

Title: Conflict of Interest in Research	Policy Number: A-COM-0009 Policy Type: Administrative Effective Date of this Policy: 02/01/04
Replaces (supersedes): Title:	Policy Chronicle: Date the Original Version of Policy was Effective: Most Recent Review (month/year): March 2011 Reviewer: _____ Date: 03/01/11 Print Name: J. Glover Taylor Title: Director, Sponsored Research Administration Previous Reviews: February 2004 Previous Reviews: _____ month _____ year Previous Reviews: _____ month _____ year Previous Reviews: _____ month _____ year
Area of Operations: Sponsored Research Administration	
Regulatory Agency: Public Health Service (PSF) National Science Foundation (NSF) National Institutes of Health (NIH) Department of Health and Human Services (DHHS) Food and Drug Administration (FDA) Office of Human Research Protections Office of Civil Rights Office of Research Integrity	THIS POLICY HAS BEEN REVIEWED AND APPROVED ELECTRONICALLY: J. Glover Taylor Director, Sponsored Research Administration Lior Givon, MD Co-Chair, Institutional Review Board Somava Stout, MD President of Medical Staff Dennis Keefe Chief Executive Officer
Keywords(s)	Conflict of Interest, Research, Significant Financial Interest

I. Purpose:

This policy establishes the definition of conflict of interest involving research conducted at Cambridge Health Alliance or by Cambridge Health Alliance employees. This policy is intended to serve as a guide for research staff in structuring their relationships with industry and other outside ventures in view of their responsibilities for research and patient care. This policy applies to any employee of Cambridge Health Alliance who is responsible for the design, conduct, or reporting of research activities

II. Personnel: All Cambridge Health Alliance employees

III. Policy:

A Conflict of Interest exists when it can be reasonably determined that an investigator's personal financial concerns could directly and significantly influence the design, conduct or reporting of research activities. Investigators conducting research funded by the Public Health Service (for example, National Institutes of Health and Department of Health and Human Services) and National Science Foundation, as well as those conducting studies regulated by the Food and Drug Administration, are subject to agency specific regulations. These regulations set forth the obligations of investigators, sponsors and institutions for research involving significant financial interests or other conflicts of interest, and affected parties are advised to review the relevant regulations prior to submissions of a research proposal or application.

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IV. Procedure:

A) Who is Covered? Investigator means the Principal Investigator/Project Director, Co-principal Investigators, and any other key personnel responsible for the design, conduct, or reporting of research. In this context, the term "Investigator" also includes the Investigator's spouse and dependent children.

B) What is Covered? "Significant Financial Interests" includes:

1. Payments in excess of \$10,000 including salary, consulting fees, royalty, or licensing payments from intellectual property, honoraria, and/or gifts received within the past 12 months or anticipated for the next 12 months (excluding salary and other payments for services from Cambridge Health Alliance).
2. Equity interest worth more than \$10,000 or more than 5% of the business entity as determined by reference to its publicly listed price (excluding mutual funds).
3. Any equity interest if the value cannot be determined by reference to publicly listed prices (e.g., start up companies).
4. A position as director, officer, partner, trustee, employee, or any other position of management; or
5. Patent rights or royalties from such rights whose value may be affected by the outcome of the research, including royalties under any royalty-sharing agreement involving Cambridge Health Alliance.

"Significant Financial Interest" does not include:

1. Salary, royalties, or other remuneration from Cambridge Health Alliance.
2. Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities.
3. Income from services on advisory committees or review panels for public or nonprofit entities.
4. 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, or does not represent more than a 5% ownership interest in any single entity.
5. Salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 over the subsequent twelve month period.

C) What Must be Disclosed? Each Investigator shall disclose, prior to the submission of a proposal and annually, all significant financial interests that would reasonably appear to be affected by or influence the research.

D) How Should it be Disclosed?

V. Project Based Disclosure: A Cambridge Health Alliance "Conflict of Interest Disclosure Form" must be completed and submitted along with an application for a PHS or NSF grant, foundation funding, or any contractual agreement providing funding for research activities. Investigators are prohibited from expending any PHS or NSF funding until after the review of their disclosure and approved resolution of any conflicts of interests.

A Cambridge Health Alliance "Conflict of Interest Disclosure Form" must also be completed and submitted to the IRB along with an IRB Application and Research Proposal.

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- VI. Annual Disclosure: Investigators must submit a Conflict of Interest Disclosure Form annually to the Cambridge Health Alliance Office of Sponsored Research Administration.

If you are a Harvard Medical School Faculty member, you are required to submit a Disclosure Form annually to Harvard Medical School. Submission of the HMS Disclosure form satisfies the CHA requirement. HMS will forward your completed Disclosure form to Cambridge Health Alliance Office of Sponsored Research Administration for review and resolution of any conflicts. HMS will contact you directly each year with the procedures and deadlines for submission.

If you are not a Harvard Medical School Faculty member, you must submit the Cambridge Health Alliance Conflict of Interest Form annually to the Office of Sponsored Research Administration. The CHA Office of Sponsored Research Administration will notify you of the procedures and deadlines each year.

- E) What Happens to the Disclosure? The Office of Sponsored Research Administration will review each Investigator's disclosure to determine if the Significant Financial Interest might influence the design, conduct or reporting of the research. If so, the Significant Financial Conflict must be reduced, eliminated, or in some cases managed, at the discretion of Cambridge Health Alliance's Office of Sponsored Research Administration. Conflicts of Interest that require resolution must be resolved prior to the expenditure of related grant funds from PHS or NSF. It is the responsibility of the Office of Sponsored Research Administration to report to the sponsoring agency that a conflict exists and is being managed by the Institution.

The Conflict of Interest disclosure form and records of all further actions related to such disclosure will be maintained in the Office of Sponsored Research Administration for five years following termination of the relevant award, or any subsequent action relating to that award.

- F) Confidentiality of the Conflict of Interest: All disclosures and information provided by an employee for the purpose of disclosure and management and all official records of disclosure and management shall be strictly considered confidential. Any information disclosed by an employee as required by this policy shall be used solely for the purpose of administering this policy and may not be used for any other purpose, unless required by law. However, Cambridge Health Alliance's Office of Sponsored Research Administration and the Institutional Review Board have the right to use and share any information for the sole purpose of evaluating, auditing, resolving, and reporting conflict of interest issues.
- G) Compliance: Any member of the Cambridge Health Alliance community who initiates a research project must evaluate whether that project is going to be of personal financial gain. Research projects must comply with specific policies and regulations designed to protect human subjects and privacy rights.

There are serious consequences for not following Cambridge Health Alliance policies and Federal regulations when conducting research. Failure to properly disclose relevant financial interests or to adhere to conditions or restrictions imposed by the Office of Sponsored Research Administration will be considered a deviation from accepted standards of conducting research at Cambridge Health Alliance.

Alleged violations of this policy will be investigated by the Office of Sponsored Research Administration. Breaches of policy include failure to file the necessary disclosure statements;

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knowingly filing incomplete, erroneous, or misleading disclosure forms; or failure to comply with procedures prescribed by this policy. If the Office of Sponsored Research Administration determines that the policy has been violated, sanctions may be imposed. Sanctions could include, but are not limited to, notification to sponsor, termination of the research project; a letter to the investigator's personnel file; and suspension of the privilege to conduct future research, at the Cambridge Health Alliance.

Criteria in determining a potential Conflict of Interest

The following guidelines are established to assist Principal Investigators, the Institutional Review Board, and the Office of Sponsored Research in evaluating potential conflicts of interest. These guidelines are not meant to establish a rigid or comprehensive code of conduct. Rather, they are to be applied consistent with the public trust placed in Cambridge Health Alliance to perform its mission with the highest ethical standards.

The following is a representative and non-inclusive list of extramural relationships subject to this policy. These examples have been divided into three groupings.

- Categories I(a), I(b), I(c), and I(d) consist of relationships that are generally not allowable with certain de minimis exceptions
- Categories II(a) - (g) consist of relations that are generally allowable only after disclosure, review, and approval with oversight by Cambridge Health Alliance with advice from the Office of Sponsored Research Administration.
- Category III consists of instances that will ordinarily be permissible following disclosure and, where necessary, the implementation of oversight procedures designed to ensure academic standards, intellectual values, and institutional integrity.
- Category IV is thought to be allowable because they are (a) accepted practices and (b) generally minimal in their personal financial impact.

CATEGORY I (a), (b), (c), and (d) Activities are generally not allowable. The only exceptions are conflicts that arise in extraordinary circumstances such as the recruitment of a new Faculty Member, where a conflict may be allowed to continue for a finite time period with disclosure and the approval of the CEO.

Research Activities

I(a) A Faculty Member Participating in Clinical Research on a Technology owned by or contractually obligated to a Business in which the Faculty Member, a member of his/her Family, or an Associated Entity has a consulting relationship, holds a stock or similar ownership interest, or has any other Financial Interest, other than receipt of University- or Hospital- supervised Sponsored Research support or post-market royalties under institutional royalty-sharing policies.

I(b) A Faculty Member receiving University- or Hospital-supervised Sponsored Research support (whether in dollars or in kind) for Clinical Research or research which does not involve human subjects, from a Business in which he/she, a member of his/her Family, or an Associated Entity holds a stock or similar ownership interest. Sponsored Research (and the prohibition of equity ownership) is considered to have ended when the term of the Sponsored Research agreement has ended and publications reporting on the research are completed (or the decision made not to publish). It is the Faculty Member's responsibility to determine when that time has been reached.

De Minimis Exception to Category I (a) and I (b) Conflicts

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(a) A Faculty Member may continue to hold stock or similar ownership interest in a Business in a situation which would otherwise create an impermissible Category I (a) or I (b) conflict only if all of the following conditions are met:

1. The stock or similar ownership interest must be in a publicly held, widely traded Business.
2. The current value of the stock or similar ownership interest may not exceed \$30,000 at any time.
3. There must be no relationship between acquisition of the stock or similar ownership interest and research to be conducted. Situations that satisfy this requirement include stock or similar ownership interest acquired in arms-length transactions or by family gift sufficiently prior to the beginning of the research to assure the lack of a relationship and stock or similar ownership interest acquired by inheritance. In any such situation there must be complete independence between a purchase decision or other acquisition and the research.
4. While meeting the above criteria excepts a Faculty Member from what would otherwise be an impermissible Category I (a) or I (b) conflict, it does not except a Faculty Member from other conflict categories such as Category II(e) which imposes an obligation to disclose a Financial Interest in the research in any publication or presentation.

(b) A Faculty Member may consult for a Business in a situation which would otherwise create an impermissible Category I (a) conflict only if all of the following conditions are met:

1. The amount of money received by the Faculty Member for consulting relationships, fees, or honoraria from a given Business should not exceed \$20,000 a year. Consulting relationships include contractual relationships with a Business (or from an agent or other representative of such Business), service on advisory boards and any other relationship whereby the Faculty Member receives, or has the right or expectation to receive, income from a Business in exchange for services. Honoraria include commissioned papers and occasional lectures (no more than four lectures a year) for which money is received, either directly or indirectly, from a given Business (or from an agent or other representative of such Business).
2. While meeting the de minimis criteria above excepts a Faculty Member from what would otherwise be a Category I(a) conflict, it does not exempt the Faculty Member from other possible conflict categories such as Category II(e) which imposes an obligation to disclose a Financial Interest in the research in any publication or presentation.

External Activities

I(c) A full-time Faculty Member is not permitted to take an Executive Position (responsible for a material part of the operations of a Business such as Chief Executive Officer, Chief Operations Officer, Scientific Director or Medical Director) in a for-profit Business engaged in commercial or research activities of a biomedical nature.

I(d) A Faculty Member who serves on the Board of Directors of a Business is not permitted to Participate in Clinical Research on a Technology owned by or obligated to the Business regardless of whether he/she has a Financial Interest in the Business and is not permitted to receive Sponsored Research from that Business regardless of whether he/she has an equity interest in the Business. This provision does not apply to a Faculty Member who is a member of a Scientific Advisory Board and who does not either hold an Executive Position or serve on the Board of Directors.

CATEGORY II (a) - (g) Activities that May be Allowable Only after Disclosure, Review, and Approval by University or Affiliated Hospital with Advice from the Standing Committee When Requested:

Research Activities

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II(a) A Faculty Member conducting research externally that would ordinarily be conducted within the University or Hospitals.

Committee Participation

II(b) A Faculty Member participating in the consideration by a committee of the FDA, other governmental agency, or private insurer of Clinical Research on a Technology which is owned by or contractually obligated to a Business in which that Faculty Member, a member of his/her Family, or an Associated Entity has a Financial Interest.

External Activities

II(c) A Faculty Member making clinical referrals to a Business in which such Faculty Member, a member of his/her Family, or an Associated Entity has a Financial Interest.

II(d) A Faculty Member possessing a Financial Interest in a Business which competes with the services provided by the University or any Hospital with which the Faculty Member is affiliated.

Public Disclosure

II(e) A Faculty Member publishing or formally presenting research results, or providing expert commentary on a subject, without simultaneously disclosing any Financial Interest in a Business which owns or has a contractual relationship to the Technology being reported or discussed or which sponsors the research being reported or discussed.

Administrative Responsibilities

II(f) A Faculty Member taking administrative action within the University or any affiliated Hospital which is beneficial to a Business in which he/she has a Financial Interest.

Applicants for Public Health Service and/or National Science Foundation Research Funding

II(g) Under federal regulations a Faculty Member who is an applicant for Public Health Service and/or National Science Foundation funding has a potential conflict under the federal regulations, if the Faculty member, spouse and/or dependent children have a "significant financial interest," which could directly and significantly affect the design, conduct or reporting of the federally funded research.

"Significant Financial Interest" for Category II(g) Conflict

For the purposes of a Category II(g) conflict, as defined above, a "significant financial interest" consists of "anything of monetary value" from the Business, including salary, consulting fees, honoraria, equity interests and intellectual property rights, with the exception of salaries, royalties and remuneration from University or an affiliated Hospital, honoraria for presentations sponsored by public or non-profit entities or income from service on advisory or review panels for public or non-profit entities. Also excepted for the purposes of a Category II(g) conflict are salary, royalties or other payments that, when aggregated for the Faculty Member, spouse and/or dependent children, are not expected to exceed \$10,000 over the subsequent twelve months and equity

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interests, that, when similarly aggregated, do not exceed \$10,000 in value or, if the monetary value cannot be ascertained, 5% ownership interest in the business.

Resolution of Category II(g) Conflict

A Category II(g) conflict as defined above must be resolved by management, reduction or elimination, prior to the expenditure of funds from the Public Health Service and/or National Science Foundation. Possible resolution of Category II(g) conflicts may include, but is not limited to, public disclosure of the significant financial interest, monitoring of research by independent reviewers, modification of research plans, disqualification from participation in Public Health Service and/or National Science Foundation funded research, divestiture of the significant financial interest, and severance of relationships that create the Category II(g) conflict.

CATEGORY III Activities that are Ordinarily Allowable Following Disclosure and, Where Necessary, the Implementation of Oversight Procedures:

Research Activities

III(a) A Faculty Member Participating in Clinical Research on a Technology developed by that Faculty Member or a member of his/her Family, unless the activity falls under the guidelines of Category I.

III(b) A Faculty Member assigning students, post-doctoral fellows or other trainees to projects sponsored by a for-profit Business in which the Faculty Member, a member of his/her Family, or an Associated Entity has a Financial Interest, unless the activity falls under the guidelines of Category I. (See section on Mentor's Obligation to Students and Trainees below)

Board Memberships

III(c) A Faculty Member serving on the Scientific Advisory Board of a Business from which that Faculty Member or a member of his/her Family receives University- or Hospital-supervised Sponsored Research support or with which the University has a substantial contractual relationship known to the Faculty Member, unless the activity falls under the guidelines of Category I. See Category I(d) above.

External Activities

III(d) A Faculty Member assuming an Executive Position in a not-for-profit Business engaged in commercial or research activities of a biomedical nature.

CATEGORY IV Activities that are Routinely Allowable:

IV(a) A Faculty Member receiving royalties for published scholarly work and other writings.

IV(b) A Faculty Member receiving post market royalties under institutional royalty-sharing policies.