Conflict of Interest Policy

Conflict of Interest Review Board
http://mayoweb.mayo.edu/conflictofinterest

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I. Rationale

The term “conflict of interest,” refers to situations in which financial or other personal considerations may compromise, or have the possible appearance of compromising, one’s professional judgement. Individual conflicts may result in bias that may occur during the collection, analysis and interpretation of data associated with clinical protocols as well as clinical decision-making, the hiring of staff, procurement of materials, issues related to public relations and misuse of the Mayo name for personal gain.

The mere appearance of a conflict of interest may be just as serious and potentially damaging as an actual lack of objectivity. Apparent conflicts of interest should be evaluated and managed with the same degree of consideration as known conflicts of interest.

The potential for conflict of interest will increase as Mayo and its staff, acting as full time employees of Mayo, forms new partnerships, relationships and alliances with industry. The key to managing these conflicts, whether real or apparent, begins with full disclosure. When in doubt whether or not a conflict of interest exists, staff should consult the Conflict of Interest policy, or contact the Office of Medical-Industry Relations or Conflict of Interest Review Board.

II. Definition of 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 clinical practice, research, investment, leadership or purchasing actions taken by the individual or the institution that may have been influenced by consideration of significant financial conflict of interest. Conflict of interest depends on the situation, and not on the character or actions of an individual.

Conflicts of Interest most often occur in the following: purchasing decisions, leadership decisions (intramural and extramural), investment decisions, research decisions and clinical practice decisions.

III. Guidelines for Management of Conflict of Interest

The first step in identifying significant 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 significant conflict of interest is present. If so, then the third step is to institute measures for management of conflict. The following are recommendations for each type of decision considered.
A. Purchasing Decisions

Purchasing departments typically make quality and price-driven decisions removed from the influence of investigators who may have been involved in development of the product. However, 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. Purchasing 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.

For Purchasing Decisions made by individuals on behalf of Mayo Foundation, the Conflict of Interest Review Board should review and develop a management strategy for the following potential conflicts of interest:

- Holders of EQUITY >5% of company or >$10,000 value (whichever is lowest) excluding investments in mutual funds
- Recipients within the previous 12 months of license fees, royalties or contractual rights to receive future royalties of >$10,000 per year where the purchasing decision is directly related to the licensed technology of interest to the individual
- Recipients within the previous 12 months of consulting fees, honoraria, salary, gifts, or other emoluments or other in-kind compensation of >$10,000 with an individual company or competing vendor from whom the purchase is being made
- Recipients of consulting fees, honoraria, salary, gifts, or other emoluments or other in-kind compensation of >$10,000 per year
- Recipients of unrestricted research or education grants within previous 12 months
- Individuals involved with other current negotiations with a potential supplier that could lead to any of the above relationships
- Individuals who serve on advisory boards or boards of directors of vendors being considered in the purchase even if no compensation is involved

It is recognized that certain types of paid-up licensing contracts, providing fixed payments or research support, generally involve low potential for significant financial conflict of interest and do not require application of management strategies. Such circumstances must be determined through
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review by the Mayo Conflict of Interest Review Board. The essential characteristics of such paid-up licenses are that Mayo has fully performed its obligations, all payments are fixed at the finalization of the contract without reference to subsequent sales or other events, and that no disputes or extenuating circumstances exist.

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. Retention of equity until research or purchase decision is completed
5. Documentation of recusal in meeting or purchase decision minutes.

B. Leadership Decisions

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 Leadership Decisions made by staff on behalf of Mayo Foundation, the Conflict of Interest Review Board should review and suggest a management strategy for the following potential conflicts of interest:

- Holders of EQUITY (held in a for-profit company for which they serve as Director) >5% of company or >$10,000 value (whichever is lowest), excluding investments in mutual funds
- Recipients of Board of Directors' fees of > $10,000 per year
- Recipients within the previous 12 months of license fees, royalties or contractual rights to receive future royalties of >$10,000 per year where the leadership decision is directly related to the licensed technology of interest to the individual
- Recipients within the previous 12 months of consulting fees, honoraria, salary, gifts, or other emoluments or other in-kind compensation of >$10,000 where the leadership decision is directly related to the licensed technology of interest to the individual
- Recipients of consulting fees, honoraria, salary, gifts, or other emoluments or other in-kind compensation of >$10,000 per year
- Recipients of unrestricted research or education grants within previous 12 months.

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

1. Full disclosure of significant financial conflicts of interest to the decision-making body
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2. Recusal from chairing a decision-making process that could indirectly affect the relationship of the person with the company or its competitors and Mayo Foundation

3. Recusal from final decision-making process that could directly or indirectly affect the relationship of the person with the company or its competitors and Mayo Foundation

4. Documentation of recusal in meeting minutes.

For Leadership Decisions made by non-staff of Mayo Foundation (e.g. members of Board of Trustees), the task force recommends full disclosures by individuals who meet the following criteria:

- Members of boards of directors of commercial entities
- Holders of equity >$10,000 held in entities that could directly or indirectly affect Mayo Foundation

In addition, the Conflict of Interest Review Board should review these situations and propose management strategies. Management strategies include, but are not limited to:

1. Recusal from final decision-making processes in their trusted capacity at Mayo Foundation whenever a personal or potential conflict of interest could directly or indirectly affect Mayo Foundation

2. Documentation of recusal in the meeting minutes.

C. Investment Decisions

Mayo Clinic investment decisions should continue to reflect the ethical and responsible stewardship of operational and development funds. Investment decisions should be unrelated to any clinical practice, research or education activity.

For Investment Decisions made on behalf of Mayo Clinic, the following principles should apply:

1. Mayo Clinic should limit its equity holding to <5% in any publicly traded company whenever it intends pursuing research or educational activities with that company. This will ensure that Mayo Clinic is protected from any perception of conflict of interest.

2. Mayo Clinic should have no limit on investment/equity ownership when there is no intention to pursue research or educational activities with the company.

3. Mayo Clinic should have no limit on equity ownership in privately held company utilizing Mayo intellectual property. This would also pertain to a privately held company utilizing Mayo intellectual property that becomes a publicly traded company through an Initial
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Public Offering. If research activities sponsored by a privately held company are contemplated, the relationship and research activity should be reviewed by the IRB to ensure patient safety and by the Conflict of Interest Review Board for management of institutional conflict of interest.

4. If a privately held company (a company whose stock is not publicly traded) intends to sponsor research at Mayo Clinic, the following individuals and entities may not make direct investments in that company.

**Individuals**

a. Members of the Board of Governors, Executive Boards at the three sites, Institutional Review Board, Conflict of Interest Review Board, Pharmacy Formulary Committee, Institutional Animal Care and Use Committee, Mayo Health Solutions executive board, administrative staff and technology licensing managers, Investment Subcommittee and administrative staff within Mayo Treasury Services and Supply Chain Management Division.

b. All individuals listed on the research protocol.

**Entities**

Mayo Treasury Services and Mayo Clinic Health Solutions (See #5 below for exception.)

External, non-compensated members of the Mayo Clinic Board of Trustees, their spouses and dependent children may make direct investments in such companies, but must disclose this information annually and must recuse themselves from participation in any final decision taken by the Board of Trustees involving relevant companies. Recusal must be documented in meeting minutes.

5. Mayo Clinic wholly or partly-owned start-up companies whose platform is wholly or partly based on Mayo technology may sponsor laboratory research at Mayo Clinic, including work with cell systems, tissues and animals. Phase I (safety, proof of concept and early efficacy) clinical trials in humans may be conducted at Mayo Clinic provided the research is reviewed by the Conflict of Interest Review Board and configured in accordance with Mayo Clinic Conflict of Interest policies. With respect to clinical trials involving human subjects, the “rebuttable presumption” must be satisfied and a strategy for managing the conflict of interest developed and implemented. Beyond Phase I trials, proposed
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research must be configured in accordance with existing Conflict of Interest policies.

* "When reviewing any of the circumstances described in Section III, the ICOI committee should apply a rebuttable presumption against conduct of the human subjects research at or under the auspices of the institution. The presumption may be rebutted when the circumstances are compelling and the committee has approved an effective conflict management plan. Whether the ICOI committee deems the circumstances to be compelling should depend in each case upon the nature of the science, the nature of the interest, how closely the interest is related to the research, the degree of risk that the research poses to human subjects and the degree to which the interest may be affected by the research. The committee should consider whether the institution is uniquely qualified, by virtue of its attributes (e.g., special facilities or equipment, unique patient population) and the experience and expertise of its investigators, to conduct the research and safeguard the welfare of the human subjects involved."


D. Research Decisions

For Research Decisions involving humans, biospecimens and all research requiring IRB approval made by or at Mayo Foundation, the Conflict of Interest Review Board should review and develop management strategies to address potential conflicts of interest in the following situations:

- Holders of equity >5% of company or >$10,000 value (whichever is lowest) in a company sponsoring the research, excluding investments in mutual funds.

NOTE: Staff may not undertake sponsored research on behalf of any company, public or private, in which they have been granted warrants or options to purchase stock. Staff owning stock in a privately held company may not undertake sponsored research for that company. Staff owning stock in a publicly traded company may undertake sponsored research for that company provided that the market value of the stock owned is less than $20,000. All stocks and stock options owned must be disclosed to the Conflict of Interest Review Board prior to the initiation of any sponsored research. This policy does not apply to investments held through mutual funds over which the staff member has no direct oversight.
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- Recipients within the previous 12 months of license fees, royalties or contractual rights to receive future royalties of >$10,000 per year where the research is DIRECTLY related to the licensed technology of interest to the individual.
- Recipients of consulting fees, honoraria, salary, gifts, or other emoluments or other in-kind compensation of >$10,000 per year.
- Recipients of unrestricted research or education grants within previous 12 months.
- Recipients of research or education grants within previous 12 months that provide funds in excess of those required for reasonable expenses incurred in the performance of the research or educational activity.
- Individuals involved with other current negotiations with a potential sponsor that could lead to any of the above relationships.

For Research Decisions made at or by Mayo Foundation, full disclosure is required from individuals engaged in non-human research only when there is licensed technology or technology to which Mayo Foundation (through MCHS) or industry has assigned a monetary value. Thus, research studies that do not involve patients or patient materials (medical record or biospecimens) are associated with lower potential for conflict. When basic research involves individual or institutional financial conflict of interest, typically by virtue of assigned monetary value to the licensed technology (not just disclosure to the MCHS), the Conflict of Interest Review Board should be consulted in order to obtain advice on management of conflict.

In general, it is perceived that the basic research should continue at the laboratory of the potentially conflicted investigator given the nature of the work, the specific expertise available, and the mandate by the Bayh-Dole law (PL 96-517) to educational institutions including not-for-profit organizations to retain ownership in patents developed and to reduce these discoveries to the practice. Management of conflict in these situations will include recommendations of disclosure at the time of publication of data in scientific journals, and re-evaluation of the management of conflict when the discovery leads to studies that would require approval by the Institutional Review Board because of involvement of humans, medical records or patient biospecimens.

This disclosure and management policy is consistent with Federal Regulations for applicants for Public Health Service and/or National Science Foundation Non-Clinical Research Funding (PHS Final Rule 42 CFR Part 50 and 45 CFR Part 94; NSF Rule 59 FR 3308 and 60 FR 35820). At Mayo, disclosure is already required at the time such a grant is submitted.
for funding. This disclosure is required of all investigators and key research personnel and can be accomplished through completion of the Mayo Significant Financial Interest Disclosure Form (MC2410).

After review by the Conflict of Interest Review Board, management strategies, such as possible recusal from research activities according to the level of conflict, may be required. In certain circumstances, recusal may not be necessary when other methods are used to manage the potential conflict, as discussed in the examples in the next section.

E. Clinical Practice Decisions

Mayo Clinic is committed to identifying and effectively managing individual and institutional conflicts of interest that may occur in the conduct of research, education, or clinical practice activities. Policies for identifying and managing conflict of interest in research and education are detailed in federal regulations and ACCME standards respectively and in Mayo Clinic policy.

The purpose of this policy is to institute systematic policies for identification and management of conflict of interest in clinical practice that parallel those that are in place for research and education.

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 Conflict of Interest Review Board 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

1. 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 informed that if they have questions regarding such relationships, they may ask their physicians or other care givers or contact the Conflict of Interest
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Review Board for information regarding their care givers’ relationships with commercial entities.

2. Information provided to patients by the Conflict of Interest Review Board should 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 fees 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 any additional information, patients will be referred directly to their physician.

3. Mayo Clinic staff who earn annual consulting fees from one commercial entity for personal gain of greater than $10,000 in the preceding year or who have contractual arrangements to receive this amount from a commercial entity within a one-year period will be referred by the Medical-Industry Relations Committee to the Conflict of Interest Review Board. The Conflict of Interest Review Board will review each situation individually to determine if there is a significant individual conflict of interest in clinical practice and if so, it will develop a management strategy. (See #6)

4. Mayo Clinic staff who receive licensing royalties from one commercial entity greater than $10,000 in the preceding year or who have rights to receive this amount within a one-year period from a commercial entity for inventions or know-how will be referred by Office of Intellectual Property to the Conflict of Interest Review Board for review. The Conflict of Interest Review Board will review each situation individually to determine if there is a significant individual conflict of interest in clinical practice and if so, it will develop a management strategy. (See #6)

5. Mayo Clinic staff who earn total annual consulting fees 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.

6. Management Strategies
   Depending on the degree of the potential conflict, management strategies will include one or more of the following:
   a. Verbal disclosure to patient with documentation of disclosure in medical record
b. Corroboration by colleague of any prescription involving a product from the commercial entity

c. Corroboration by colleague documented in the medical record of any prescription involving a product from the commercial entity

d. Appointment of an Oversight Committee to monitor practice patterns

e. Transfer of patient care to another colleague

f. Cessation or modification of relationship with a commercial entity, if necessary

IV. Operational Guidelines for the Conflict of Interest Review Board

The Conflict of Interest Review Board will be responsible for communicating to the Personnel Committee leadership at Mayo Foundation sites situations where Mayo Foundation policies and procedures have not been followed. The potential for conflict may vary, as will the resulting management strategy, within the following scenarios:

A. Single center research studies with no technology for which a monetary value has been assigned, e.g., the technology has not been licensed to or purchased by a company.

B. Single center research studies with technology for which a monetary value has been assigned, when:

1. there is no Mayo Foundation equity
2. there is Mayo Foundation equity

C. Assigned monetary value occurs when the technology disclosed is licensed or sold. Since the royalty stream may not be active, each case will need to be reviewed individually to determine whether conflict actually exists, e.g., technology may be licensed, but no royalties immediately accrue.

Multicenter research studies for which neither Mayo Foundation nor the investigator has a conflict of interest, although Mayo participation and leadership in the study are strongly encouraged with the usual need for IRB review of human studies and IACUC review of animal studies.

D. Multicenter research studies in which the investigator and Mayo entities (including M ACT, NCCTG, and MCHS) both have a conflict. Participation of Mayo staff in a leadership role may be perceived as potentially conflicting, and hence, it increases the potential perception of bias to or inability to serve the best interests of research participants. In these circumstances, apart from IRB
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approval, Conflict of Interest Review Board review is required to determine whether the Mayo investigator may participate under certain conditions previously promulgated by the Mayo Foundation Medical/Industry Relations Committee and IRB. Management strategies include, but are not limited to:

- Study development is made by a steering committee consisting of Mayo (investigator) and non-Mayo members (including plans for design, conduct and analysis)
- Mayo will enroll less than twenty percent of total participants
- Conflicted investigator may not participate in operational aspects of study, may not enroll patients, gain informed consent, and cannot be site (Mayo) PI
- Informed consent must be obtained by a non-conflicted investigator who has no access to the data
- Study must follow a triple blind design: Investigators, assistants and technicians should be unaware of results
- Data management activities may not occur at investigator institution (Mayo)
- There must be an independent Data Safety Monitoring Board (DSMB) and Clinical Event Committee with a priori stopping rules for both safety and efficacy
- Central Core lab must be used when using surrogate endpoints for efficacy
- Dataset must be given to an independent statistician for comparison at the end of the study
- Data analysis and interpretation monitoring committee review any journal or regulatory reports
- Full disclosure of individual or institutional conflict of interest must occur to all study participants in informed consent, to all co-investigators, fellows and students.
- For single center research studies to be performed by Mayo Foundation staff the disclosure to MCHS in itself does not constitute a conflict of interest. However, the patient consent form must reflect the fact that a patent application has been made or the patent has been granted. Once license or royalty fees are received, the investigator and Mayo are conflicted.
- For multicenter research studies Mayo should not play a leadership role if both the investigator and the Mayo entity have a conflict.
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The following are flow charts for guidance on single and multicenter studies:

For Single Center Research Studies to be performed by
MAYO FOUNDATION staff

Pilot/feasibility/proof of concept

NO SIGNIFICANT
FINANCIAL CONFLICT e.g.,
Technology disclosed to MCHS
and not purchased or licensed

To IRB

SIGNIFICANT FINANCIAL CONFLICT e.g.,
- Technology disclosed to MCHS and
  licensed to or purchased by company
- Technology purchased by company
  independent of MCHS

No Mayo Foundation
EQUITY

Conflict exists

Studies at Mayo require review
and approval by
COI Review Board of MIRC

Mayo Foundation
EQUITY

Significant Conflict exists
V. Additional Potential Conflicts of Interest

In addition to the specific examples resulting in conflict of interest cited earlier, the following would also be considered as possible conflicts of interest:

A. An investigator undertakes basic or clinical research when the investigator or the investigator’s immediate family has a financial, managerial or ownership interest in the sponsoring organization.

B. A staff member accepts significant gratuities or special favors from sponsors of investigations or providers of health care products.

C. A staff member enters into a consulting arrangement as a member of an advisory board or protocol evaluator with an organization or company that is presently sponsoring his or her research study. This is permissible under certain circumstances, but requires approval from the Medical-Industry Relations Committee.

D. Mayo employees perform services for a company in which the employee has an ownership interest or receives any type of remuneration.

E. Institutional resources are used without authorization or reimbursement for personal purposes or to support the activities of MultiCenter Research Studies, MAYO should NOT play a leadership role if investigator and Mayo entities (including MPACT, NCCTG, MCHS) both have a conflict.

Potential or Significant Conflict exists

Studies at Mayo require approval by IRB and COI subcommittee, since there is a potential risk to participants

Mayo investigator may participate under certain conditions
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a company in which the staff person holds a financial or other interest.

F. A staff member associates his or her name or work with Mayo in such a way as to profit monetarily by trading on the reputation and goodwill of Mayo.

G. Privileged information acquired in connection with one’s professional responsibilities is used for personal gain without authorization.

H. Access to privileged information developed within Mayo is provided to any external entity with or without personal gain.

I. Equipment, instruments or supplies are purchased from a firm in which the staff person has a financial or other interest.

J. A staff member influences the negotiation of contracts between Mayo and an outside organization with which that person has a financial interest or other relationship.

Investigators are expected to report any real or perceived conflict of interest relating to research at the time a protocol is submitted for review to the Institutional Review Board. Summary of Information for Review of Research Involving Human Subjects (MC1407) should be used by investigators to indicate a potential conflict of interest. A letter describing the relationship that might represent a conflict of interest should be submitted with the protocol. These review boards will submit protocols involving all such relationships to the Medical-Industry Relations Committee for review before approving the protocol. Investigators also are expected to contact the Conflict of Interest Review Board at any time during the course of the protocol should additional conflicts of interest arise.

VI. Oversight Committees

In very specific circumstances, appointment of a new staff member who has a potential conflict of interest as outlined in this document may be approved as an exception to policy by the Mayo Clinic Board of Governors. New staff candidates must disclose such potential conflicts to Mayo. To manage these potential conflicts, the Mayo Clinic Board of Governors has approved development of Oversight Committees to review potential conflicts, establish a plan of management and monitor the activities of the individual to ensure adherence to Mayo, federal and state policies regarding conflict of interest and conflict of commitment. These individual Oversight Committees report to the Conflict of Interest Review Board, and ultimately to the Mayo Clinic Board of Governors.
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Prior to the candidate’s appointment to staff, the Oversight Committee will assess whether the candidate’s commercial interests constitute impermissible conflicts and/or whether the conflicts can be appropriately managed while the individual is employed by Mayo. The Oversight Committee also will assess whether the staff member’s commercial interests are consistent with the initial and continued appointment to Mayo by reviewing both conflicts of interest and conflicts of commitment.

VII. Definitions

Significant Financial Interests

Significant financial interests are defined as interests valued at greater than $10,000 or interests representing more than 5 percent ownership or an equity interest valued at $10,000 or greater for any one enterprise or entity when aggregated for the investigator and the investigator’s spouse and dependent children.

These interests include:

A. Any financial interest of the principal investigator or key personnel that could possibly affect or be perceived to affect the results of the research, educational, or services activities funded or proposed for funding;

B. Salary or other payment for services (e.g., consulting fees or honoraria);

C. Equity interests (e.g., stocks, stock options or other ownership interests); or

D. Intellectual property rights (e.g., patents, copyrights and royalties from such rights including licensing arrangements through Mayo Health Solutions).

The term does not include:

- Salary or other non-royalty remuneration from Mayo Foundation;
- Income from seminars, lectures or teaching engagements sponsored by nonprofit entities;
- Income from service on advisory committees or review panels for nonprofit entities; or
- Financial interests in business enterprises or entities if the value of such interests does not exceed $10,000 (or $10,000 per annum if such interests represent salary, fees or other continuing payments) or does not represent more than 5 percent ownership or an equity interest valued at $10,000 or greater for any one enterprise or entity.
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when aggregated for the investigator and the investigator’s spouse and dependent children.

Investigator
Investigator is defined as any Mayo Foundation employee responsible for the design, conduct or reporting of the activity funded or to be funded by the sponsored project. Generally, this includes the principal investigator, co-investigators and key scientific personnel. For the purposes of disclosure, the term “investigator” includes the investigator’s spouse and dependent children.

Forms
Mayo Significant Financial Interest Disclosure (MC2410)
http://mayoweb.mayo.edu/sp-forms/mc2400-mc2499/mc2410.pdf

Annual Financial Interest Disclosure - 2005 (MC0219-13)