



Conflict of Interest Policy

Approved May 2016
Mayo Clinic Board of Governors

Table of Contents

I. Overview	4
A. Guiding Principles	4
B. What is a Conflict of Interest?.....	4
C. What Can Cause a Financial Interest or Financial Conflict of Interest at Mayo Clinic?	5
D. What Group Has Oversight Over Conflict of Interest at Mayo Clinic?.....	5
E. How is Conflict of Interest Managed at Mayo Clinic?	6
F. Determinations Matrix	7
II. Conflicts of Interest in Research.....	8
A. Disclosure	8
B. Review Criteria and Determinations Process.....	9
C. Management	10
III. Regulations Regarding Conflicts of Interest in PHS/NIH-Funded Research (42 Cfr Part 50, Subpart F-“Promoting Objectivity in Research”)	12
A. Purpose	12
B. Applicability.....	12
C. PHS/NIH Definition for Significant Financial Interest	12
D. Institutional Responsibilities	13
E. Investigator Requirements.....	13
F. Disclosure/Documentation for PHS/NIH Grant Awards	14
G. Reports to PHS/NIH after Grant Award.....	15
H. Sanctions.....	15
I. Record Retention	15
J. Subrecipient Monitoring	15
K. Travel.....	16
L. Training.....	16
M. Reporting to the Public.....	17
IV. Conflict of Interest in Clinical Practice.....	18
V. Conflict of Interest in Education	19
VI. Conflict of Interest in Investments.....	19
VII. Conflict of Interest in Leadership	20
VIII. Conflict of Interest in Purchasing	20
IX. Staff Participation – Board of Directors/Trustees.....	21
X. Conflict of Interest in Professional Activities	22
XI. Development Department	22
XII. Mayo Clinic Board of Trustees	22

XIII. COI Policy Implementation	23
A. Disclosure.....	23
1. Annual Financial Disclosure	23
2. Disclosure for Select Leadership, Groups and Work Areas.....	24
a. Groups, Committees and Work Areas.....	24
b. Leadership	24
c. Mayo Clinic Ventures.....	24
XIV. Entrepreneurship Activities	25
Appendix A: Definitions	26
Appendix B: Disclosure of Financial Interests and Related Research.....	29
Appendix C: Frequently Asked Questions.....	30
Appendix D: Resources.....	31
Appendix E: Promoting Objectivity in Research for which PHS/NIH Funding is Sought (42 CFR Part 50, Subpart F).....	32-40

I. Overview

The mission of Mayo Clinic is to inspire hope and contribute to health and well-being by providing the best care to every patient through integrated clinical practice, education and research. In support of that mission, Conflict of Interest Policies at Mayo Clinic have been developed to ensure that our patients' needs for information regarding institutional and individual conflicts of interest are met and exceeded; our patients' safety is ensured; and the integrity of our research and researchers is maintained.

A. Guiding principles

"I would admonish you, above all other considerations, to be honest. I mean honesty in every conception of the word: let it enter into all the details of your work; in the treatment of your patients and in your association with your brother practitioners." - Dr. Will Mayo

1. Honesty and transparency are hallmarks of Mayo Clinic's clinical practice, research, education and administrative endeavors.
2. Objectivity of research and research results is paramount in protecting patients and maintaining the public's trust.
3. Conflicts of interest are inevitable and can be managed effectively in a majority of cases or eliminated when necessary.
4. The first step to managing any conflict of interest is thorough disclosure.
5. Mayo Clinic conducts its research, clinical practice and education activities in full compliance with all federal and state regulations.

B. What is a conflict of interest?

A conflict of interest occurs when there is a divergence between an individual's or an institution's private interests and their professional obligations either to a patient or to society such that an independent observer might reasonably question research, clinical practice, education, leadership, investment purchasing, or other professional actions taken by the individual or the institution that may have been influenced by consideration of conflict of interest. Conflict of interest often depends on the situation, and not on the character or actions of an individual.

While conflict of interest is possible in a variety of academic pursuits including the desire for professional and scholarly advancement, acquisition of research funding, recognition by peers, etc., the Conflict of Interest Policy at Mayo Clinic addresses only disclosed financial interests related to research, clinical practice, education, leadership, purchasing and other professional activities.

The potential for conflict of interest will increase as Mayo and its staff develop new technologies and form new relationships and alliances to understand, predict, prevent, diagnose, optimally treat and ultimately cure disease.

C. What can cause a financial interest or Financial Conflict of Interest at Mayo Clinic?

This section addresses financial interests that 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 and administrative activities. Financial 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.

Institutional Financial Conflicts of Interest may occur when Mayo Clinic:

- Receives royalties** from a technology invented by staff and licensed to a commercial entity
- Accepts equity and/or makes a direct investment in a company to which it licenses technology
- Starts a company based on technology developed at Mayo
- Approves participation by its leaders to serve as a member of the board of directors for a commercial entity
- Enters a joint venture, collaboration or partnership with a commercial entity.

**Mayo Clinic and its staff members do not receive any royalties for inventions or technology developed at Mayo and subsequently prescribed for Mayo Clinic patients.

D. What group has oversight over Conflict of Interest at Mayo Clinic?

The Conflict of Interest Review Board has oversight over conflict of interest within relationships between:

- Individual Mayo staff members and industry, and
- Entities within Mayo Clinic and industry.

Where intellectual property with a potential conflict of interest exists, the Conflict of Interest Review Board also will interpret and apply federal regulations and Mayo Clinic principles and policies regarding conflict of interest. These relationships may involve individual staff members as well as Mayo Clinic entities, including Mayo Clinic Ventures, MCSI, MML, and other internal entities. The Conflict of Interest Review Board also will provide counsel to the Mayo Clinic Board of Trustees, Mayo Clinic Board of Governors, the Executive Operations Teams of Mayo Clinic and members of the Mayo Clinic Health System.

E. How is conflict of interest managed at Mayo Clinic?

The first step in identifying conflict of interest is full disclosure of relevant information. The next step is evaluation of the disclosed information to determine whether, according to established criteria, a conflict of interest is present. If so, then the third step is to institute measures for management of conflict.

Disclosure

Annual financial disclosure is required for all members of the voting staff, professional associates in research, fellows and Mayo Clinic Health System physicians and key administrative leaders. Disclosures through the annual financial disclosure process pertain to all institutional responsibilities including research, education, clinical practice, purchasing and administrative activities. In all cases, disclosure is required from the first dollar for all financial interests resulting from equity, royalties, consulting income, gifts or unrestricted research or education grants.

Annual financial disclosures are reviewed by the Conflict of Interest Review Board and appropriate administrative actions or management plans developed and communicated when necessary. Please click here to view a sample Annual Financial eDisclosure form:

[Sample Annual Financial Disclosure form](#)

Research-related disclosures are required for each research effort regardless of funding source. In consultation with the investigator, the Conflict of Interest Review Board is responsible for determining if any of the items disclosed result in a financial interest, significant financial interest or a Financial Conflict of Interest in accordance with Mayo Clinic policies and federal regulations. (Please see Determinations Matrix below.) Please click here to view a sample Research-related Financial eDisclosure form: [Sample Research-related Disclosure form](#)

For federal definitions regarding significant financial interest and Financial Conflict of Interest, click here: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

Administrative actions or a management plan may be required based on the content of the disclosure and its relationship to the proposed research. All individuals listed on the grant budget or research protocol will be apprised of actions taken by the Conflict of Interest Review Board when administrative actions or management plans are required. Notification to the NIH may also occur in accordance with federal regulations regarding PHS/NIH-funded research.

F. Determinations Matrix

Disclosure	Research not related	Research is related, but no D&S* (see#2)	Research is related and D&S*(see#2)
Significant Financial Interest Greater than \$5,000 in consulting income, royalties or publicly traded equity Any equity in a privately held company Fiduciary role	No action	Administrative action	FCOI with management plan
Financial Interest Less than \$5,000 in consulting income, royalties or publicly traded equity Contractual rights Institutional equity only Unrestricted research or education grant	No action	Administrative action	Administrative action

Administrative Action Options

- Disclosure publications/presentations
- Disclosure consent form
- Corroboration
- Other **

FCOI Management Options

- Requires formal management plan
- May require rebuttable presumption
- Requires notification to NIH
- Requires corroboration
- Other**

1. SFI (Significant Financial Interest) or FI (Financial Interest) is related when:
 - The disclosure could be affected by the research
 - The disclosure is in an entity whose financial interest could be affected by the research.
2. If SFI without management could be perceived to “directly or significantly”* affect the design, conduct or reporting of research, it becomes a Financial Conflict of Interest according to federal regulations and Mayo Clinic Conflict of Interest Policy and requires a formal conflict of interest management plan.
3. If FI without management could be perceived to “directly or significantly”* affect the design, conduct or reporting of research, it requires administrative action.

** Other Administrative Action or Management Options may include but are not limited to:

- Oversight Committee
- Protocol modification
- Limitation on number of participants Mayo can enroll
- Assignment of independent statistician
- Transfer of data management and/or analysis responsibility
- Separate Data Safety Monitoring Committee.

II. Conflicts of Interest in Research

The purpose of this section is to identify and manage through the process of open disclosure and review conflicts of interest between an investigator's research project obligations and his/her private interests or obligations. Policies herein apply to all internally or externally funded research involving humans, animals, biospecimens and all other research requiring IRB, IACUC, OSPA or departmental approval. This 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.

While Mayo Clinic Conflict of Interest Policies state that a financial interest, including equity, consulting income, 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. Click here to view federal definitions: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

A. Disclosure

Disclosures submitted through Research-related financial eDisclosure processes pertain to all institutional responsibilities including research, education, clinical practice, leadership, purchasing and administrative activities.

Who must disclose?

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 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, his/her spouse or domestic partner and dependent children.

How must disclosures occur?

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 policies extend this requirement for disclosure to all research projects regardless of funding source to ensure that financial interests are identified and managed. Such 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.

In addition, 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.

B. Review Criteria and Determinations Process

Financial disclosures will be reviewed by the Conflict of Interest Review Board to determine whether any reported financial interest is related to the research and:

- could be affected by the research
- is in an entity whose financial interest could be affected by the research
- may directly and significantly affect the design, conduct or reporting of the research.

Based on the information provided in the financial disclosure, the Conflict of Interest Review Board will assess whether the financial interest or significant financial interest is related to the research or is related to an entity whose financial interest could be affected by the research.

After determining relatedness, the COI Review Board will determine further through established criteria if the financial interest or significant financial interest directly or significantly affects the design, conduct or reporting of research.

A direct impact occurs when the project results would be directly relevant to the development, manufacturing, or improvement of the products or services of the entity or technology in which the investigator or any other individual responsible for the design, conduct, or reporting of the activity has a financial interest. A significant impact on the financial interest is one that will materially affect the value of the technology or the entity, its earnings, or the sales of its products. Conflicts of interest may occur when an investigator at Mayo Clinic has a financial interest in a commercial entity funding the research or supporting the research in any way, including contributions, gifts or substantial loans of equipment, or whose product is the subject of the research.

Based on information provided in the financial disclosure, the Conflict of Interest Review Board may determine that there is no reasonable basis on which to conclude that a project could affect the financial interest. In this case, the project proponents, the IRB, OSPA (Office of Sponsored Projects Administration) or IACUC (Institutional Animal Care and Use Committee) will be informed that the project can proceed without further review.

In the event that the Conflict of Interest Review Board concludes that the financial interest may have a direct and significant impact on the project, the Board will work with the investigator to develop strategies to manage, reduce or eliminate the conflict.

At that point, either administrative actions or a management plan will be required in accordance with Mayo Clinic Conflict of Interest policies and federal regulations. The NIH will be notified of a Financial Conflict of Interest as specified in federal regulations.

To view the Determinations Matrix, please click on link: [Determinations Matrix](#)

In addition to assessing information provided through the financial disclosure referenced above, the Conflict of Interest Review Board may also consider the following in its deliberations:

- Degree of risk in the study
- Vulnerability of population
- Early phase vs. late phase research
- Single vs. multicenter study
- Amount of royalties, equity, consulting income

C. Management

The Conflict of Interest Review Board, in consultation with the investigator, will develop management strategies that define specific actions to manage, reduce or eliminate conflicts of interests. Actions that may be required to manage conflicts of interest may include, but are not limited to:

1. Public disclosure of financial interests to:
 - Appropriate state and federal officials
 - Research funders or sponsors
 - Researchers, students, trainees, all personnel listed as key personnel
 - Publication editors
 - All forms of public communication including press releases, posters, web postings, communications to shareholders, etc.
 - Human subjects participating in research
 - Disclosure to human subjects must include a statement that the financial interest has been reviewed by the Conflict of Interest Review Board, managed subject to board oversight and determined by both the Conflict of Interest Review Board and the Institutional Review Board not to pose any additional significant risk to the welfare of the research subjects or to the integrity of the research. (Click here to view the document entitled, "[Disclosure of Financial Interests and Related Research.](#)")
2. Monitoring of the project by independent reviewers and/or Oversight Committees. Oversight Committees may also be appointed by the Conflict of Interest Review Board as a management strategy for research that requires the rebuttable presumption or for research with particularly complex conflict of interest issues.
3. Modification of the research or project plan;
4. Disqualification from participation in all or a portion of the project;
5. Divestiture of significant financial interests; or
6. Severance of relationships that create actual or potential conflicts of interest that are unmanageable.
7. Rebuttable Presumption*

Investigators for clinical trials whose financial disclosures reflect significant financial interests that are related and will directly and significantly impact the research will be asked to submit to the Conflict of Interest Review Board compelling reasons why the research should be conducted at Mayo Clinic.

Research projects that require the rebuttable presumption and are determined by the Conflict of Interest Review Board to meet the rebuttable presumption due to compelling reasons, despite individual and/or institutional conflict of interest, will be approved to go forward with appropriate management strategies. Additional review will be required at least annually or at the discretion of the Conflict of Interest Review Board.

Research projects that require the rebuttable presumption but are determined by the Conflict of Interest Review Board not to meet the rebuttable presumption due to a lack of compelling reasons may not go forward until and unless sufficient modifications are made to the overall research design, the roles of personnel associated with the research; and/or the conduct of the research itself to ensure the safety of patients and the integrity of the research. These modifications must be approved by the Conflict of Interest Review Board and the Institutional Review Board.

If a financial interest, significant financial interest or Financial Conflict of Interest is determined, a management strategy, including but not limited to the criteria listed above, will be developed by the Conflict of Interest Review Board and communicated to all individuals listed on a grant award budget, all individuals listed on an IRB protocol, and all individuals for whom disclosure is required for IACUC research. The related administrative groups supporting such research efforts, i.e., Office of Sponsored Projects Administration, Institutional Review Board and Institutional Animal Care and Use Committee, also will receive notification of the determination and required management strategy relative to the specific grant award or research project.

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.

*See Appendix A - Definitions

Note:

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. Please click on link to view the Federal Regulations: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

III. 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 F) located in Appendix 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 must 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 must 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 an institution identifies a significant financial interest that was not disclosed timely by an investigator or, for whatever reason, was not previously reviewed by the institution 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 the institution to constitute a Financial Conflict of Interest; failure by the institution 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, the institution shall, within 120 days of the institution's 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 is required to 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.

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 must 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 found by the institution 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.

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 must maintain records relating to all investigator disclosures of financial interests and the institution's 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 the institution's 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.

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 must 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 must 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 receive administrative review. Commercially sponsored travel of more than 15 days per year sponsored by the same company will be reviewed by the Conflict of Interest Review Board Executive Subcommittee.

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, must 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 must be submitted in writing to the Office of Conflict of Interest Review and must 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 must identify the name of the senior/key personnel as well as the title of the grant. 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.

IV. Conflict of Interest in Clinical Practice

The purpose of this policy is to institute systematic policies for identification and management of conflict of interest in clinical practice.

Institutional Conflict of Interest

A statement will be included in patient information materials received by all patients that acknowledges that Mayo Clinic has institutional relationships with medically related commercial entities. These relationships may result from licensing agreements, institutional partnerships or leadership activities. Patients will be informed that if they have questions about potential institutional conflicts of interest, they may contact the Office of Conflict of Interest Review for general information about Mayo Clinic's institutional relationships with commercial entities.

An additional statement will clarify for patients that Mayo Clinic receives no royalties on the sale of items invented at Mayo Clinic that are prescribed for Mayo Clinic patients.

Individual Conflict of Interest

A statement will be included in patient information materials received by all patients acknowledging the potential for relationships between Mayo Clinic staff members and commercial entities. Those relationships generally result from technology licensing agreements, know-how agreements, consulting agreements or board membership involving the individual, Mayo Clinic and a commercial entity. Patients will be invited to ask physicians or other care givers directly about such relationship or contact the Conflict of Interest Review Board for information regarding their care givers' relationships with commercial entities.

Information provided to patients by the Office of Conflict of Interest Review will include the nature of the relationship (consulting, technology license, know-how agreement or board membership); the name of the commercial entity; an acknowledgement that the physician or other care giver does receive royalties or consulting income personally; and a clarification that neither Mayo Clinic nor its physicians or other care givers receive royalties from the sale of items invented at Mayo Clinic that are prescribed for Mayo Clinic patients.

For specific information regarding physician relationships with commercial entities, patients will also be directed to the federal National Physician Payment Transparency Program at <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>. Mayo Clinic staff who have a significant financial interest related to diagnostic or treatment modalities that they prescribe in their clinical practice should disclose the nature of this interest to the patient. They should also disclose that they receive no royalties or other payments for the use of the diagnostic or treatment modality with Mayo patients. Patients who request further information should be referred to the Office of Conflict of Interest Review.

Individual Conflict of Commitment

Mayo Clinic staff who earn total annual consulting income for personal gain of greater than 20 percent of their annual Mayo Clinic salary from a relationship with a commercial entity or commercial entities also will be reviewed by the Conflict of Interest Review Board to determine the potential for conflict of commitment.

V. Conflict of Interest in Education

Financial disclosures related to education activities are governed by general Mayo Clinic Conflict of Interest Policies. Additional conflict of interest requirements in the area of Continuing Medical Education (CME) have been established by the Accreditation Council for CME (ACCME). ACCME requires that relevant financial relationships of all individuals in a position to control CME content be identified and resolved prior to that individual's participation in development or delivery of CME activities.

- All individuals in position to control CME content – including planners, faculty, course directors – must disclose ALL relevant financial relationships, of any amount within the past 12 months, to the Mayo School of Continuous Professional Development.
- The School is required to ensure proper review of these potential conflicts and to resolve those conflicts prior to continued participation.
- A financial interest does not mean that an individual cannot participate in the CME activity. School staff will work with the course director and individuals involved to appropriately manage these potential conflicts.

The purpose of these requirements is to ensure that CME programming, including recommendations for treatment and therapeutic options, is free from bias.

The Conflict of Interest Review Board will provide assistance in reviewing and determining if a disclosed financial interest results in a conflict of interest with respect to educational activities.

VI. Conflict of Interest in Investments

Mayo Clinic investment decisions reflect the ethical and responsible stewardship of operational and development funds. In general, investment decisions occur through the Section of Treasury Services which manages the investment portfolios of Mayo Clinic and the Mayo Pension Fund and conducts general Treasury Services operations on an enterprise-wide basis.

For investment decisions made directly by Mayo Clinic, the following statements apply: (Investment decisions made on behalf of Mayo Clinic by its designated equity fund managers do not result in a conflict of interest for the institution.)

- Direct investments in either publicly traded or privately held companies to which Mayo has licensed intellectual property in exchange for equity and/or royalties may result in a conflict of interest for the institution and for the inventor(s) especially when the institution or individuals contemplate ongoing research on the licensed technology.
- Direct investments in either publicly traded or privately held companies with which Mayo intends to pursue research, educational or clinical practice activities may result in an institutional conflict of interest.
- Direct investments in companies for which a member of the Mayo Clinic Board of Trustees serves as an employee, director or officer are addressed through the Mayo Clinic Trustee Conflict of Interest Policy.

While the scenarios above may result in institutional and/or individual conflict of interest, in almost all instances they are manageable through Mayo Clinic Conflict of Interest Policies that ensure appropriate disclosure and transparency.

Questions regarding specific investments, with the exception of those already addressed in the Mayo Clinic Trustee Conflict of Interest Policy, should be directed to the Office of Conflict of Interest Review.

VII. Conflict of Interest in Leadership

For those in a leadership role, full disclosure and subsequent management of conflict of interest is essential in order to maintain credibility, trust and effectiveness with patients, staff and Mayo's external stakeholders.

For decisions related to any Mayo Clinic Clinical Practice, Education, Research, Purchasing or Administrative activity made by any staff member in a leadership role who has a financial interest related to the decision, full disclosure of the financial interest must occur to all those involved in the decision-making process. In addition, the staff member who has the financial interest may participate in the decision-making process sharing his/her expertise, but may not lead the process or vote on the final outcome. The staff member's disclosure of the financial interest and recusal from leading the process or voting on the final outcome should be documented in meeting minutes summarizing the overall decision-making process.

VIII. Conflict of Interest in Purchasing

The mission of the Department of Supply Chain Management (SCM) at Mayo Clinic is to deliver innovative solutions that result in the acquisition of high value supplies and services, sustained financial improvement, excellent customer service, and operational efficiency. This department may make quality and price-driven decisions removed from the influence of investigators who may have been involved in development of the product. With many technologies or devices, often the user of the technology with the best knowledge is the investigator who invented it or is funded to study it. For this reason, SCM decisions include, but are not restricted to, the following:

1. The decision to actually purchase a product or technology (i.e., the request that a purchase order be generated)
2. The selection of a supplier for a product or technology for evaluation, competitive bid or proposal
3. The actual negotiation of a purchasing agreement or contract with a supplier of a product or technology.

Management strategies may include, but are not limited to the following:

1. Full disclosure of potential conflicts to the decision-making body at the time of purchase discussions
2. Recusal from chairing a decision-making process
3. Recusal from final decision-making process
4. Documentation of recusal in meeting or purchase decision minutes.

A. Purchasing – Operational Guidelines

Teams, units or work groups considering a purchase or other decision involving an expenditure of \$100,000 or greater should use the "[Disclosure Form for Potential Conflicts of Interest in Purchasing and Other Decision-Making Processes](#)" to identify and manage financial interests for individuals. Disclosure is required for all members involved in the decision-making process, including those who initiate, review and make decisions about proposals to purchase goods or services. Individuals who disclose a financial interest should recuse themselves from leading the purchase or decision-making process and recuse themselves from voting during the process. (They may participate in all discussions.) Recusal should be documented. Disclosure information should be available to all those participating in the purchasing or decision-making process and should be included as part of the record documenting the final decision.

Team leaders should also clarify whether or not Mayo has a financial interest with proposed vendors. An institutional financial interest occurs when Mayo has licensed technology to the company and/or when Mayo has made a direct investment in the company. This information is available through Mayo Clinic Ventures. When the potential for institutional conflict of interest has been identified, the Conflict of Interest Review Board should be contacted for additional management strategies.

Current policies within Supply Chain Management expressly prohibit any vendor from attempting to influence a purchase decision by promising future charitable donations to Mayo Clinic or any of its entities or by acknowledging past gifts. Vendors who attempt to emphasize this information will be instructed that such information will not be considered in any purchase decision. Repeated attempts to include such information in vendor negotiations will result in the vendor being eliminated from consideration.

Departments or divisions involved in solicitation, review and/or negotiation activities related to vendor proposals regarding the purchase of goods, equipment or services should coordinate these activities through Supply Chain Management. While such activities are underway, staff directly involved in reviewing the vendor proposal may not concurrently solicit any funding or in-kind support from a potential vendor. In addition, the potential for future funding or in-kind support should not be a consideration within the purchase process.

IX. Staff Participation – Board of Directors/Trustees

Any Mayo staff member who is asked to become a member of the governing board (board of trustees or board of directors) or to accept appointment as a corporate officer or other commensurate position for any for-profit commercial entity in which Mayo Clinic does not hold a majority equity position must submit the invitation for review to the Conflict of Interest Review Board along with a full description of the time commitment and remuneration offers. Similarly, staff asked to join the governing board or accept appointment as a corporate officer for a not-for-profit entity involved in furnishing health care goods or services must submit the invitation and related information for review to the Conflict of Interest Review Board. The Conflict of Interest Review Board will determine the potential for a conflict of interest and/or conflict of commitment and develop an appropriate management strategy if necessary.

If service on the governing board or as a corporate officer or other commensurate position occurs on personal time, any remuneration provided may be retained personally.

Service on boards of directors/trustees for not-for-profit entities that are not involved in furnishing health care goods and services, e.g., philanthropic, religious, community, education, fraternal or professional organizations, does not require review. If service for such organizations does involve one's professional expertise, the Legal Department should be consulted for advice on professional liability.

X. Conflict of Interest in Professional Activities

Mayo Clinic staff participate in a variety of professional activities both internally and externally that pertain to research, education and clinical practice. Staff are expected to follow all Mayo Clinic Conflict of Interest Policies in these activities. Specifically, Mayo staff who participate in the development of practice guidelines, disease management strategies or other Mayo products related to clinical care, such as “Ask Mayo Expert,” are required to disclose any financial interests they may have in any invention, technology, company or product referenced in the materials created.

In addition, staff who participate in internal publishing activities including authoring, editing or being interviewed for articles in Mayo Clinic publications must make a similar disclosure. Mayo Clinic staff who participate in external professional activities must follow all Mayo Clinic disclosure requirements related to conflict of interest as well as disclosure requirements established by external publishers, professional societies, academic journals or other external entities regarding research, education or clinical practice activities.

XI. Development Department

Within Development solicitation activities, should a benefactor express interest in receiving favorable consideration for a future business relationship with Mayo Clinic or any of its entities based on past, current or future gifts, the Development Department will immediately cease any solicitation efforts and inform the benefactor that until any current or future proposed business contract has been culminated, no further gifts can be accepted. Following execution of a purchase agreement or selection of an alternate vendor, the Development Department may resume solicitation.

Further, within the Development negotiation process and within the final gift agreement, language must be included clearly stating that gifts to Mayo Clinic will not influence Mayo policies regarding ownership of intellectual property, purchasing policies and processes, education, employment, and /or research decisions. The gift agreement also must state that any proposed use of the Mayo name by the vendor must be reviewed by the Mayo Clinic Brand Team and that the gift to Mayo Clinic does not represent a direct endorsement of the benefactor’s organization, its products or services.

XII. Mayo Clinic Board of Trustees

The Conflict of Interest Review Board shall administer the Conflict of Interest Policy for Mayo Clinic trustees as specified in the Trustee Conflict of Interest Policy. (Please click here to view this policy: [Trustee COI Policy](#)) A compilation of all commercial entities disclosed will be provided to Supply Chain Management, Treasury Services and Legal Contract Administration. Any proposed contracts, e.g., research, purchasing, consulting, MTAs, CDAs, collaborations, etc., with any entity disclosed by a Mayo Clinic trustee will be reviewed either prior to execution or in an annual compilation by the Conflict of Interest Review Board.

The Trustee Conflict of Interest Policy requires disclosure by trustees of ownership interests. Specifically, the policy requires each trustee to disclose ownership interest of greater than one percent (1%) in public companies and all ownership interest in non-public companies. In addition, trustees are required to disclose any entity regardless of equity holdings in which they or their “Covered Family Member” are an employee, officer or director.

In order to manage any actual or perceived conflicts of interest associated with Mayo Clinic, the following situations involving companies disclosed by Mayo Clinic Trustees will be identified by the Division of Supply Chain Management and submitted to the Conflict of Interest Review Board for review:

- single purchases of greater than \$1M, if the disclosed company is publicly traded
- single purchases of greater than \$500,000, if the disclosed company is privately held
- aggregate purchases of greater than \$1M within a calendar year, if the disclosed company is publicly traded
- aggregate purchases of greater than \$500,000 within a calendar year, if the disclosed company is privately held

The review by the Conflict of Interest Review Board of single purchases above the listed thresholds will take place before agreements are finalized. The Conflict of Interest Board will assess the independence of transactions reaching these thresholds and will develop additional management strategies for the individual and the institution if necessary.

Mayo Clinic entities making sales to publicly traded or privately held companies disclosed by a Mayo Clinic trustee should provide documentation regarding such transactions to the Conflict of Interest Review Board for review and notation following completion of the transaction.

In addition to the ongoing review cited above, the Conflict of Interest Review Board shall compile an annual report of all transactions completed between Mayo Clinic and companies disclosed by Mayo Clinic trustees. This report will be submitted to the Governance Committee of the Board of Trustees. Management strategies will be developed and provided for trustees where necessary.

XIII. COI Policy Implementation

A. Disclosure

1. Annual Financial Disclosure

The Office of Conflict of Interest Review, at the request of the Conflict of Interest Review Board, shall implement annually a mandatory process for financial disclosure for all voting staff, fellows and professional associates in research at Mayo Clinic and for all physician and key administrative staff within Mayo Clinic Health System. Required information includes disclosure of relationships with commercial entities including personal receipt of consulting income and travel expenses; receipt of royalties from technology or know-how licenses; equity holdings; service on for-profit boards of directors; and unrestricted grants or gifts. Each relationship disclosed must fall within institutional policies. Individuals disclosing relationships that do not fall within institutional policies will be required to cease any further activity with the commercial entity and/or bring the relationship forward to the appropriate approval body for review and approval.

Information received through the Annual Financial eDisclosure process will be compiled for review by the Conflict of Interest Review Board, the Medical-Industry Relations Committee and the Board of Governors. Failure to complete this annual disclosure will be considered a disciplinary issue for review by the Personnel Committee.

2. Disclosure for Select Leadership, Groups and Work Areas

a. Groups, Committees and Work Areas

Members of groups, committees and work areas cited below must disclose financial interests in any commercial entity related to agenda items prior to review, discussion and/or decisions. Disclosures should encompass financial interests for the staff member, spouse or domestic partner, and dependent children. Information disclosed should include equity in publicly traded or privately held companies; receipt of royalties or contractual rights to receive royalties from licensing of inventions; receipt of compensation from consulting activities; and service on for-profit boards of directors. Members who disclose a financial interest must recuse themselves from any decision made by the group related to the commercial entity disclosed. Such recusal must be documented in the minutes of the group or committee.

- Conflict of Interest Review Board
- Department of Treasury Services
- Institutional Animal Care and Use Committee (IACUC)
- Institutional Review Board (IRB)
- Medical-Industry Relations Committee
- Mayo Clinic Ventures
- Pharmaceutical Formulary Committee
- Supply Chain Management Division
- Mayo Clinic Research Space and Equipment Subcommittee

b. Leadership

Members of the Board of Governors, regularly invited guests (“sit- withs”) and all corporate officers must provide the same disclosure information as that required by the Mayo Clinic Board of Trustees through the “[Annual Financial Disclosure and Conflict of Interest Acknowledgement](#)” form. Such information will be collected by the Office of Conflict of Interest Review annually and provided to the secretary of the Board of Governors and to the Conflict of Interest Review Board. Members of the Board of Governors and regularly invited guests must recuse themselves from any decision-making process at Mayo Clinic regarding any public or private commercial entity that they have disclosed. Documentation of such recusal should be noted within proceedings of the meeting.

c. Mayo Clinic Ventures

The Conflict of Interest Review Board shall review a compilation provided by Mayo Clinic Ventures of all commercial entities to which Mayo Clinic has licensed technology in exchange for equity and/or royalties or made a direct investment through Mayo Clinic Ventures’ Technology Based Venture fund.

Mayo Clinic Ventures should review proposed investments in commercial entities that may sponsor human subjects research or provide a product for human subjects research at Mayo Clinic or any of its entities with the Conflict of Interest Review Board prior to making the investment.

The Conflict of Interest Review Board shall receive notification from Mayo Clinic Ventures regarding any change in status in intellectual property commencing when the intellectual property is licensed. The Conflict of Interest Review Board should also receive notification when a technology or a license agreement has expired.

XIV. Entrepreneurship Activities

Mayo Clinic Employee Entrepreneurship

Mayo Clinic Employees may establish or participate in establishing non-Mayo business ventures on personal time subject to requirements outlined by the Medical-Industry Relations Committee. (Click here to review policy entitled "[Establishment of a Non-Mayo Business Enterprise on Personal Time.](#)")

Some of these business ventures may involve intellectual property licensed by Mayo Clinic Ventures to a business enterprise in which an employee inventor or other employee proponent holds equity.

Financial interests resulting from this activity may result in conflicts of interest for business owners/inventors especially if further development of the technology is envisioned using any Mayo resources; if the business enterprise wishes to enter into a research agreement with Mayo Clinic; and/or if Mayo Clinic pursues purchasing agreements with the company.

Mayo Clinic Conflict of Interest policies and processes as defined for research, clinical practice, education, purchasing, leadership, investment or leadership activities apply to all interactions with employee-owned companies. Such companies may or may not involve intellectual property licensed from Mayo Clinic.

Questions may be directed to the Office of Conflict of Interest Review, (77) 4-0024.

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 the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

Appendix B: Disclosure of Financial Interests and Related Research

Intellectual Property Status	Submit related research to the Conflict of Interest Review Board	Disclosure required	Language
1. Intellectual property disclosed to Mayo Clinic Ventures 2. Intellectual property for which a provisional patent application has been filed	No	No	N/A
3. Intellectual property for which a non-provisional patent application has been filed 4. Intellectual property for which a patent has issued	No	Disclosure in patient consent form in any clinical research	One (or more) of the investigators is the inventor of technology related to this research.
5. Intellectual property licensed to a commercial entity. You and Mayo Clinic have received royalties or have contractual rights to receive royalties. Mayo may hold equity in the licensee. 6. Equity in publicly traded or privately held companies. 7. Consulting for personal income from a commercial entity	Yes	<p>Disclosure in all publications, presentations and media releases regarding this research and to all staff, students and personnel associated with this research.</p> <p>Disclosure in patient consent form in any clinical research.</p> <p>Select for intellectual property</p> <p>Select for equity</p> <p>Select for consulting</p>	<ul style="list-style-type: none"> Mayo Clinic and I have a financial interest related to this research or I have a financial interest related to this research. This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and is being conducted in compliance with Mayo Clinic Conflict of Interest policies. This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and is being conducted in compliance with Mayo Clinic Conflict of Interest policies. Both the Mayo Clinic Conflict of Interest Review Board and the Institutional Review Board have reviewed the financial interest for one or more of the investigators and/or Mayo Clinic related to this research and they have determined that this financial interest poses no additional significant risk to the welfare of participants in this research project or to the integrity of the research. Additional information is available to any interested study participant regarding the details of this financial interest and how it is being managed by contacting the study coordinator or the Office of Conflict of Interest Review at 507-284-0075. One or more of the investigators associated with this project and Mayo Clinic have a financial interest in technology used in the research and that the investigator(s) and Mayo Clinic may stand to gain financially from the successful outcome of the research. One of the investigators associated with this project has a financial interest in one of the companies sponsoring this research, providing a product for the research or whose product is the subject of this research and that the investigator may stand to gain financially from the successful outcome of the research. One of the investigators associated with this project has received within the past 12 months consulting income from the company sponsoring this research, providing a product for the research or whose product is the subject of this research

Appendix C: Frequently Asked Questions

1. **If I disclose something to MCV, does that mean I can no longer do research?** In almost all cases, you can continue to participate in research projects up to the Phase 2(b) or Phase 3 stage. Management strategies may require slight modification of the protocol and/or internal corroboration of the results, but you will be able to continue your research. However, as the financial interest becomes more complex, you may not be able to serve as principal investigator or consent patients.
2. **Can I continue to do research if I receive royalties from the company sponsoring the research?** In most instances, you can continue conducting the research. Beyond \$5,000, for single-center, human subjects research, you will need to provide compelling circumstances why your participation is necessary.
3. **Can I continue to do research and receive consulting income personally from the company sponsoring the research?** No. Consulting income is viewed differently than royalties in that participation in consulting activities occurs at an individual's discretion with institutional approval. Royalties accrue as the result of a licensing agreement for specific technology or know-how.
4. **Do I have to disclose my intellectual property?** Yes. According to Mayo Clinic policy, all Mayo employees, appointees and students are required to promptly disclose any intellectual property believed to be patentable or of commercial value to Mayo Clinic Ventures.
5. **What about my NIH funding? Do I have to disclose to the NIH that I have a conflict beyond what I disclose through the grant submission process?** No. As required by federal regulation, the Conflict of Interest Review Board must alert the NIH acknowledging that a Financial Conflict of Interest has been identified and is being managed in accordance with Mayo Clinic policies and federal regulations.
6. **Are there other disclosures I need to make?** Please make sure when you submit a manuscript for publication that you ask the journal specifically for its requirements for conflict of interest. Some journals have more stringent disclosure requirements than either federal regulations or Mayo Clinic policy.
7. **Who can help me?** Contact the Office of Conflict of Interest Review, (77) 4-0024. Staff will help you complete forms, ensure that your disclosure is correct, place your item on the weekly agenda of the Conflict of Interest Review Board if necessary, communicate the appropriate management strategy as determined by the Conflict of Interest Review Board and ensure NIH is notified as required by federal regulations. Staff can also assist you with disclosure statements for consent forms, publications, presentations and internal meetings. To view sample disclosure statements for presentations, click here: [Sample Disclosure Slides](#)

Appendix D: Resources

[Conflict of Interest Review Board website](#)

[Conflict of Interest Training](#)

[Link to eDisclosure System](#)

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

NIH

[NIH Revised Regulations](#)

[Frequently Asked Questions \(FAQs\) about the final rule](#)

[FCOI Tutorial from NIH](#)

[FCOI Case Studies](#)

NSF

[NSF - Grants Policy Manual - COI Policy Guidelines](#)

AAMC

[General AAMC website](#)

[The Association of American Medical Colleges \(AAMC\) Forum on Conflict of Interest in Academe \(FOCI A\)](#)

[Implementing the Final Rule on Financial Conflicts of Interest in Public Health Service Funded Research](#)

[Implementing the Final Rule on Financial Conflicts of Interest in Public Health Service funded Research \(March 2012\)](#)

[Report of the Task Force on Financial Conflicts of Interest in Clinical Care \(June 2010\)](#)

[Report on Industry of Funding of Medical Education \(June 2008\)](#)

[Report of the AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research \(February 2008\)](#)

[Report on Institutions Financial Interest in Human Subjects Research \(October 2002\)](#)

[Report on Individual Financial Interest in Human Subjects Research \(December 2001\)](#)

FDA

[FDA Regulations](#)

Appendix E: Promoting Objectivity in Research for which PHS/NIH Funding is Sought (42 CFR Part 50, Subpart F)

§ 50.601

(b) In determining whether a dispensing fee is reasonable, the Secretary will take into account:

(1) Cost components such as overhead, professional services, and profits,

(2) Payment practices of third-party payment organizations, including other Federal programs such as titles XVIII and XIX of the Social Security Act; and

(3) Any surveys by States, universities or others of costs of pharmacy operations and the fees charged in the particular area.

(c) A certification by a prescriber, pursuant to paragraph (a) of this section, that a brand of drug is medically necessary for a particular patient shall be in the prescriber's own handwriting, in such form and manner as the Secretary may prescribe. An example of an acceptable certification is the notation "brand necessary". A procedure for checking a box on a form will not constitute an acceptable certification.

Subpart F—Promoting Objectivity in Research

AUTHORITY: 42 U.S.C. 216, 289b-1, 299c-4; Sec. 219, Tit. II, Div. D, Pub. L. 111-117, 123 Stat. 3034.

SOURCE: 76 FR 53283, August 25, 2011, unless otherwise noted.

§ 50.601 Purpose.

This subpart promotes 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.

§ 50.602 Applicability.

This subpart is applicable to each Institution that is applying for, or that receives, PHS research funding by means of a grant or cooperative agreement and, through the implementation of this subpart by the Institution, to each Investigator who is planning to participate in, or is participating in, such research; provided, however, that this subpart does not apply to SBIR Program Phase I applications. In those

42 CFR Ch. I (10-1-11 Edition)

few cases where an individual, rather than an Institution, is applying for, or receives, PHS research funding, PHS Awarding Components will make case-by-case determinations on the steps to be taken, consistent with this subpart, to provide a reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from a financial conflict of interest of the individual.

§ 50.603 Definitions.

As used in this subpart:

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

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

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional responsibilities means 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 means 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, or proposed for such funding, which may include, for example, collaborators or consultants.

Manage means 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 means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

PHS means 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 means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 *et seq.*

Research means 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 Awarding Component through a grant or cooperative agreement, whether authorized under the PHS 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 means 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 by the Institution under this subpart.

Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the In-

vestigator's spouse 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 fees, 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 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 income related to such rights and interests.

(2) Investigators also must disclose the occurrence 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, 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. The Institution's FCOI policy

will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) 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.

Small Business Innovation Research (SBIR) Program means 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.

§ 50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest.

Each Institution shall:

(a) Maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with this subpart, and make such policy available via a publicly accessible Web site. If the Institution does not have any current presence on a publicly accessible Web site (and only in those cases), the Institution shall make its written policy available to any requestor within five business days of a request. If, however, the Institution acquires a presence on a publicly accessible Web site during the time of the PHS award, the requirement to post the information on that Web site will apply within 30 calendar days. If an Institution maintains a policy on financial conflicts of interest that includes standards that are more stringent than this subpart (e.g., that require a more extensive disclosure of financial interests), the Institution shall adhere to its policy and shall provide FCOI reports regarding identified financial conflicts of interest to the PHS Awarding Component in accordance with the Institution's own standards and within the timeframe prescribed by this subpart.

(b) 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-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.

(c) If the Institution carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by:

(1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

(i) 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 this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required by this subpart;

(iii) Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this subpart.

(2) Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent

with this subpart, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

(d) Designate an institutional official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

(e)(1) Require that each Investigator who is planning to participate in the PHS-funded research 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-funded research.

(2) Require each Investigator who is participating in the PHS-funded research to 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 pursuant to paragraph (e)(1) of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-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).

(3) Require each Investigator who is participating in the PHS-funded research to 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.

(f) Provide guidelines consistent with this subpart for the designated institutional official(s) to determine whether an Investigator's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to PHS-funded research when the Institution, through its designated official(s), reasonably determines that

the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The Institution may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the PHS-funded research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

(g) Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator pursuant to paragraph (c) of this section. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to § 50.605(a).

(h) Provide initial and ongoing FCOI reports to the PHS as required pursuant to § 50.605(b).

(i) Maintain records relating to all Investigator disclosures of financial interests and the Institution's 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 the Institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations.

(j) Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

(k) Certify, in each application for funding to which this subpart applies, that the Institution:

(1) Has in effect at that Institution an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS;

(2) Shall promote and enforce Investigator compliance with this subpart's requirements including those pertaining to disclosure of significant financial interests;

(3) Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with this subpart;

(4) Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and

(5) Shall fully comply with the requirements of this subpart.

§ 50.605 Management and reporting of financial conflicts of interest.

(a) Management of financial conflicts of interest.

(1) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the designated official(s) of an Institution shall, consistent with § 50.604(f): review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

(i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

(ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;

(iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;

(iv) Modification of the research plan;

(v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

(vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

(vii) Severance of relationships that create financial conflicts.

(2) Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Institution, the designated official(s) of the Institution shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest 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 such financial conflict of interest. Depending on the nature of the significant financial interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Institution's review.

(3) Whenever an Institution identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS-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-funded research; determine whether a financial conflict of interest exists; and, if so:

(i) 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;

(ii)(A) In addition, whenever a financial conflict of interest is not identi-

fied or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution 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, the Institution shall, within 120 days of the Institution's determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the non-compliance, was biased in the design, conduct, or reporting of such research.

(B) The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

(1) Project number;

(2) Project title;

(3) PD/PI or contact PD/PI if a multiple PD/PI model is used;

(4) Name of the Investigator with the FCOI;

(5) Name of the entity with which the Investigator has a financial conflict of interest;

(6) Reason(s) for the retrospective review;

(7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

(8) Findings of the review; and

(9) Conclusions of the review.

(iii) Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken

to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

(4) Whenever an Institution implements a management plan pursuant to this subpart, the Institution shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

(5)(i) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:

(A) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;

(B) The Institution determines that the significant financial interest is related to the PHS-funded research; and

(C) The Institution determines that the significant financial interest is a financial conflict of interest.

(ii) The information that the Institution makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in 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.

(iii) If the Institution uses a publicly accessible Web site for the purposes of this subsection, the information that the Institution posts shall be updated at least annually. In addition, the Institution shall update the Web site within sixty days of the Institution's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if the Institution determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest. If the Institution responds to written requests for the purposes of this subsection, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

(iv) Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests or for posting via the Institution's publicly accessible Web site for at least three years from the date that the information was most recently updated.

(6) In addition to the types of financial conflicts of interest as defined in this subpart that must be managed pursuant to this section, an Institution may require the management of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

(b) Reporting of financial conflicts of interest.

(1) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with this subpart. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit an FCOI report to the PHS Awarding Component.

(2) For any significant financial interest that the Institution identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Institution shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this subpart. Pursuant to paragraph (a)(3)(ii) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institution also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to paragraph (a)(3)(iii) of this section, if bias is found, the Institution is required to notify the PHS Awarding

Component promptly and submit a mitigation report to the PHS Awarding Component.

(3) Any FCOI report required under paragraphs (b)(1) or (b)(2) of this section shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- (i) Project number;
- (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (iii) Name of the Investigator with the financial conflict of interest;
- (iv) Name of the entity with which the Investigator has a financial conflict of interest;
- (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (vi) Value of the 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;
- (vii) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- (viii) A description of the key elements of the Institution's management plan, including:
 - (A) Role and principal duties of the conflicted Investigator in the research project;
 - (B) Conditions of the management plan;
 - (C) How the management plan is designed to safeguard objectivity in the research project;
 - (D) Confirmation of the Investigator's agreement to the management plan;
 - (E) How the management plan will be monitored to ensure Investigator compliance; and

(F) Other information as needed.

(4) For any financial conflict of interest previously reported by the Institution with regard to an ongoing PHS-funded research project, the Institution shall provide to the PHS 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-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The Institution 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 specified by the PHS Awarding Component.

(5) In addition to the types of financial conflicts of interest as defined in this subpart that must be reported pursuant to this section, an Institution may require the reporting of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

§ 50.606 Remedies.

(a) If the failure of an Investigator to comply with an Institution's financial conflicts 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, the Institution shall 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 the Institution for further action, which may include directions to the Institution 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.

(b) The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any

Investigator disclosure of financial interests and the Institution's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interest. An Institution is required to submit, or permit on site review of, all records pertinent to compliance with this subpart. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular financial conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with this subpart. The PHS Awarding Component may determine that imposition of special award conditions under 45 CFR 74.14 and 92.12, or suspension of funding or other enforcement action under 45 CFR 74.62 and 92.43, is necessary until the matter is resolved.

(c) In any case in which the 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 a financial conflict of interest that was not managed or reported by the Institution as required by this subpart, the Institution shall require the Investigator 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.

