



FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL
AND MASSACHUSETTS GENERAL HOSPITAL

Title:	IRB Member Conflicts of Interest		
Department:	Human Research Affairs/Research Management		
Policy Type: <i>(please check the appropriate box)</i>	<input checked="" type="checkbox"/> Partners System-wide	<input type="checkbox"/> Partners System-wide Template	
	<input type="checkbox"/> Partners Corporate	<input type="checkbox"/> Partners Corporate Departmental	
	<input type="checkbox"/> Entity		
Applies to:	Employees, Professional Staff or Other Agents of Brigham and Women's Hospital (BWH), Faulkner Hospital (FH) and Massachusetts General Hospital (MGH)		
Approved by:	Partners Chief Scientific Officer		
Approval Date:	April 29, 2008		
Effective Date:	April 29, 2008		
Revision Date(s):	September 7, 2010		
Next Review Date:	September 7, 2013		
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 clinical investigations, and to avoid actual or perceived conflicts of interests in the review of such research, by defining the process for managing conflicts of interests of members of the IRBs for *Massachusetts General Hospital and Brigham and Women's Hospital (the "Partners IRBs" or the "IRB")* who are participating in the initial or continuing review of such research and investigations. This policy applies to all members of the Partners IRBs and to *ad hoc* reviewers, who are not IRB members but sometimes are asked to review a research project because of their expertise (collectively, "IRB members" or "members").

DEFINITIONS:

See Definition of Human-Subjects Research

"Financial Interest" means an interest of the IRB member or any interest of his/her Family Member of which the IRB member is currently aware in the Sponsor or Trial 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 the individual does 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.

(2) For purposes of this policy, financial interest shall also include serving on the Board of Directors or holding an Executive Position, regardless of whether the position is compensated.

“Executive Position” means any position in the Sponsor or Trial Company that includes responsibility for a material segment of the operation or management of a business; it explicitly includes the titles of “Scientific Director” and “Medical Director.”

“Family Member” means a spouse, minor/dependent children, or other persons living in the same household.

“Sponsor” means the business, if any, that provides funding for or otherwise supports the project.

“Trial Company” means the business that owns, manufactures, or licenses any technology on which the project is focused, or which would reasonably be expected to be identified in a publication of the project, or which is otherwise significantly involved in the project, or that would reasonably appear to be affected by the project.

“Non-financial interest” means participation in the project such that the member is listed on the protocol/project, or will be included (or reasonably may be expected under academic standards to be included) as a co-author on a publication of the project’s results. Participation in the project excludes serving as a member of the IRB or the data monitoring board overseeing the project. Other relationships which may reasonably appear to influence the judgment of the IRB member in reviewing the project, for example:

- is a direct supervisor or trainee of the researcher(s)
- is related to a researcher whose protocol is under consideration
- has a prominent role in a directly competing research team or product
- has a close personal relationship with a researcher, or for other reasons feels unable to render a fair and unbiased review.

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 Director and chair of the IRB, or his or her designee. Disclosures are to be reported prior to the relevant IRB meeting, but if that is not possible, disclosures should be reported at the beginning of the meeting where any such protocols are being reviewed. The Director and chair of the IRB 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 Director and chair of the IRB or designee determine 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 or make determinations of exemption for that protocol. *Ad hoc* reviewers 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 Partners.

PROCEDURES:

1. All IRB members will regularly be notified and reminded of this policy.
 - 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 for initial or continuing review 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 Medical School Conflict of Interest Policy and the Partners Conflict of Interest Policy) pertaining to the project. Any such interests should be disclosed to the 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 frequently at the beginning of meetings of the conflicts policy and should disclose any previously unreported interests at that time.
3. When performing expedited review, the IRB reviewer will promptly report to the IRB Director and Chair his or her financial and non-financial interests with the project. Upon determination by the IRB Director and Chair of a conflict of interest, the project will be reassigned to another reviewer.
4. The Director and Chair of the IRB shall review all disclosures, determine whether a conflict of interest exists (including a conflict arising from financial interests that are permitted by the Harvard Medical School Conflict of Interest Policy and the Partners Conflict of Interest policy), and determine appropriate management of those conflicts. In general, financial interests that amount to less than \$10,000 in a 12 month period are not expected to be considered a conflict.
5. Any IRB member or member who has a conflict of interest in a project (including any such interest that is attributable to a family member) must leave the room during the discussion of the project and the related vote, except if the member is providing 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 the member has a conflict).

6. *Ad hoc* reviewers will receive a copy of this policy with materials for the project they are reviewing and will be asked to disclose any financial or non-financial interests to the Director and Chair of the IRB who will determine management.
7. As a reminder, IRB members who are subject to the HMS and Public Health Service conflict of interest policies are also expected to comply with such policies.

OTHER APPLICABLE PARTNERS HEALTHCARE POLICIES:

Conflicts of Interest

REFERENCE:

45 CFR 46
21 CFR 56

DEVELOPMENT AND CONSULTATION

Human Research Affairs
Office of the General Counsel

Reviewed by:	Original Review Date:	Revision Approval Dates:
D. Ausiello, M.D.		