

Title:	Individual Financial Conflicts of Interest
Department:	Human Research Affairs
Policy Type:	Mass General Brigham System-wide
Applies to:	Employees, Professional Staff or Other Agents of Mass General Brigham
Approved by:	Chief Academic Officer
Original Approval Date:	May 24, 2007
Original Effective Date:	May 24, 2007
Revision Approval Date(s):	December 6, 2007; September 7, 2010; May 16, 2011; July 14, 2014
Current Revision Effective Date:	December 1, 2020
Next Review Date:	January 15, 2022
Contact Person:	Director, Human Research Office

KEYWORDS:

IRB, Institutional Review Board

PURPOSE:

The purpose of this policy is to ensure the objectivity of human subject research, and to avoid actual or perceived conflicts of interest in such research, by defining the process for consideration by the Mass General Brigham Institutional Review Board (Mass General Brigham IRB) of financial conflicts of interest in the review of human subject research and clinical investigations.

This policy applies to human subject research and clinical investigations reviewed by the Mass General Brigham IRB. While the scope of this policy extends to all human subject research and clinical investigations, the IRB may choose to review financial conflicts of interest only in certain categories of such research and investigations as 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 Definitions in Human Subject Research

POLICY STATEMENT:

Review of human subject research by the Mass General Brigham IRB must take into consideration financial interests that may be relevant to the conduct of the research. In cases when the Mass General Brigham 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 Mass General Brigham IRB, in its discretion, may consult or coordinate with other committees within the institutions in making such determinations. The Mass General Brigham 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 Mass General Brigham 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 subject research or clinical investigations in such categories as determined by the IRB must disclose their Financial Interests through 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 or Mass General Brigham. 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 (OII) for review.

The OII shall review any disclosed financial interests of individuals that are not prohibited by the Harvard Medical School Conflicts of Interest Policy, the Mass General Brigham 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 OII and to the Mass General Brigham IRB 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 Senior IRB Chair 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 Senior IRB Chair 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 Mass General Brigham IRB shall be informed of the referral and shall be notified of the outcome of the review. Full approval of the Mass General Brigham IRB shall be contingent upon the outcome of the committee/referral process. The Mass General Brigham IRB has final authority to make decisions regarding management of the conflict and the conduct of the research.

The Mass General Brigham IRB shall review the recommendations of the Senior 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 Mass General Brigham IRB with respect to disclosed financial interests as part of the IRB review notification process.

OTHER APPLICABLE MASS GENERAL BRIGHAM POLICIES:

Partners Policy for Interaction with Industry and Other Outside Entities

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