

Title:	IRB Member 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 Scientific Officer
Approval Date:	April 29, 2008
Effective Date:	April 29, 2008
Revision Date(s):	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 clinical investigations, and to avoid actual or perceived conflicts of interest in the review of such research, by defining the process for managing Mass General Brigham IRB members' conflicts of interest, when such members are participating in the review of such research and investigations. This policy applies to all Mass General Brigham IRB members and to consultants, who are not IRB members but sometimes are asked to review a research project because of their expertise.

POLICY STATEMENT:

IRB members will disclose all (zero threshold) financial and non-financial interests with respect to the protocols of which they are proposed to be involved in the review to the Senior IRB Chair, or designee. Disclosures are to be reported prior to the relevant IRB meeting, but if that is not possible, disclosures must be reported at the beginning of the meeting where any such protocols are being reviewed. The Senior IRB Chair or designee will determine the appropriate management of an IRB member's involvement in the review of a specific protocol with respect to which the IRB member has disclosed a financial or non-financial interest. If the Senior IRB Chair or designee determines that the disclosed interest(s) would reasonably appear to affect the ability of the IRB member to objectively review the project, and therefore constitute a "conflict of interest," the IRB member will not be allowed, in full committee, to participate in the discussion and vote on that protocol, and will not be allowed to perform expedited review(s) or make determinations of exemption for that protocol. Consultants who are determined to have a

conflict of interest regarding a specific protocol will not be allowed to review the protocol. An IRB member who has been determined to have a conflict of interest may provide information to the IRB, at the IRB's request. An IRB member may not consult, with or without compensation, for a business to assist it in shepherding a project through the IRB process when the project will be performed within Mass General Brigham.

PROCEDURES:

1. All IRB members will regularly be notified and reminded of this policy.
 - The IRB Member COI policy will be part of new IRB member orientation.
 - Members will be directed to the policy in preparation for each meeting, a summary of which appears on IRB members' agenda documents (included with meeting materials and protocols).
2. When IRB members receive materials before a meeting, they will be asked to review the list of protocols on the agenda and identify any of their financial or nonfinancial interests (zero threshold including a conflict arising from financial interests that MAY BE permitted by the Harvard Conflict of Interest Policy and the Mass General Brigham Policy for Interactions with Industry and Other Outside Entities) pertaining to the project. Any such interests should be disclosed to the Senior IRB Chair in advance of the meeting when possible, and if not then at any meeting where any protocol for which the Member has a conflict is being reviewed. Members will also be reminded at the beginning of each meeting of the conflicts policy and must disclose any previously unreported interests at that time.
3. When performing expedited reviews, the IRB reviewer will promptly report to the Senior IRB Chair his or her financial and non-financial interests with the project. Upon determination by the Senior IRB Chair of a conflict of interest, the project will be reassigned to another reviewer.
4. The Senior IRB Chair shall review all disclosures, determine whether a conflict of interest exists (including a conflict arising from financial interests that are permitted by the Harvard Conflict of Interest Policy and the Mass General Brigham Policy for Interactions with Industry and Other Outside Entities), and determine appropriate management of the disclosed interest(s). In general, financial interests that amount to receipt of remuneration less than \$10,000 in a 12 month period are not considered a conflict.
5. Any IRB member or member who has a conflict of interest related to a protocol under review (including any such interest that is attributable to a family member) must be removed from the discussion of the protocol and the related vote, except to provide information at the IRB's request. The meeting minutes will document the recusal (*i.e.*, the temporary absence of the IRB member during the deliberation and vote on the project with respect to which a member has a conflict).
6. Consultants will receive a copy of this policy with materials for the protocol they are reviewing and will be instructed to disclose any financial or non-financial interests to the Senior IRB Chair who will determine management.
7. As a reminder, IRB members who are subject to the Harvard Conflict of Interest Policy or the Public Health Service regulation regarding objectivity in research (42 CFR Part 50, Subpart F) are also expected to comply with such policies.

OTHER APPLICABLE MASS GENERAL BRIGHAM POLICIES:

Mass General Brigham Policy for Interactions with Industry and Other Outside Entities

REFERENCES:

42 CFR Part 50, Subpart F

45 CFR 46

21 CFR 56

DEVELOPMENT AND CONSULTATION:

Human Research Affairs

Office of the General Counsel