

**PARTNERS HUMAN RESEARCH COMMITTEE
POLICIES AND PROCEDURES**

Financial Conflicts of Interest

1.0 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, and Faulkner Hospital (the "Partners IRBs" or the "IRB") of financial conflicts of interest in the review of human-subjects research and clinical investigations.

2.0 SCOPE

This policy applies to human-subjects research and clinical investigations reviewed by the Partners IRBs that involve any of the following:

- (1) for-profit sponsor or funding source;
- (2) a marketed drug, device, or other technology, or a drug, device or other technology in development; or
- (3) a new technology, software or therapeutic approach.

While the scope of this policy extends to all human-subjects research and clinical investigations described above, 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.

3.0 POLICY

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.

4.0 DEFINITIONS

As used in this document, human-subjects research encompasses activities that meet the DHHS definitions of *research* and *human subject* and/or the FDA definitions of *clinical investigation* and *human subject*. The DHHS definition for *research* and *human subject* and the FDA definition for *clinical investigation* and *human subject* are provided below.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(d)]

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. [45 CFR 46.102(f)(1)(2)]

Clinical investigation means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research

or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical studies. The terms *research*, *clinical research*, *clinical study*, *study*, and *clinical investigation* are deemed to be synonymous... [21 CFR 50.3(c) and 21 CFR 56.102(c)]

Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. [21 CFR 50.3(g) and 21 CFR 56.102(g)]

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.

5.0 PROCEDURES

- 5.1 Principal investigators and co-investigators conducting human-subjects research or clinical investigations in such categories as determined by the IRB must complete and submit with each new protocol to the Human Research Office the Investigator Financial Disclosure Form when the research/investigation involves any of the following:
 - (1) for-profit sponsor or funding source;
 - (2) a marketed drug, device, or other technology, or a drug, device or other technology in development; or
 - (3) a new technology, software or therapeutic approach.
- 5.2 Investigators must report 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.

- 5.3 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.
- 5.4 The Assistant Director of the Partners IRBs or designee shall review the completed Investigator Financial Disclosure Forms and shall refer those with disclosed financial interests to the Director and Chair of the Partners IRBs or designee for review.
- 5.5 The Director and Chair of the Partners IRBs or designee 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.
- 5.6 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.
- 5.7 In the course of reviewing 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.
- 5.8 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.

- 5.9 The Principal Investigator and any co-investigator(s) 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.