



Conflict of Interest Policy

Conflict of Interest Review Board

<http://mayoweb.mayo.edu/conflictofinterest>

Approved by the Mayo Foundation Executive Committee -
April 14, 2003

Amended and approved by the Mayo Foundation Executive Committee -
January 5, 2004

Amended and approved by the Mayo Clinic Board of Governors -
January 16, 2006

Amended and approved by the Mayo Clinic Board of Governors -
October 30, 2006

Amended and approved by the Mayo Clinic Board of Governors -
February 9, 2009

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Mayo Clinic Conflict of Interest Policy

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 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 research, clinical practice, education, leadership, investment or purchasing actions taken by the individual or the institution that may have been influenced by consideration of *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: research decisions, clinical practice decisions, education decisions, leadership decisions (intramural and extramural), investment decisions and purchasing 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.

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A. Research

Introduction

The purpose of this policy is to avoid, through the process of open disclosure and review, actual or potential conflicts of interest between an investigator's research project obligations and private interests or obligations. This policy applies to all internally or externally funded research and to any research involving a disclosure to the Office of Intellectual Property within Mayo Clinic Health Solutions (MCHS). It is consistent with the Public Health Service (PHS) regulations, "Objectivity in Research," 42 CFR, Part 50 and 45 CFR, Part 94 and the National Science Foundation (NSF) regulations, "Investigator Financial Disclosure Policy," effective June, 28, 1995. This Policy supplements, but does not supplant, related Mayo Clinic policies on Conflict of Interest.

1. Classification

a. All Research

For **Research Decisions** involving humans, animals, biospecimens and all other research requiring IRB, IACUC or departmental approval made by or at Mayo Clinic, 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 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.
- Recipients within the previous 12 months of license fees, royalties or contractual rights to receive future royalties per year where the research is DIRECTLY related to the licensed technology of interest to the individual.

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- Recipients of consulting fees, honoraria, salary, gifts, or other emoluments or other in-kind compensation per year.
- Recipients of unrestricted research or education grants within the previous 12 months.
- Recipients of research or education grants within the 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.

The parameters outlined above are supplemented, but not supplanted, by the federal definition of Significant Financial Interest as cited in 42 CFR Part 50, Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought*, Section 50.603.

Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

- Salary, royalties, or other remuneration from the applicant institution; NOTE: Mayo Clinic Conflict of Interest Policy requires disclosure of royalties from any source.
- Any ownership interests in the institution, if the institution is an applicant under the SBIR Program;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or nonprofit entities;
- An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or
- Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000. NOTE: Mayo Clinic Conflict of Interest Policy requires disclosure of financial interests from the first dollar.

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

b. Preclinical Research

For **Research Decisions** made at or by Mayo Clinic, full disclosure is required from individuals engaged in *preclinical research* only when there is licensed technology or technology to which Mayo Clinic (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.

For preclinical research, research investigators must indicate whether or not the proposed research that is related to the financial interest disclosed is anticipated to (1) be a component of an IND submission or (2) progress to research involving human subjects within the next 12 months.

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2. Reporting

Generally, this 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's spouse and dependent children.

All individuals listed on a protocol who may be responsible for design, conduct, or reporting of activity must complete a "Significant Financial Interest Disclosure for Research" form (MC2410) in order to disclose all financial interests that would reasonably appear to be directly and significantly affected by the research, educational, or service activities funded or proposed for funding or supported through the provision of a drug or medical device; and/or by an external sponsor; and/or in entities whose financial interests would reasonably appear to be directly and significantly affected by such activities.

Mayo Clinic Conflict of Interest Policy requires disclosure of financial interests from the first dollar.

Federal regulations require institutions to have policies and procedures in place to ensure that research project investigators disclose any significant financial interests that may present an actual or potential conflict of interest in relationship to externally sponsored research projects. Mayo Clinic policies extend this requirement for disclosure to all internally funded projects as well in order to ensure that any potential conflicts of interest are identified and managed. Such disclosures must be made prior to the submission of a proposal for funding. 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 Significant Financial Interests as defined in federal regulation, and/or financial interests as defined by Mayo Clinic Conflict of Interest Policy, must be reported to the Conflict of Interest Review Board and managed, reduced or eliminated and reported to the PHS Awarding Component within 60 days of identification.

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3. Review Criteria

Disclosures will be reviewed by the Conflict of Interest Review Board to determine whether any reported financial interest would reasonably appear to be directly and significantly affected by the proposed project. 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. 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, Research Services (for grants or contracts requesting funding) 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 a project might have a direct and significant impact on the financial interest, the Board will work with the investigator to develop strategies to manage, reduce or eliminate the potential conflict.

Certain types of paid-up exclusive 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 review by the Mayo Clinic Conflict of Interest Review Board. The essential characteristics of such paid-up exclusive 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.

4. Management

The Conflict of Interest Review Board, in consultation with the investigator, will develop management strategies that define special conditions or restrictions to manage, reduce or eliminate conflicts of interests. Examples of conditions or restrictions that may be imposed to manage or eliminate actual or potential conflicts of interest include:

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- a. Public disclosure of financial interests;
When noted in a conflict of interest management strategy, disclosure must include:
 - 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 researchDisclosure to human subjects must include a statement that the conflict has been reviewed by the Conflict of Interest Review Board, approved 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.
- b. 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.
- c. Modification of the research or project plan;
- d. Disqualification from participation in all or a portion of the project;
- e. Divestiture of significant financial interests; or
- f. Severance of relationships that create actual or potential conflicts.
- g. Rebuttable Presumption*
Investigators whose financial disclosures reflect significant individual and institutional financial interest 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 are determined by the Conflict of Interest Review Board to meet the rebuttable presumption due to compelling reasons, despite individual and institutional conflict of interest, will be approved to go forward with appropriate management strategies for one year only. Additional review will be required in the interim if the technology is patented, licensed, subject to milestone payments based on research and/or if royalties exceed \$10,000 for the individual and the institution, and at one-year intervals. This is necessitated by

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the designation of meeting the rebuttable presumption.

(*See Appendix B - Definitions)

NOTE:

Management strategies to satisfactorily manage, reduce, or eliminate conflicts of interest must be approved by the Conflict of Interest Review Board prior to expenditure of an award.

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 Appendix A.

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), as well as standards proposed in *Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research*, AAMC 2008.

5. Reports to PHS after Grant Award

Prior to expenditure of any PHS funds under an award, Mayo Clinic will report to the PHS Awarding Component the existence of a conflicting interest found by the institution and assure that the interest has been managed, reduced or eliminated in accordance with Section 50.604 (g)(2); 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.

6. Sanctions

When an investigator has financial interests that would reasonably appear to be directly and significantly affected by the research project, the Conflict of Interest Review Board will recommend to the Mayo Clinic Board of Governors that the project not proceed. Failure to file a completed "Significant Financial Interest Disclosure for Research" form for research project proposals or to update this information on an annual basis, in addition to at any point 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.

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If the failure of an Investigator to comply with Mayo Clinic Conflict of Interest Policy has biased the design, conduct, or reporting of the PHS-funded research, Mayo Clinic will promptly notify PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to Mayo Clinic for further action, which may include directions to Mayo Clinic on how to maintain appropriate objectivity in the funded project.

7. Record Retention

In accordance with federal regulation, Mayo Clinic will maintain records of all financial disclosures and all actions taken by Mayo Clinic with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report, or where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.

8. Subrecipient Monitoring

Sub-recipients, subgrantees, contractors, and/or collaborators will be required through the contractual language to notify Mayo Clinic Office of Sponsored Projects Administration of any financial conflicts of interest and the attendant management strategies in place at the sub-recipient institution. Those notifications will be forwarded to the Conflict of Interest Review Board for approval. In addition, at the time of Mayo Clinic's annual A-133 audit, sub-recipients will be asked to provide copies of their conflict of interest policies, a list of sub-awards from Mayo that have a positive disclosure and a report containing resolutions determined by all the positive disclosures. This report will be forwarded to the Conflict of Interest Review Board. To review the entire Subrecipient Monitoring Policy, please go to:
<http://mayocontent.mayo.edu/research-policy/MSS639876>.

Awardee subrecipient institutions must report to the Mayo Clinic the existence of any conflicting interests arising from those entities and assure that the interest has been managed, reduced, or eliminated in accordance with the regulation.

B. Clinical Practice

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

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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 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 in the preceding year or who

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have contractual arrangements to receive personal consulting fees 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 in the preceding year or who have rights to receive royalties 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

C. Education

Education decisions 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

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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 potential conflict 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.

D. 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 **Leadership Decisions** made by staff on behalf of Mayo Clinic, 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 or Trustee in a company excluding investments in mutual funds)
- Recipients of Board of Directors' or Trustees' fees per year
- Recipients within the previous 12 months of license fees, royalties or contractual rights to receive future royalties 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 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

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emoluments or other in-kind compensation per year within the previous 12 months

- Recipients of unrestricted research or education grants within the 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
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 Clinic
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 Clinic
4. Documentation of recusal in meeting minutes.

For **Leadership Decisions** made by non-staff of Mayo Clinic (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 held in entities that could directly or indirectly affect Mayo Clinic

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 Clinic whenever a personal or potential conflict of interest could directly or indirectly affect Mayo Clinic
2. Documentation of recusal in the meeting minutes.

E. Investment

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:

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1. Mayo Clinic should limit its equity holding 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 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, Pharmaceutical Formulary Committee, Institutional Animal Care and Use Committee, Mayo Clinic 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.

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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 research must be configured in accordance with existing Conflict of Interest policies.

^{*} “When reviewing any of the circumstances described in this Section, the Conflict of Interest Review Board 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 Conflict of Interest Review Board 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.”

**Taken from Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution’s Financial Interests in Human Subjects Research, Association of American Medical Colleges Task Force on Financial Conflicts of Interest in Clinical Research, 2002.*

F. Purchasing

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:

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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 Clinic, the Conflict of Interest Review Board should review and develop a management strategy for the following potential conflicts of interest:

- Holders of EQUITY in a company excluding investments in mutual funds within the previous 12 months
- Recipients within the previous 12 months of license fees, royalties or contractual rights to receive future royalties 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 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 within the previous 12 months
- Recipients of unrestricted research or education grants within the previous 12 months
- Individuals involved with other current negotiations with a potential supplier that could lead to any of the above relationships within the previous 12 months
- Individuals who serve on advisory boards or boards of directors of vendors being considered in the purchase even if no compensation is involved within the previous 12 months

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.

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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” (MC0219-07) to identify and manage potential conflicts of interest 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 potential conflict 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 potential institutional conflict of interest with proposed vendors. An institutional conflict of 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 the Office of Intellectual Property. 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.

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IV. 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.
- D. An individual performs services for a company in which the individual has an ownership interest or receives any type of remuneration.
- E. 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.
- F. Privileged information acquired in connection with one's professional responsibilities is used for personal gain without authorization.
- G. Access to privileged information developed within Mayo is provided to any external entity with or without personal gain.
- H. Equipment, instruments or supplies are purchased from a firm in which the staff person has a financial or other interest.
- I. Membership – 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) for any for-profit commercial entity or for a not-for-profit entity involved in furnishing health care goods or services must submit the invitation to the Conflict of Interest Review Board along with a full description of the time commitment and remuneration offered. 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. The request and related management strategy will then be forwarded to the Mayo Clinic Board of Governors for final review and approval.

If service on the governing board occurs on personal time, any remuneration provided may be retained personally. Mayo staff are restricted to service on no more than two for-profit external boards that are not affiliated with Mayo Clinic.

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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.

V. Operational Guidelines

A. Annual Industry Financial Interest 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 Health System. Required information includes disclosure of relationships with commercial entities including personal receipt of consulting fees, travel expenses and/or per diem; 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 Industry Financial Interest Disclosure 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.

B. Conflict of Interest Review Board

Members of the Conflict of Interest Review Board must at the time of their appointment and annually thereafter complete the form entitled, "Annual Disclosure for Selected Leadership Groups, Committees and Work Areas" (MC0219-12). Individual members must recuse themselves from any decision made by the Conflict of Interest Review Board regarding research either funded by or related to the commercial entity disclosed or for which the commercial entity is providing a product. Such recusal must be documented in the minutes of the Conflict of Interest Review Board.

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C. Supply Chain Management Division

Members of the Supply Chain Management Division must at the time of their appointment and annually thereafter complete the form entitled, “Annual Disclosure for Selected Leadership Groups, Committees and Work Areas” (MC0219-12). Individual members must recuse themselves from any decision made by the Supply Chain Management Division regarding purchases of any goods or services from the commercial entity disclosed.

D. Department of Treasury Services

Members of the Department of Treasury Services must at the time of their appointment and annually thereafter complete the form entitled, “Annual Disclosure for Selected Leadership Groups, Committees and Work Areas” (MC0219-12). Individual members must recuse themselves from any decision made by the Department of Treasury Services regarding investments in the commercial entity disclosed.

The Conflict of Interest Review Board shall review monthly a compilation provided by Treasury Services of all companies in which Mayo Clinic through Treasury Services holds equity directly and/or has made a direct investment.

E. Development

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.

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F. Educational Grants

Educational grants or gifts >\$10,000 solicited by any department, division or individual for programs that have no relationship to or review by the Mayo Clinic College of Medicine must be reviewed by the Conflict of Interest Review Board prior to expenditure of any funds.

G. Medical-Industry Relations Committee

Members of the Medical-Industry Relations Committee must at the time of their appointment and annually thereafter complete the form entitled, "Annual Disclosure for Selected Leadership Groups, Committees and Work Areas" (MC0219-12). Individual members must recuse themselves from any decision made by the Medical-Industry Relations Committee regarding the commercial entity disclosed. Such recusal must be documented in the minutes of the Medical-Industry Relations Committee.

H. Pharmaceutical Formulary Committee

Members of the Pharmaceutical Formulary Committee and its task forces must at the time of their appointment and annually thereafter complete the form entitled, "Annual Disclosure for Selected Leadership Groups, Committees and Work Areas" (MC0219-12). Individual members must recuse themselves from any decision made by the Pharmaceutical Formulary Committee regarding purchases of any goods or services from the commercial entity disclosed. Such recusal must be documented in the minutes of the Pharmaceutical Formulary Committee.

I. IACUC

Members of the Institutional Animal Care and Use Committee must at the time of their appointment and annually thereafter complete the form entitled, "Annual Disclosure for Selected Leadership Groups, Committees and Work Areas" (MC0219-12). Individual members must recuse themselves from any decision made by the IACUC regarding research either funded by or related to the commercial entity disclosed or for which the commercial entity is providing a product. Such recusal must be documented in the minutes of the IACUC.

J. IRB

Members of the Institutional Review Board must at the time of their appointment and annually thereafter complete the form entitled, "Annual Disclosure for Selected Leadership Groups, Committees and Work Areas" (MC0219-12). Individual members must recuse themselves from any decision made by the IRB regarding research

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either funded by or related to the commercial entity disclosed or for which the commercial entity is providing a product. Such recusal must be documented in the minutes of the IRB.

Whenever research is funded or a product is provided for that research by a privately held company in which Mayo has an equity position, the research must be referred to the Conflict of Interest Review Board for development of a conflict of interest management strategy prior to its consideration by the IRB.

K. Leadership

Covered individuals include the Board of Governors and regularly invited guests (“sit-withs”), Executive Boards at Mayo Clinic Rochester, Mayo Clinic Arizona and Mayo Clinic Florida and all corporate officers.

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” (MC0219-21) 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.

L. 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. A compilation of all commercial entities disclosed will be provided to Supply Chain Management and Legal Contract Administration. Any proposed contracts, e.g., research, purchasing, consulting, etc., with any entity disclosed by a Mayo Clinic trustee must be reviewed prior to execution by the Conflict of Interest Review Board.

M. Office of Intellectual Property

- The Conflict of Interest Review Board shall review a compilation provided by the Office of Intellectual Property of all commercial entities to which Mayo Clinic has licensed technology and/or made a direct investment through the Office of Intellectual Property’s Technology Based Venture fund.

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- The Office of Intellectual Property 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 the Office of Intellectual Property regarding any change in status in intellectual property commencing at the non-provisional patent application stage and continuing through licensing, royalties accrual and institutional investments. The Conflict of Interest Review Board should also receive notification when a technology or a license agreement has expired.
- Members of the Office of Intellectual Property must at the time of their appointment and annually thereafter complete the form entitled, “Annual Disclosure for Selected Leadership Groups, Committees and Work Areas” (MC0219-12). Individual members must recuse themselves from any decision made by the Office of Intellectual Property regarding license agreements with the commercial entity disclosed. Such recusal must be documented by the Office of Intellectual Property.

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.

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.

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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.

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Appendix A

Additional Guidelines Regarding Research for the Conflict of Interest Review Board

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 Clinic equity
 2. there is Mayo Clinic equity
- C. Assigned monetary value occurs when the technology disclosed 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 Clinic 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.

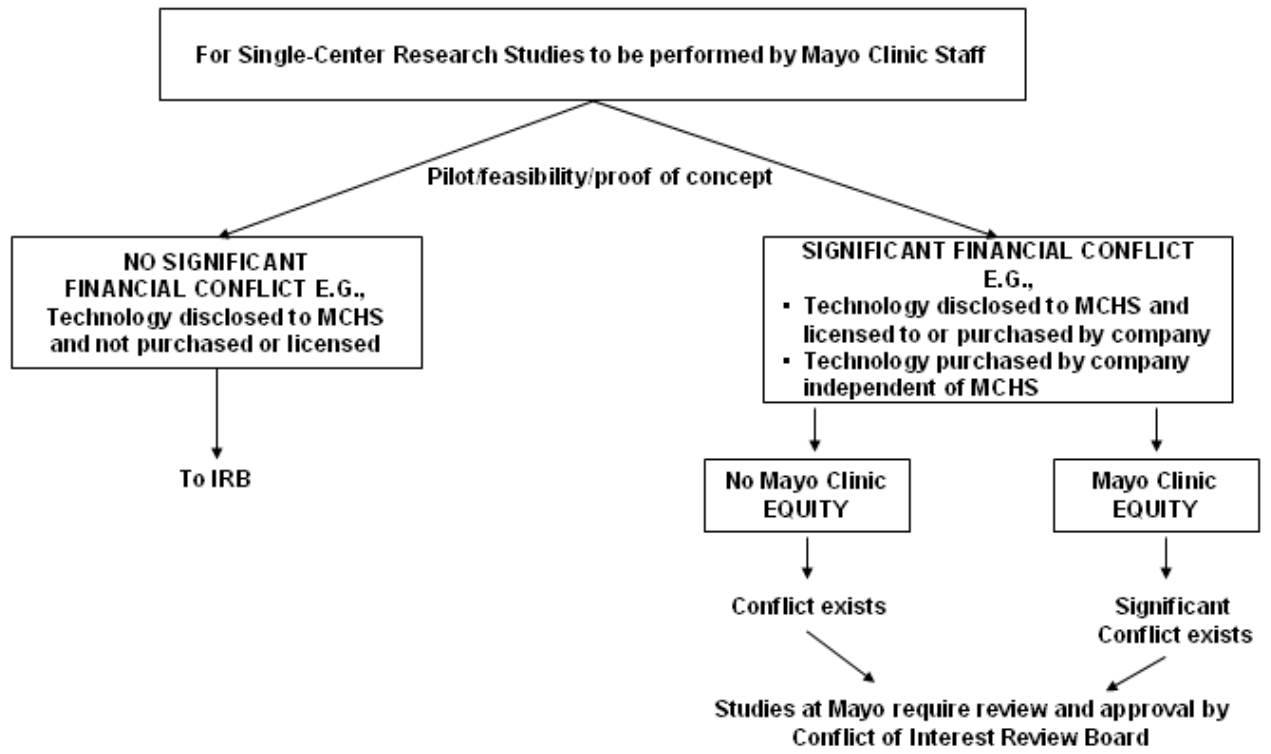
- D. Multicenter research studies in which the investigator and Mayo entities (including NCCTG, and MCHS) both have a conflict. Participation of Mayo staff in a leadership role may be perceived as potentially conflicting, and hence, it increases the potential perception of bias to or inability to serve the best interests of research participants. In these circumstances, apart from IRB approval, Conflict of Interest Review Board review is required to determine whether the Mayo investigator may participate under certain conditions. 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 20 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

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- 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 Clinic 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
- E. Whenever research is funded or a product is provided for that research by a privately held company in which Mayo has an equity position, the research must be referred to the Conflict of Interest Review Board for development of a conflict of interest management strategy prior to its consideration by the IACUC, IRB or Office of Sponsored Projects Administration.

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The following are flow charts for guidance on single and multicenter studies:



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Appendix B

Definitions

HHS

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

Human Subjects Research

Any research that involves humans as subjects or any clinical investigation.

Institution

Any domestic or foreign, public or private, entity or organization (excluding a Federal agency).

Intellectual Property

Any inventions, discoveries, improvements, ideas, know-how, trade secrets, trademarks, trade names, and works of authorship, whether or not patentable or copyrightable, or reduced to writing or practice, and any rights thereto, including, without limitation, patents and copyrights. Intellectual property encompasses a product of the mind, such as an invention or literary work. Examples include any new and useful idea, process, composition of matter, software, copyrighted work or tangible property. Intellectual property may be protected by law through, for example, obtaining a copyright, patent or trademark. Know-how, defined below, is also considered intellectual property. Intellectual property, including that within know-how licenses, developed by Mayo employees, students and contractors as part of consulting activities is the property of Mayo Clinic for Medical Education and Research.

Invention

All discoveries, works of authorship, visual works and the like, including all associated intellectual property. An invention may be any new and useful process, machine, article of manufacture, composition of matter, or related improvement. The process of invention begins with conception of the invention, and ends in reduction to practice (actually making the invention). In order for an invention to be patentable it must have utility (be useful), it must be novel (new and original), and it must be non-obvious to one of ordinary skill in the technical field related to the invention at the time the invention was made.

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Inventor

A person who conceives an invention. Under U.S. patent law, an inventor is the person(s) who contributes to conception of the invention as claimed in a patent. Any Mayo employee, student, contractor or appointee may be an inventor.

Investigational Device Exemption

A FDA approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have pre-market approval to be shipped lawfully for the purpose of conducting investigations of that device.

Investigational New Drug (IND)

FDA granting of permission that a new drug, agent or biologic may be used in humans prior to FDA review of clinical data that has determined that a particular new drug, agent, or biologic is safe and effective for a specific use. This FDA permission is evidenced by the assignment of an IND number by the FDA or the granting of an IND exemption.

Investigator

The principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. For purposes of this subpart relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children.

Know-how

Information not generally known to the public and that may be useful to a third party in its business activities. Know-how is intellectual property.

Minimal Risk

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination).

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PHS

Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

PHS Awarding Component

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

Public Health Service Act or 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.

Relevant Financial Relationships

For educational programs that are designated for AMA Physician Recognition Award Category 1 Credit™ (commonly known as 'CME Credit'), the Accreditation Council for CME defines a "relevant financial relationship" as "financial relationships in any amount occurring within the past 12 months that create a conflict of interest." [See www.accme.org] ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.

Research

A systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and

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applied research and product development. 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.

Significant Financial Interest

Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

1. Salary, royalties, or other remuneration from the applicant institution;
NOTE: Mayo Clinic Conflict of Interest Policy requires disclosure of royalties from any source.
2. Any ownership interests in the institution, if the institution is an applicant under the SBIR Program;
3. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
4. Income from service on advisory committees or review panels for public or nonprofit entities;
5. An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or
6. Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.
NOTE: Mayo Clinic Conflict of Interest Policy requires disclosure of financial interests from the first dollar.

Small Business Innovation Research (SBIR) Program

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

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Forms

Mayo Significant Financial Interest Disclosure for Research (MC2410)

<http://mayoweb.mayo.edu/sp-forms/mc2400-mc2499/mc2410.pdf>

Annual Industry Financial Interest Disclosure - 2007 (MC0219-13)

<http://mayoweb.mayo.edu/sp-forms/mc0200-mc0299/mc0219-13.pdf>



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MC0219-09rev0409

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