

Title:	Financial Conflicts of Interest
Department:	Human Research Affairs
Policy Type:	<input checked="" type="checkbox"/> Partners System-wide <input type="checkbox"/> Partners System-wide Template <input type="checkbox"/> Partners HealthCare <input type="checkbox"/> Partners HealthCare Departmental <input type="checkbox"/> Institution
Applies to:	Employees, Professional Staff or Other Agents of Brigham and Women's Hospital (BWH), Faulkner Hospital (FH), Massachusetts General Hospital (MGH), McLean Hospital (McLean), and North Shore Medical Center (NSMC)
Approved by:	Chief Academic Officer
Original Approval Date:	May 24, 2007
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Current Revision Effective Date:	July 14, 2014
Next Review Date:	July 14, 2017
Contact Person:	Director, Human Research Review and Compliance

KEYWORDS:

IRB, Institutional Review Board

PURPOSE:

The purpose of this policy is to ensure the objectivity of human-subjects research, and to avoid actual or perceived conflicts of interest in such research, by defining the process for consideration by the IRBs for Massachusetts General Hospital, Brigham and Women's Hospital, Faulkner Hospital, McLean Hospital (McLean), and North Shore Medical Center (NSMC) (the "Partners IRBs" or the "IRB") of financial conflicts of interest in the review of human-subjects research and clinical investigations.

This policy applies to human-subjects research and clinical investigations reviewed by the Partners IRBs. While the scope of this policy extends to all human-subjects research and clinical investigations, the IRB may choose to review financial conflicts of interest only in certain categories of such research and investigations as are determined by the IRB to be of heightened risk or concern. The IRB may also choose to delegate portions of the collection, review, analysis, and proposed resolution of any particular situation to other institutional officials, subject always to the final approval of the IRB of the resolution.

DEFINITIONS:

See Definition of Human Subjects Research

Financial Interest is defined as an interest in a company consisting of: (1) any stock, stock option or similar ownership interest in the business, but excluding any interest arising solely by reason of investment in a company by a mutual, pension, or other institutional investment fund over which you do not exercise control; or (2) receipt of, or the right or expectation to receive, any income from such business (or from an agent or other representative of such business), whether in the form of a fee (e.g., consulting), salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing of technology, rent, capital gain, real or personal property, or any other form of compensation, or any combination thereof. For the purposes of this policy, the term financial interest includes, but is not limited to: (i) royalties presently being received; (ii) the right to receive royalties in the future; and (iii) licensing fees or milestone payments; including any of the foregoing (i)-(iii) which are paid or payable to the individual directly or through institutional revenue-sharing policies.

Investigator means the principal investigator, site responsible investigator, co-investigators, and any other person who is responsible for the design, conduct, or reporting of the research.

POLICY STATEMENT:

Review of human-subjects research by the Partners IRBs must take into consideration financial interests that may be relevant to the conduct of the research. In cases when the Partners IRB determines that there is a financial conflict of interest that could affect or otherwise be relevant to the research, the IRB must determine that the conflict is either eliminated or appropriately managed to ensure that the rights and welfare of human subjects are protected. The Partners IRB, in its discretion, may consult or coordinate with other committees within the institutions in making such determinations. The Partners IRB has final authority to make decisions regarding resolution of the conflict and the conduct of the research. Note: Investigators are also subject to the disclosure and other requirements of the Faculty of Medicine Harvard University Policy on Conflicts of Interest and Commitment (“Harvard Medical School Conflicts of Interest Policy”) and/or the Partners Conflicts of Interest Policy.

PROCEDURES:

Principal investigators, site responsible investigators, co-investigators and any other member of the study staff identified by the Principal Investigator as being responsible for the design, conduct, or reporting of human-subjects research or clinical investigations in such categories as determined by the IRB must disclose their Financial Interests through the Partners Disclosure System in Insight by completing the Investigator Financial Disclosure Form on a study-by-study basis. For each study, investigators are required to disclose, whether they, or to their knowledge, any family member have a financial interest in a company that could reasonably appear to be related to the study, specifically whether a company in which they have a financial interest:

- a. Is the sponsor of the study;
- b. Owns, manufactures, or develops any drug, device, or technology that is used in a significant way in the study;
- c. Is developing products or technology similar to any drug, device, or technology that is being investigated by the study;
- d. Owns, manufactures or develops any drug, device, or technology, the value of which could be influenced by the results of the study;
- e. Could reasonably be interested in any new IP resulting from the study; or
- f. Could otherwise reasonably appear to be affected by the study.

Completion of the Investigator Financial Disclosure Form does not take the place of the obligation of staff to fill out other periodic conflict of interest disclosure forms that are required by Harvard Medical School or Partners HealthCare.

Investigator Financial Disclosure Forms that disclose financial interests that could reasonably be related to the study shall be referred to the Office for Interactions with Industry for review.

The Office for Interactions with Industry (OII) shall review any disclosed financial interests of individuals that are not prohibited by the Harvard Medical School Conflicts of Interest Policy, the Partners Conflicts of Interest Policy, or other applicable policies and shall make recommendations to the IRB relating to the disclosed financial interest. The recommendations may include, but need not be limited to, the following options: that the disclosed financial interest is: (a) not acceptable (in which case the financial interest must be divested or other action taken); (b) acceptable with some form of management (such as disclosure, restrictions on the activities of the investigator, or such other form as determined appropriate); or (c) acceptable without any need for management.

Investigators must report to the Office for Interactions with Industry (OII) and to the Partners IRBs any changes to the information provided in the Investigator Financial Disclosure Form, as soon as possible, but in no event later than thirty (30) days after the change.

The Director and Chair of the Partners IRB or designee may request information on and review any other financial interests that could affect or otherwise be relevant to a specific research protocol.

In the course of reviewing recommendations from OII relative to the disclosed financial interest, the Director and Chair of the Partners IRBs or designee may consult with representatives of the Professional and Institutional Conduct Committee (PICC) or other institutional committees as would be helpful, or with legal counsel, as well as establish whatever subcommittees of the IRB that may be useful to assist in rendering a determination. If a referral to PICC or another committee is made, the Partners IRB reviewing the research shall be informed of the referral and shall be notified of the outcome of the review. Full approval of the Partners IRB shall be contingent upon the outcome of the committee/referral process. The Partners IRB has final authority to make decisions regarding management of the conflict and the conduct of the research.

The Partners IRB responsible for review of the research shall review the recommendations of the Director and Chair and shall determine whether the recommendations are acceptable. If not, the IRB may determine that other action needs to be taken.

The investigator with disclosed financial interests, and other pertinent institutional officials as appropriate, shall be notified of the determinations of the Partners IRBs with respect to disclosed financial interests as part of the IRB review notification process.

OTHER APPLICABLE PARTNERS HEALTHCARE POLICIES:

Partners Conflicts of Interest Policy

REFERENCE:

45 CFR 46
21 CFR 56
21 CFR 54

DEVELOPMENT AND CONSULTATION

Human Research Affairs
Office of the General Counsel
Office for Interactions with Industry

Reviewed by:	Original Review Date:	Revision Approval Dates:
Dennis A. Ausiello, MD, Chief Scientific Officer	December 16, 2010	
Anne Klibanski, MD, Chief Academic Officer		May 5, 2015