value cannot be readily determined;
- A description how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- Key elements of the Institution's management plan.

For any Financial Conflict of Interest previously reported by Mayo Clinic with regard to an ongoing PHS/NIH-funded research project, Mayo Clinic shall provide to the PHS/NIH Awarding Component an annual FCOI report that addresses the status of the Financial Conflict of Interest and any changes to the management plan for the duration of the PHS/NIH-funded research project. The annual FCOI report shall specify whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists. Mayo Clinic shall provide annual FCOI reports to the PHS/NIH Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS/NIH Awarding Component.

### **H. Sanctions**

Failure to file a completed "Financial eDisclosure" form for each PHS/NIH-funded research project or to update this information on an annual basis, in addition to within 30 days when the status of the financial disclosure may change, in compliance with this policy will be grounds for termination of the award, and when appropriate, further sanctions as recommended by the Conflict of Interest Review Board to the Personnel Committee.

## **I. Record Retention**

Mayo Clinic will maintain records relating to all investigator disclosures of financial interests and their review of, and response to, such disclosures (whether or not a disclosure resulted in the institution's determination of a Financial Conflict of Interest), and all actions under their policy or retrospective review, if applicable, for at least three years from the date of final payment or, where applicable, for the time periods specified in 48 CFR part 4, subpart 4.7 [eCFR :: 2 CFR 200.334 -- Retention requirements for records.](#)

## **J. Subrecipient Monitoring**

To comply with regulations regarding PHS/NIH-funded research, when Mayo Clinic carries out the PHS/NIH-funded research through a subrecipient (e.g., subcontractors, or consortium members), Mayo will take reasonable steps to ensure that any subrecipient investigator complies with federal regulations by:

1. Incorporating as part of a written agreement with the subrecipient terms that establish whether the Financial Conflicts of Interest policy of Mayo Clinic or that of the subrecipient will apply to the subrecipient's investigators.
  - a. If the subrecipient's investigators must comply with the subrecipient's Financial Conflicts of Interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with federal regulations. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient investigators are subject to the Financial Conflicts of Interest policy of Mayo Clinic for disclosing significant financial interests that are directly related to the subrecipient's work as part of the award;
  - b. Additionally, if the subrecipient's investigators must comply with the subrecipient's Financial Conflicts of Interest policy, the agreement referenced above shall specify 30 days as the time period in which the subrecipient must report all identified Financial Conflicts of Interest to Mayo Clinic.;
  - c. Alternatively, if the subrecipient's investigators must comply with Mayo Clinic's Financial Conflicts of Interest policy, the agreement referenced above shall require the subrecipient to submit all investigator disclosures of significant financial interests to Mayo Clinic within 30 days.
2. Mayo Clinic will provide FCOI reports to the PHS/NIH Awarding Component regarding all Financial Conflicts of Interest of all subrecipient investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.
3. If a Financial Conflict of Interest is identified for a subrecipient investigator who must comply with Mayo Clinic's Conflict of Interest Policy, Mayo Clinic will monitor compliance with the required management plan on an ongoing basis until completion of the PHS/NIH-funded research project.

## **K. Travel**

For Mayo staff participating in PHS/NIH-funded research, additional disclosures are required in accordance with 42 CFR, Part 50-Policies of General Applicability, Subpart F – Promoting Objectivity in Research, §50.603 Definitions (2) effective August 24, 2012.

Investigators must disclose the occurrence within 30 days of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, or 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. Disclosures should:

- Include the purpose of the trip, the identity of the sponsor/organizer, the destination and duration
- Reflect sponsored or reimbursed travel for the investigator, spouse or domestic partner and dependent children
- Include only externally reimbursed or sponsored travel that when aggregated per entity (organization) meets or exceeds \$5,000. Once that threshold is achieved, disclose all externally reimbursed or sponsored travel per entity that led to that amount, as well as the externally reimbursed or sponsored travel per entity that exceeded that amount.
- Reflect reimbursed or sponsored travel in the initial disclosure that occurred in the previous 12 months.

Click here to submit disclosures related to Externally Reimbursed or Sponsored Travel:

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

All travel disclosed under this section will be considered as part of the Conflict of Interest Review Board's determination for the existence of a Significant Financial Interest.

## L. Training

Mayo staff participating in PHS/NIH-funded research must complete training regarding Mayo Clinic's Conflict of Interest Policy and federal regulations regarding conflict of interest prior to engaging in any research related to any PHS/NIH-funded grant and at least every four years, and immediately when:

- Mayo Clinic revises its Financial Conflict of Interest Policies or procedures in any manner that affects the requirements of the investigators;
- An investigator is new to Mayo Clinic; or
- A Mayo Clinic investigator is not in compliance with Mayo's Financial Conflict of Interest Policies or management plan.

Click here to access the mandatory COI training: [Conflict of Interest Training](#)

## M. Reporting to the Public

Prior to expenditure of any funds under a PHS/NIH-funded research project, Mayo Clinic in compliance with federal regulations, will ensure public accessibility of information concerning senior/key personnel\* who have any significant financial interest determined to be a Financial Conflict of Interest\* related to the PHS/NIH-funded research.

Requests for information will be submitted in writing to the Office of Conflict of Interest Review and will specify the investigator's name and the name or number PHS/NIH-funded grant. Mayo Clinic will respond to written requests received in the Office of Conflict of Interest Review within five working days. Requests will identify the name of the senior/key personnel as well as the title of the grant. This information will be available for responses to written requests for at least three years from the date the information was most recently updated.

Information provided will include:

- Investigator's name
- Title with respect to the research project
- Name of entity in which a significant financial interest has been disclosed
- Nature of the financial interest
- Approximate dollar amount
  - \$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

Note: Pertains only to those investigators participating in PHS/NIH-funded research who have a Financial Conflict of Interest\* requiring a management plan.

\*See Definitions for Senior/key personnel and Financial Conflict of Interest.



## ***Appendix A: 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**

- (1) 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:
  - (i) 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;
  - (ii) 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
  - (iii) 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