

**Beth Israel Deaconess Medical Center
BIDMC Manual**

Title: Conflict of Interest Policy for Research

Policy #: ADM-19

Purpose:

The purpose of this policy is to identify, manage, and resolve conflicts of interest that may affect the research decisions, transactions, and operations of Beth Israel Deaconess Medical Center, Inc. This policy is also intended to comply with [Harvard University Faculty of Medicine's Policy on Conflicts of Interest and Commitment](#) ("HMS COI Policy")¹, as well as the requirements set forth in the HHS Final Rule, [Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors](#) (August 25, 2011).²

This policy shall be subject to any appropriate modifications required from time to time to conform to applicable governmental regulations and to policies of the Harvard University Faculty of Medicine.

Policy Statement:

The mission of Beth Israel Deaconess Medical Center (BIDMC) is to provide extraordinary care, where the patient comes first, supported by world-class education and research.³ All individuals who serve BIDMC and its patients are expected to put this mission first and foremost whenever conducting activities relating to BIDMC.

Translating scientific and medical discovery into improved clinical care requires open collaboration and synergies achieved through thoughtful and complex partnerships with industry, government, academia, and others. These partnerships are consistent with the mission of BIDMC. However, it is important that such relationships do not create conflicts of interest that might undermine the validity of the research, or the safety of research participants. Such concerns arise when an individual's own interests have the potential to affect the design, conduct or reporting of research, or when an institution's interests have the potential to undermine its oversight of research activities.

For these reasons, BIDMC has established the following Conflict of Interest Policy for Research. The policy outlines unacceptable practices, and guides individuals in identifying and disclosing relationships with outside Organizations. The disclosures will assist BIDMC in identifying and managing conflicts so that these important collaborations can be undertaken without compromising integrity.

All individuals who are participating in research at or under the auspices of BIDMC are required to comply with this Policy, relevant procedures and guidelines established to carry out this policy, and with any additional requirements imposed by the BIDMC Committee on Clinical Investigations (CCI), the BIDMC Conflicts of Interest Committee (COIC), or other IRB or oversight body with jurisdiction over their research.

Other related policies:

¹ Harvard Medical School (2016). Retrieve from <http://hms.harvard.edu/about-hms/integrity-academic-medicine/faculty-policies-integrity-science/faculty-medicine-policy>.

² 42 C.F.R. § 50.601 et seq. and 45 C.F.R. § 94.1 et seq.

³ [Beth Israel Deaconess Medical Center Mission Statement](#).

- [Harvard University Faculty of Medicine Policy on Conflicts of Interest and Commitment](#)
- [ADM-18 Conflict of Interest Policy for Institutional Transactions](#)
- [ADM-62 Policy on Consulting, Speaking, and Other Outside Activities](#)
- [ADM-17A Personal Gifts, Travel, Meals, and Entertainment](#)
- [ADM-17B Industry-Supported Speaking, Programs, Fellowships, and Preceptorships](#)
- [ADM-15 Supplier Contact and Negotiation](#)

I. Individual Interests and Activities Related to Research

Investigators conducting Research at or under the auspices of BIDMC must ensure that personal financial interests and outside positions that may conflict with the best interests of patients, Research, and BIDMC are disclosed and addressed to maintain the integrity of not only Research, but also decision-making in all transactions. All Investigators conducting Research, or proposing to conduct Research, at or under the auspices of BIDMC, will disclose all outside interests or relationships, and gifts from an Organization, and intellectual property rights held by the Investigator or the Investigator's Family. The Investigator will also comply with any management plan or transparency requirements imposed by BIDMC.

A. Disclosure Obligations

1. Disclosure to BIDMC. Investigators are required to disclose to BIDMC the financial interests, outside activities, intellectual property, and gifts of:

- the Investigator;
- the Investigator's Family; and
- an Organization in which the Investigator (either alone or with a Family member) exercises a controlling interest;

that reasonably appear to be related to the Investigator's institutional responsibilities.

Disclosure must be made at the time and format specified by BIDMC. Examples include:

- Research funding submissions;
 - Human subjects research protocol submissions;
 - Annual disclosure
2. Disclosure to Research Subjects and Research Community. BIDMC may require individual interests and activities to be disclosed:
 - In CCI-approved consent forms;
 - To the Research personnel working on the Research project;
 - To the sponsor of multi-center trials; and
 - To Institutional Review Boards of other participating institutions.
 3. Disclosure to Trainees.⁴ Investigators are responsible for ensuring that those who conduct Research under their supervision do so with full information about the nature of any relationships with industry that may be impacted positively or negatively by the work. An Investigator's outside activities should not adversely influence the instruction, guidance or supervision of trainees. Academic assignments should principally serve the interests of the trainees in their academic advancement. To that end, Investigators should not assign trainees to participate

⁴ [HMS COI Policy](#) (2016).

in projects that could constrain their ability to freely discuss, defend and publish their research. Additionally, no Investigator may assign any trainee to any project in which the Investigator has an Income or Equity Interest, either directly or through an outside entity.

- a. *General Disclosure to All Trainees.* Investigators must disclose to all individuals whose job description includes assisting with the Investigator's research any Income Interests, Equity Interests, or activities of the Investigator in any Organization related to the Investigator's Research, teaching or clinical care. The individuals to whom such disclosure must be made may include, but are not limited to, students, trainees, and other Investigators. Such disclosure must be made prior to or at the time an individual is offered a position or collaboration with the Investigator's Research team or Research laboratory, or any other job that may encompass assisting with the Investigator's work.
 - b. *Project-specific Disclosures.* Before a trainee may be involved in any specific Research project, the Investigator must provide a clear description of the following:
 - the source of funding (industry or otherwise) of the specific research project;
 - any Income or Equity Interests or activities of the Investigator in an Organization:
 - that provides Sponsored Research support to the project; or
 - whose Technology is being investigated in the Research; and
 - any restrictions that may be imposed on the timing of the scientific communication of data.
4. *Disclosure in Publications, Public Comments, or Presentations.* Investigators are required to disclose financial interests in related outside entities and sources of support related to a presentation, public comment, including online, or publication of research results, the provision of expert testimony on a subject, or if members of an audience would give weight to those interests in assessing the opinions, advice, or work they are receiving. This includes the disclosure of a financial interest (by entity name) in an Organization that owns or has a contractual relationship to the Technology being reported or discussed or which sponsors the research being reported or discussed.

Certain Income Interests, Equity Interests, and activities are prohibited in the context of Clinical Research and Sponsored Research to protect against the introduction of bias or unnecessary risk in the Research.

The Research Rules outlined in this section do not apply when the relevant Financial Interests fall below a certain monetary amount, on the assumption that interests below such de minimis thresholds are unlikely to meaningfully affect the Investigator's judgment in a manner that creates unacceptable risk. Such de minimis thresholds are specified where applicable. In addition, the BIDMC Committee on Clinical Investigations has the authority to impose further management requirements to activities over which it has jurisdiction.

B. Clinical Research Rule

1. *Prohibited Activity:* Investigators who have any of the following roles at an Organization may not Participate in Clinical Research investigating that

Organization's Technology:

- Fiduciary role⁵ to a for-profit Organization; or
 - Executive Position⁶ at a for-profit Organization engaged in commercial or Research activities of a biomedical nature.
2. ***Presumptively Prohibited Activity:*** It is presumed that Investigators may not Participate in Clinical Research investigating the Technology of an Organization if the Investigator and/or a Family member has an **Income Interest or an Equity Interest exceeding the *de minimis* thresholds** in that Organization.
- The presumption may be overcome when, in the judgment of the BIDMC Conflict of Interest Committee (COIC) and the Harvard Medical School Standing Committee on Conflicts of Interest and Commitment (“HMS Standing Committee”), the Investigator presents *demonstrable, compelling justification—consistent with the rights and welfare of clinical research subjects*—for being permitted simultaneously to hold the financial interest and to Participate in the Clinical Research.⁷
3. ***De Minimis Thresholds:*** Faculty may receive **\$25,000 or less annually** from an Organization in the form of Income Interests (e.g., consulting fees or other remuneration for services) and still Participate in Clinical Research on the Organization's Technology. Furthermore, Investigators may have an Equity Interest of **\$50,000 or less in a publicly-traded Organization** and continue to Participate in Clinical Research on the Business' Technology, so long as the equity was not given in connection with the Clinical Research at issue. **Holding any equity in a privately-held Organization is presumed to be prohibited.**
4. ***Duration of Restriction.*** An Investigator must be free of all Income and Equity Interests above the *de minimis* thresholds, all fiduciary roles, and all Executive Positions for a relevant Organization prior to commencing the Clinical Research. Participation in Clinical Research shall apply for the entire duration of the Clinical Research, and the rule continues to apply even should the Investigator elect to terminate Clinical Research activities.⁸ This rule applies until the later of the following to occur:
- six (6) months following the last day that a human study participant completes the Clinical Research (e.g., data lock plus 6 months); or
 - the first Publication of the data derived from the Clinical Research, or a decision not to publish.
5. ***Previous Policy Exceptions:*** Under previous policy, the COI Committee had authority to consider requests for exceptions in certain situations. For the sake of clarity, those exceptions have not been eliminated, but rather will continue to be

⁵ A fiduciary role includes, but is not limited to members of the fiduciary board of directors, managers, or members of a member-managed limited liability company and partners in a partnership or limited liability partnership. Scientific Advisory Boards (SABs) are not fiduciary boards, and participation in an SAB alone will not necessarily prohibit the Investigator's Participation in Clinical Research.

⁶ The [HMS COI Policy](#) strictly prohibits full-time faculty members from holding an Executive Position in a for-profit Business engaged in commercial or research activities of a biomedical nature. While part-time faculty may hold approved Executive Positions, they are still prohibited from Participating in Clinical Research on that Business' Technology and from receiving Sponsored Research support from the Business.

⁷ Investigators can use the [Clinical Research Rule Petition for Exception](#) to overcome this presumption. Investigators should submit the Petition form to the BIDMC Office of Compliance and Business Conduct.

⁸ Investigators may petition for relief from the application of the Clinical Research Rule to the entire period set forth here. If granted, however, the expectation is that Participation has been surrendered for the duration of the Clinical Research.

considered by the COIC upon petition. They are:

- *Dual-Career Family Exception.* Upon petition to the COIC, an Investigator may overcome the presumption that s/he may not Participate in Clinical Research or receive Research support if:
 - a. the conflict arises solely by virtue of the career pursuits of the Investigator's spouse or partner;
 - b. the COIC determines, in its discretion, that strict application of one or both of the Rules under the circumstances would unduly inhibit scientific progress; and
 - c. any potential conflict of interest is one that the COIC finds, in its discretion, can be managed adequately through a formal management plan.
- *Institutional License/Royalty Sharing Agreement Exception:* With respect to an *Income Interest*, upon petition to the COIC, Investigators may overcome the presumption that s/her may not Participate in Clinical Research or receive Research Support if:
 - a. the conflict arises solely because of income received through an institutional license or royalty sharing agreement;
 - b. the COIC determines, in its discretion, that strict application of the rule under the circumstances presented is unduly restrictive after weighing the merits of allowing the research to go forward and the risks of the potential conflict of interest; and
 - c. the potential conflict arising by reason of the income received through the institutional agreement can be managed through a formal management plan.

Petition Factors: Research that involves human study participants is subject to heightened scrutiny. This is because the ramifications of bias or the appearance of bias in Clinical Research are more immediate, and can directly impact the safety and welfare of Clinical Research participants. Accordingly, when the COIC considers a petition to rebut the presumption under the Clinical Research Rule, it shall consider factors which may include, but are not limited to, the following:

- Nature of the proposed Research;
- Anticipated role in the proposed Research;
- Nature of the Income or Equity Interest and relationship with the Organization;
- How closely the Income or Equity Interest is related to the proposed Research;
- The degree to which the Income or Equity Interest may be affected by the proposed Research;
- The degree to which the proposed Research may be affected by the Income or Equity Interest;
- Reasons for the Faculty with the Financial Interest to be involved in the Research;
- Impact on trainees,
- If applicable, role in developing intellectual property for technology to be studied;
- If applicable, whether the Clinical Research is on the technology subject to an institutional license or royalty sharing agreement, and if so, type of license/royalty sharing income received (i.e. one time signing fee, success based milestone, non-success based milestone);

- The best interests of study participants who could benefit from the Clinical Research; and
- Likely effectiveness of potential management strategies.

Petitions and exceptions are subject to case-by-case assessment by the BIDMC COI Committee, following a formal petition by the individual investigator. The decision of the COIC may be subject to the approval of the HMS Standing Committee.

C. Research Support Rule

1. *Prohibited Interests*: Investigators who have any of the following interests in an Organization may not receive Sponsored Research support from that Organization for Research.

- Fiduciary role⁹ at a for-profit Organization; or
- Executive Position¹⁰ at a for-profit Organization engaged in commercial or Research activities of a biomedical nature.

2. *Presumed Prohibited Activity*: It is presumed that Investigators may not receive Sponsored Research support from an Organization if the Investigator and/or a Family member has an Equity Interest exceeding the *de minimis* threshold in that Organization.

The presumption may be overcome when, in the judgment of the COIC, the Investigator presents *sufficient countervailing circumstances* (the benefits of the proposed research must outweigh the risks and the Equity Interest must be able to be appropriately managed) for being permitted simultaneously to hold the Equity Interest and receive Sponsored Research Support.¹¹

Sponsored Research: Sponsored Research includes research, training and instructional projects involving funds, personnel, certain proprietary materials or technology, or other compensation from outside sources that (i) the institution classifies as a sponsored award in accordance with institutional policy, or (ii) gives the donor, or an identifiable third party designated by the donor, preferred access to or ownership rights over the Research or the products of the Research, e.g. raw data, scientific developments or intellectual property. Provision of periodic general reports and copies of publications shall not be considered preferred access.

Sponsored Research also includes *gifts that are made solely for the support of the Investigator's Research or that of the Investigator's laboratory*. Additionally, Sponsored Research includes the provision of proprietary material or technology which is proposed to be the subject of the research in question and where the Organization is granted the right to intellectual or tangible property created in or resulting from the use of the Material in the proposed research.

3. *De Minimis Threshold*: Investigators may have an Equity Interest of **one percent or less in a publicly-traded Organization** and accept Sponsored Research

⁹ A fiduciary role includes, but is not limited to members of the fiduciary board of directors, managers, or members of a member-managed limited liability company and partners in a partnership or limited liability partnership. Scientific Advisory Boards (SABs) are not fiduciary boards of directors, and participation in an SAB alone will not necessarily prohibit the Investigator's Participation in Clinical Research.

¹⁰ The [HMS COI Policy](#) strictly prohibits full-time faculty members from holding an Executive Position in a for-profit Business engaged in commercial or research activities of a biomedical nature. While part-time faculty may hold approved Executive positions, they are prohibited from Participating in Clinical Research on that Business' Technology and from receiving sponsored Research support from the Business.

¹¹ Investigators can use the [Research Support Rule Petition for Exception](#) to overcome the presumption. Investigators should submit the Petition form to the BIDMC Office of Compliance and Business Conduct.

support from the Organization, so long as:

- (a) the company was not founded by the investigator, or
- (b) the equity was not acquired in connection with the Research at issue.

Any interest exceeding 1% of the publicly-traded Business's value would require an exception from the COIC. Nevertheless, the Investigator must obtain the advance approval from the CCI of his or her Participation and be subject to such restrictions as are imposed for the protection of human subjects and the maintenance of scientific integrity.

Review of Faculty Equity Financial Interest in a Privately-Held Business: Any Equity Interest in a privately-held Organization will require a petition to the BIDMC COI Committee to Participate in Research using Sponsored Research support from the Business. The de minimis threshold does not apply to privately-held companies.

4. Duration of Restriction. An Investigator must be free of all Equity Interests above the *de minimis* threshold, all fiduciary roles, and all Executive Positions for a relevant Organization prior to commencing the Sponsored Research. Participation in the Sponsored Research shall be considered to apply for the entire duration of the Sponsored Research, and the rule continues to apply even should one elect to terminate Sponsored Research activities. This rule applies until the later for the following to occur:

- six (6) months following the last day that data is collected (data lock plus 6 months); or
- the first Publication of the data derived from the Sponsored Research, or a decision not to publish the data derived from the Sponsored Research.

5. Previous Policy Exceptions: Under previous policy, the COI Committee had authority to consider requests for exceptions in certain situations. For the sake of clarity, those exceptions have not been eliminated, but rather will continue to be considered by the COIC upon petition. They are:

- SBIR/STTR Exception: If the anticipated Sponsored Research support that will violate the Sponsored Research Rule will be through a subgrant under the Small Business Innovation Research (SBIR) Program or the Small Business Technology Transfer (STTR) Program,¹² then the involved Investigator may conduct the research notwithstanding the Equity Interest or fiduciary role if BIDMC determines that any potential conflict of interest held by the Investigator, given his or her Equity Interest or fiduciary role in the small business, may be managed effectively with an institutional management plan. This exception does not apply to Clinical Research. This exception is subject to additional restriction and/or prohibition based on applicable federal law and institutional policy.

6. Dual-Career Family Exception. Upon petition to the COIC, an Investigator may overcome the presumption that he/she may not receive Sponsored Research Support from the Organization if:

- a. the conflict arises solely by virtue of the career pursuits of the Investigator's spouse or partner;
- b. the COIC determines, in its discretion, that strict application of the

¹² The COIC may determine that other grant programs of a similar structure and aim to the SBIR/STTR programs warrant consideration under this exception and may grant these exceptions following review.

Research Support Rule under the circumstances would unduly inhibit scientific progress; and

- c. any potential conflict of interest is one that the COIC finds, in its discretion, can be managed adequately through a formal management plan.

Petition Factors: Research must be protected from bias to ensure that the results of the Research are valid and can be relied on in the development of medical therapies and in furtherance of scientific knowledge. Concerns about the ultimate impact of financial conflicts on end-users of the Research and research integrity exist in all Research. Accordingly, when the COIC considers a petition to rebut the presumption under the Research Support Rule, it shall consider factors which include, but are not to be limited to, the following:

- Nature of the proposed Research;
- Anticipated role in the proposed Research;
- Nature of the Equity Interest and relationship with the Organization;
- How closely the Equity Interest is related to the proposed Research;
- The degree to which the Equity Interest may be affected by the proposed Research;
- The degree to which the proposed Research may be affected by the Equity Interest;
- Reasons for the Investigator with the Equity Interest to be involved in the Research;
- If applicable, role in developing intellectual property for technology to be studied;
- Impact on trainees;
- If applicable, whether the Sponsored Research is on the technology subject to an institutional license or royalty sharing agreement, and if so, type of license/royalty sharing income received (i.e. one time signing fee, success based milestone, non-success based milestone); and
- Likely effectiveness of potential management strategies.

Petitions and exceptions are subject to case-by-case assessment by the BIDMC COI Committee, following a formal petition by the individual investigator. The decision of the COIC may be subject to the approval of the HMS Standing Committee.

II. PHS-Funded Research

Investigators who engage in research projects funded by the Public Health Services (“PHS”), or a sponsor who has adopted the PHS regulations, must also comply with applicable federal conflict of interest regulations summarized in this Section II.¹³

- A. Training.** Investigators engaging or planning to engage in PHS-funded Research at or under the auspices of BIDMC must complete conflicts of interest training required by a relevant PHS awarding agency prior to engaging in PHS-funded Research, and, if still engaged in PHS-funded Research, at least every four years following the initial training. Investigators must also complete the training immediately in any of the following circumstances:

1. BIDMC revises the portion of its policy or procedures governing financial

¹³ Public Health Service Final Rule 42 C.F.R. Part 50 and 45 C.F.R. Part 94.

conflicts of interest in PHS-funded research that affect the requirements applicable to PHS-funded Investigators.

2. An Investigator is new to BIDMC.
3. BIDMC finds that an Investigator is not in compliance with the portion of BIDMC's policy governing FCOI in PHS-funded research or an imposed management plan.

B. Disclosure and Review. The Vice President, Research is the designated institutional official to solicit and review disclosures required by this section.

All Investigators applying for funding from or conducting Research funded by the PHS must disclose the following interests related to their Institutional Responsibilities:

- all Significant Financial Interests (SFIs) belonging to the Investigator or the Investigator's spouse and dependent children during the preceding 12 months; and
- any Travel during the preceding 12 months.

Disclosure will be made before application for funding. During the period of the PHS award, the disclosure must be updated annually, as well as within 30 days of discovering or acquiring a new Significant Financial Interest.

Prior to expenditure of any funds under a PHS award, BIDMC will determine:

- whether the disclosed SFI is related to the PHS-funded Research; and if so,
- whether it constitutes a Financial Conflict of Interest (FCOI).

If an FCOI is identified, the COIC will determine how the FCOI will be resolved.

SFI's That Arise During a Research Project. In the event that:

- a new interest is disclosed to BIDMC in the course of an on-going PHS-funded Research project (i.e., an Investigator who is new to participating in the Research discloses an interest or an existing Investigator discloses a new interest), or
- BIDMC identifies a disclosed interest that was not previously reviewed in a timely manner in accordance with this Policy,

BIDMC will, within 60 days from the date of the disclosure: (i) determine if the disclosed interest is related to the Investigator's Research; and if so, (ii) determine if it is an FCOI; and if it is, (iii) implement, on at least an interim basis, a management plan in accordance with this Policy.

Late Identification/Management of FCOI. In the event that an FCOI was not timely identified or managed, including due to:

- failure of Investigator to timely disclose an SFI that is subsequently determined to be an FCOI;
- BIDMC's failure to review or manage such an FCOI; or
- Investigator failure to comply with an FCOI management plan,

BIDMC will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities on the PHS-funded Research project to determine if there was any bias in the design, conduct or reporting of Research during the time period of the noncompliance. BIDMC will document the

following key elements of the retrospective review:

- a. Project number and title;
- b. Principal Investigator or Project Directors (or if multiple, the contact PI/PD);
- c. Investigator and entity resulting in the FCOI;
- d. Reason retrospective review was conducted;
- e. Detailed description of methodology used to conduct the retrospective review; and
- f. findings and conclusions.

If the retrospective review finds that the project has been biased, BIDMC will notify the PHS awarding agency, and promptly develop and implement a mitigation plan, and submit the PHS-required mitigation report, which will include at least:

1. Key elements documented in the retrospective review;
2. Description of the impact of the bias on the Research project; and
3. BIDMC's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Any FCOI report submitted to the PHS awarding agency with respect to such Research will be updated as necessary in light of the results of the retrospective review.

C. Financial Conflict of Interest.

Management: For any identified FCOI, BIDMC will take appropriate action to either reduce/eliminate the conflict, or develop and implement a plan to manage the FCOI until the completion of the project.

BIDMC reserves the right to impose any requirements it sees fit on any disclosed interest, even those that are not Reviewable Interests and/or do not constitute an FCOI requiring management in accordance with the PHS regulations and this Policy. Such requirements for non-FCOIs might include, but are not limited to, a reminder of general transparency obligations regarding competing interests when conducting Research.

In any case in which the Department of Health and Human Services (HHS) determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by BIDMC, the Investigator will be required to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

Investigators have an on-going obligation to adhere to an imposed management plan and failure to do so may be grounds for sanctions under this Policy. OCBC will monitor Investigator compliance with an imposed management plan on an ongoing basis until the completion of the PHS-funded Research project.

Reporting: During the award period of each PHS award until completion of the project, BIDMC will report identified FCOIs to the PHS awarding agency:

- prior to expenditure of funds;
- Within 60 days of any subsequently identified FCOI;
- Annually, to update previously filed FCOI reports, at the time of the progress report or extension; and
- Following a retrospective review, as needed to update previously filed

FCOI reports.

- D. Public Accessibility.** This Policy (ADM-19) is available on a publicly-accessible web site. BIDMC will ensure public accessibility of information concerning the FCOIs of Senior/Key Personnel as required by applicable regulations.¹⁴ Additional information and directions to make a request are accessible from the same web page as this policy.
- E. Subrecipients.** When PHS-funded research is to be carried out through or in conjunction with a subrecipient, BIDMC will establish in writing, at the time of proposal submission, whether BIDMC's conflict of interest policy or that of the other awardee will apply to the subrecipient's Investigators, as well as the time frames within which the subrecipient must provide any information necessary to ensure that Prime awardee is able to meet its reporting obligations to the PHS awarding agency.
- E. Record Retention:** Records required by the PHS regulations (42 CFR §50.601 et seq.) and all action taken pursuant to the PHS regulations shall be maintained for a period of at least three (3) years from the date when the final expenditure report, final annual report, or disclosure occurred, whichever is later. If any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

III. Institutional Interests Related to Clinical Research

Institutional conflicts of interest may result when BIDMC conducts Clinical Research sponsored by, or investigating the Technology of, an Organization in which BIDMC or an Institutional Official has certain types of financial interests. BIDMC requires these interests to receive special review and oversight, as described in this Section III.

- A. Royalties for Sales to BIDMC.** BIDMC may not receive royalties that are based on BIDMC's purchase of products incorporating BIDMC's licensed Technology, unless the Conflicts of Interest Committee approves an arrangement under which all such royalties will be donated to a specific non-institutional charitable organization. BIDMC license agreements must include this provision.
- B. Interests Related to Clinical Research.** When BIDMC conducts Clinical Research (other than Nominal Risk Clinical Research) investigating the Technology of an Organization, and has one of the following financial interests, the Conflict of Interest Committee will determine, on a case-by-case basis, whether the interests have the potential to affect, or reasonably appear to affect, the design, conduct, reporting, review, or oversight of the Clinical Research:
1. When BIDMC will simultaneously receive more than \$25,000 per year in pre-market success-based milestone payments from the license of that Technology that is being investigated in the Clinical Research. Unless prohibited by paragraph III.A. above, all other royalties, license fees, annual maintenance fees, milestone payments or other income that may become due under a license need not be reviewed by the COI Committee; *or*
 2. When BIDMC simultaneously owns an Equity Interest in that Organization (other than shares acquired through normal treasury investment or

¹⁴ See standard operating procedures for responding to Public Requests for FCOI Information.

Development Office acquisition processes). However, an Equity Interest of \$50,000 or less in a publicly-traded Organization is below the *de minimis* threshold and need not be reviewed by the COI Committee, so long as there is no connection between the acquisition of the Equity Interest and the Clinical Research; *or*

3. When BIDMC or any of its departments or Research units simultaneously receives a single gift exceeding \$100,000 in value from the Organization; *or*
4. When a BIDMC Institutional Official,¹⁵ or a member of his/her Family, has one or more of the interests described above, and an individual under their direct supervision simultaneously conducts Clinical Research (other than Nominal Risk Research) at BIDMC investigating the Technology of that Organization.

The goal of this policy is not to preclude BIDMC from accepting philanthropy from Organizations that sponsor Research activities, or that own or control Technology that is being used, studied or tested in Research activities. Rather, the policy is intended to help BIDMC identify and examine such circumstances, and to manage, through disclosure, separation of responsibilities, and as otherwise appropriate, any actual or apparent conflicts of interest that may result. All gifts should be accepted in conformance with these policies and reported to the Development Office for record-keeping purposes. Investigators are accountable for adhering to institutional gift policies, such as ADM-64, Gift Acceptance Policy and [ADM-17A Personal Gifts, Travel, Meals, and Entertainment](#).

C. Assessing Institutional Conflicts of Interest. The COIC may determine that, despite the financial interests of BIDMC or a Research Official, the Clinical Research may be conducted at or by BIDMC pursuant to a management plan approved by the COIC and ratified by the CCI. In making this determination, the COIC may take into account any factors it deems relevant to the analysis, but shall give particular consideration to the factors below:

Interests of BIDMC:

1. the nature of the Research,
2. whether the Research involves the use of platform Technology or a generic method used broadly,
3. the magnitude of the interest and the degree to which it is related to the Research,
4. the extent to which the interest could be directly and substantially affected by the Research,
5. the degree of risk to human subjects involved that is inherent in the Research protocol, and
6. the degree of risk to the reputation of BIDMC.

Interests of an Institutional Official – Additional Factors:

1. the degree of authority, if any, that he or she has over the relevant Clinical Research and research personnel;
2. the degree to which the value of the interest could be affected by the Clinical Research; and
3. the degree to which the interests of the relevant Organization could be affected

¹⁵ See Definitions below. An Institutional Official is an individual who has direct authority over faculty appointments, salaries, promotions, and/or allocation of institutional resources, such as assignment of graduate students or other trainees, funding or space, for faculty who are conducting Clinical Research. As examples, it may include the CEO, CAO, CFO, COO, Vice President of Research, department chairs, division heads, and institute and center directors. In addition, it includes IRB chairs and COI Committee members.

by the Clinical Research.

D. Management of Institutional Conflicts of Interest. If the COIC determines the Clinical Research may be conducted at or by BIDMC pursuant to a management plan, then the existence of an institutional Income or Equity Interest in Clinical Research that has been approved by the COIC must be disclosed as follows and as applicable:

1. In CCI-approved consent forms, with an explanation that additional information will be provided to the Research subjects upon request,
2. In or with a manuscript submitted for publication concerning the Research,
3. In any substantive public communication of the Research results,
4. To the principal Investigator, co-Investigators, collaborators, other Research personnel working on the Research project,
5. To the sponsor of multi-center trials, and
6. To the Institutional Review Boards (IRBs) of other participating institutions.

IV. BIDMC Committee on Conflicts of Interest

The BIDMC Committee on Conflicts of Interest has authority delegated by the BIDMC Board of Directors Committee for Compliance, Risk, and Audit to implement, and enable compliance with, the BIDMC Conflict of Interest Policies, and other BIDMC policies governing interactions with industry and other outside activities; to determine and manage cases of individual and institutional conflicts of interest; to implement and enforce BIDMC policies governing industry-support for BIDMC educational activities; to adopt additional guidelines, rules, or standards relating to the Committee's responsibilities, including requiring reporting of personal financial interests and outside activities. In carrying out their responsibilities, the Committee may delegate specific responsibilities to other institutional committees, offices, or individuals. The Committee is comprised of representatives from BIDMC leadership, and from the clinical and pre-clinical faculty. The Office of Compliance and Business Conduct shall refer specific issues under this policy to the Committee for evaluation. Following a review of a specific issue, the Committee shall make formal recommendations to BIDMC as to how the matter should be resolved or managed.

The Institutional Official shall inform the Executive Committee of the Institutional Review Board (IRB) of those determinations made by the Conflict of Interest Committee that concern Human Subjects Research. The Chair and Director of the IRB shall report such determinations to the IRB, which shall have the final authority to decide whether the interest and its management, if any, allows the research to be approved and/or if additional restrictions are necessary for the protection of human subjects and the maintenance of scientific integrity.

V. Investigator's Responsibility to Comply

Investigators are required to comply with all aspects of this Policy and associated standard operating procedures. Such compliance shall include disclosing in a timely manner all required information to BIDMC to facilitate the identification of existing conflicts of interest, taking any required training, and complying with any management plan or transparency requirements imposed by BIDMC.

VI. Confidentiality

While the disclosed information will be treated confidentially to the extent possible, it

may be necessary to use and share such information to facilitate the purposes of this Policy. For example, information may be shared with the Office of Compliance and Business Conduct, the BIDMC Conflicts of Interest Committee, and the Office of the Dean at Harvard Medical School for review when it has jurisdiction over a faculty member or trainee, as well as with supervisors, division chiefs, and department chairs. Information will be shared as may be required by law, including the PHS requirements related to public accessibility (described above) and other applicable regulations that may require an Investigator's relationship with an Organization be made publicly available.

VII. Sanctions

BIDMC has wide discretion to impose a variety of sanctions in the event of noncompliance with any aspect of this policy, related guidelines, or any other institutional requirements.

Noncompliance may occur in varying degrees and along a continuum of intention. Such a continuum may encompass deliberate acts in violation of this policy, reckless disregard of applicable requirements, negligent behavior resulting in a violation, and even inadvertent or technical violations for which there exist a reasonable explanation. The totality of the facts and circumstances of an incident of noncompliance, along with the Investigator's prior history of compliance, will be considered when assessing appropriate sanctions. Each case will be analyzed individually with careful consideration of factual nuances and any mitigating factors. Although prior cases may serve as an internal point of reference when deciding what sanctions should be applied, strict comparisons between cases and their outcomes are usually unproductive given the extremely fact-specific nature of the analysis.

Noncompliance with this policy shall include but is not limited to the failure to submit or submission of an incomplete, erroneous, or misleading disclosure form as required by this policy and/or accompanying standard operating procedures, failure to provide additional information related to a disclosure or identified conflict as may be requested by BIDMC, undertaking an activity or receiving an interest in violation of the rules set forth in this policy, or failure to comply with the management plan.

Upon a finding of noncompliance with this policy, sanctions may include corrective actions in accordance with BIDMC's Employee Corrective Action Policy,¹⁶ the Committee on Clinical Investigations' Guidelines for Corrective Action,¹⁷ the Medical Staff By-Laws¹⁸, and/or the Graduate Medical Education Remediation and Disciplinary Policy¹⁹ as may be applicable. In addition, where Harvard University Faculty of Medicine policies apply, the Committee may refer the individual to Harvard Medical School, where possible sanctions may include the following:

1. Formal admonition by the Dean;
2. The inclusion in the Faculty Member's file of a letter from the Office of the Dean indicating that the individual's good standing as a member of the Faculty has been called into question;
3. Ineligibility of the Faculty Member for supervision of graduate students;
4. Non-renewal of appointment;

¹⁶ [BIDMC Policy PM-04, Employee Corrective Action](#)

¹⁷ CCI Policy Manual, <https://research.bidmc.harvard.edu/OST/CCI/Documents/CCIPolicyManual.doc>

¹⁸ [BIDMC Medical Staff Bylaws](#)

¹⁹ [BIDMC Policy GME-10, Graduate Medical Education Remediation and Discipline](#)

5. Dismissal from the HMS Faculty of Medicine.

VIII. Inquiries and Investigations

If, at any time, a member of the BIDMC's workforce becomes aware of any apparent or suspected violation of BIDMC's policies, he or she must report the violation. Any questions or concerns regarding the existence of a potential or actual conflict of interest must be referred immediately to the Office of General Counsel or the Office of Compliance and Business Conduct, which shall investigate and make findings regarding conflicts of interest.

You can contact the BIDMC Office of Compliance and Business Conduct by telephone at (617) 667-1897 and by mail at 109 Brookline Avenue, Suite 200, Boston, MA 02215. You also can submit your questions or concerns in an e-mail to conduct@bidmc.harvard.edu. For anonymous inquiries, you can reach the BIDMC Compliance Helpline at (888) 753-6533.

IX. Definitions

For the purposes of this Conflict of Interest Policy for Research, the following definitions shall apply:

Clinical Research.²⁰ Any Research that is subject to IRB approval (excluding those studies determined to be Nominal Risk Clinical Research by an IRB and/or COIC). Also see definition of Participate in Clinical Research.

Equity Interest.²¹ Any type of ownership interest, such as owning stock or stock options (vested and unvested), but excludes equity that arises solely by reason of investment in an Organization by a mutual, pension, or other institutional investment fund over which the Investigator and/or their Family does not exercise control.

Executive Position. Any position that is responsible for a material part of the operation or management of an Organization.

- This term specifically includes, but is not limited to, the following positions: Chief Executive Officer, Chief Operations Officer, Chief Scientific Officer, Chief Medical Officer, Scientific Director, and Medical Director.

Family.²² An Investigator's spouse or domestic partner and dependent children.

Financial Conflict of Interest (FCOI). A Significant Financial Interest (defined below) or Travel that could directly and significantly affect the design, conduct, or reporting of research.

Income Interest.²³ This may take the form of various types of compensation and may be paid either by the Organization or by an agent or other representative of the Organization on its behalf. Examples of income that might be paid or owed by an Organization to an Investigator and/or their Family include, but are not limited to, consulting fees, salary, or other payments for services, interests in real or personal property, dividend payments, payments derived from the licensing of Technology, and forgiveness of debt. The term explicitly excludes, however, Post-market Royalties.

Institutional Official. An individual who has direct authority over faculty appointments, salaries, promotions, and/or allocation of institutional resources, such as assignment of graduate students or other trainees, funding or space, for faculty who are conducting Clinical

²⁰ [HMS COI Policy](#) (2016).

²¹ Id.

²² Id.

²³ Id.

Research. As examples, it may include the CEO, CAO, CFO, COO, Vice President of Research, department chairs, division heads, and institute and center directors. In addition, it includes IRB chairs and COI Committee members.

Institutional Responsibilities. An Investigator's professional responsibilities on behalf of BIDMC. These may include, for example, activities such as research, research consultation, teaching, and professional practice.

Investigator.²⁴ The project director (PD) or principal investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Research, which may include, for example, collaborators or consultants.

Investigators who, alone or together with one or more members of their Family, exercise a controlling interest in any Organization will be evaluated under this policy based on any income or equity held by the entity in which the controlling interest is held. Such entities are viewed, for purposes of this policy, as extensions of the term "Investigator."

Nominal Risk Clinical Research. Clinical Research that is determined by the Institutional Review Board and/or the COIC as both:

- minimal risk (as defined in 45 CFR 46);²⁵ and
- falls within one or more of the following categories:
 - a. Use of bodily fluids, secretions or other biospecimens (excluding such materials obtained for clinical care purposes, which are covered in paragraph b, below), that are obtained through non-invasive, routine and established collection procedures from a healthy, non-pregnant individual who is not a member of a vulnerable population (as defined in 45 CFR part 46) and provided that the samples cannot be linked to any individually identifiable person by any Investigator who Participates in the Nominal Risk Research;
 - b. Use of excess bodily fluids, secretions or other biospecimens, which may be linked by an Investigator who Participates in the Nominal Risk Research to an individually identifiable patient, where the samples are otherwise obtained during the course of clinical care by an individual who (1) does not Participate in the Nominal Risk Clinical Research; (2) is not under the direction or control of any individual who Participates in the Nominal Risk Clinical Research; and (3) is not supervising any individual who Participates in the Nominal Risk Clinical Research;
 - c. Medical records review, including collection of coded identifiable data, provided, however, that the protocol ensures that, after collection of the data, any Investigator who Participates in the Nominal Risk Clinical Research cannot link it to an individually identifiable patient;
 - d. Non-sensitive survey research on individuals or group characteristics or behavior, provided that if the subjects are considered members of a vulnerable population as defined by 45 CFR Part 46, the BIDMC COIC and/or IRB may, on a case-by-case basis, conclude that the research is not Nominal Risk Clinical Research; or
 - e. Such other categories of research activities as may from time to time be designated by the BIDMC Conflicts of Interest Committee.

²⁴ PHS Regulations, 42 C.F.R. Part 50 and 45 C.F.R. Part 94.

²⁵ Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.html>

Organization.²⁶ Any legal entity organized for profit or for non-profit purposes.

- This term includes but is not limited to corporations, limited liability companies, partnerships (including limited liability partnerships), sole proprietorships, associations, organizations, holding companies, and business or real estate trusts.
- An Organization is considered to be “non-profit” if it is legally organized for charitable purposes (e.g., 501(c) (3) and equivalents), unless it is principally organized, funded and/or managed by one or more for-profit entities engaged in commercial or Research activities of a biomedical nature.
- Not included in this term are BIDMC, HMFP, any BIDMC or HMFP affiliate, and any other entity controlled by, controlling, or under common control with BIDMC.

Participate.²⁷ To be responsible for the design, conduct, or reporting of Research, regardless of title or position. (See also the definition of Participate in Clinical Research.)

- This term assumes that the individual may have the opportunity to influence or impact the results. It is not intended to apply to individuals who provide primarily technical support to a research study or who act in a purely advisory capacity with no direct access to the study data, unless such individuals are nonetheless in a position to influence or impact the study’s results or have privileged information as to its outcome.
- If an Investigator Participates in Research pursuant to this definition, such participation shall be considered to be for the entire duration of the study (one cannot elect to terminate participation prior to the end of the study).

Participate in Clinical Research.²⁸ Investigators who are either:

1. responsible for the **design, conduct, or reporting of an IRB-approved study** and, as part of that IRB-approved study:
 - a. have access to information about living individuals by intervening or interacting with them for research purposes; and/or
 - b. have access to identifiable private information about living individuals for research purposes; and/or
 - c. obtain the voluntary informed consent of individuals to be subjects in research; and/or
 - d. study, interpret, or analyze identifiable private information or identifiable data for research purposes; or
 - e. have access to the study treatment assignment made through, for example, a randomization process.
2. the primary author, or one of the primary authors, of a publication reporting the results of an IRB-approved study. A primary author of a publication is the individual who, in compliance with [HMS Authorship Guidelines](#) and [ICMJE Authorship Guidelines](#) takes primary responsibility for the integrity of the work as a whole even if he or she does not have an in-depth understanding of every part of the work.²⁹

Post-market Royalties. Royalties received by an Investigator directly or under an institutional

²⁶ [HMS COI Policy](#) (2016).

²⁷ [HMS COI Policy](#) (2016)

²⁸ Id.

²⁹ For purposes of this rule, the first, last and corresponding authors are considered to be primary authors unless the first, last or corresponding author demonstrates to the satisfaction of the BIDMC COI Committee that he or she should not be considered a primary author.

royalty-sharing agreement as a result of the sale of a Technology invented by the Investigator in the public market (e.g., if applicable, post-FDA-approval). This term does not include license fees, annual maintenance fees, milestone payments or other income that may become due under a license prior to market approval of the Technology.

Primary Author. An individual who, in compliance with [HMS Authorship Guidelines](#) and [ICMJE Authorship Guidelines](#) takes primary responsibility for the integrity of the work as a whole even if he or she does not have an in-depth understanding of every part of the work.³⁰ For the purposes of applying the Clinical Research Rule, the first, last and corresponding authors are considered to be primary authors unless the first, last or corresponding author demonstrates to the satisfaction of the COIC that he or she should not be considered a primary author. The decision of the COIC may be subject to the approval of the HMS Standing Committee.

Publication.³¹ Publication ordinarily refers to a peer-reviewed indexed manuscript or the substantial equivalent as determined by the BIDMC COIC and the HMS Standing Committee or its designee. Abstracts alone will not typically meet this definition.

Research.³² A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic, Sponsored, and Clinical Research, including applied research and product development.

Significant Financial Interest (SFI).³³ A financial interest consisting of one or more of the following interests:

1. With regard to any publicly-traded entity, when the value of any remuneration (salary and any payment for services not otherwise identified as salary, for example consulting fees, honoraria, paid authorship) received from the entity in the twelve (12) months preceding disclosure of the interest aggregated with the value of any equity in the entity (for example, stock, stock options, or other ownership interests as determined through reference to public prices or other reasonable measures of fair market value) in the entity as of the date of the disclosure exceeds \$5,000;
2. With regard to any non-publicly-traded entity, when the aggregated value of any remuneration received from the entity in the twelve (12) months preceding disclosure of the interest exceeds \$5,000, or any equity in the entity; or
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Exclusions: The term Significant Financial Interest **does not include** the following types of financial interests:

1. Salary, royalties, or other remuneration paid by BIDMC to an Investigator if the Investigator is currently employed or otherwise appointed by BIDMC, including intellectual property rights assigned to BIDMC and agreements to share in royalties related to such rights;
2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made

³⁰ For purposes of this rule, the first, last and corresponding authors are considered to be primary authors unless the first, last or corresponding author demonstrates to the satisfaction of the BIDMC COI Committee that he or she should not be considered a primary author.

³¹ [HMS COI Policy](#) (2016).

³² Id.

³³ 42 CFR §50.603

in these vehicles;

3. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
4. Income from service on advisory committees or review panels for a federal, state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Sponsored Research. Research, training and instructional projects involving funds, personnel, certain proprietary materials or technology, or other compensation from outside sources under an agreement that: (1) BIDMC classifies as a sponsored award in accordance with BIDMC policy or (2) gives the donor, or an identifiable third party designated by the donor, preferred access to or ownership rights over the Research or the products of the Research, e.g. raw data, scientific developments or intellectual property. Provision of periodic general reports and copies of publications shall not be considered preferred access.

Notwithstanding the forgoing, Sponsored Research shall not incorporate the following agreements:

1. Gifts. Agreements that BIDMC classifies as a gift in accordance with BIDMC policy³⁴ except as specifically set forth below:
 - Investigators who hold equity in the donor company are prohibited from receiving gifts that are made solely for the support of the Investigator's Research or that of the Investigator's laboratory.
2. Certain Material Transfer Agreements. Agreements that provide for the provision of tangible materials, including equipment ("Material") from an outside source pursuant to a material transfer or other agreement provided each of the following factors are met:
 - a. The proposed protocol does not consist of Research on the Material in question either directly or indirectly (e.g., the primary usefulness of the Material in the proposed protocol is as a research tool to achieve scientific aims distinct from the donor company's business aims and not as a potential product or integral component of such product);
 - b. The proposed agreement does not grant to the Organization any rights to intellectual or tangible property created in or resulting from the use of the material in the proposed Research, except:
 - 1) Options to negotiate (even if such options are exclusive) a license to intellectual property made in, and derived directly from the use of the Material in, the Research; or
 - 2) A non-exclusive license for *research purposes* to intellectual property made in, and derived directly from the use of the Material in, the Research.
 - c. The agreement otherwise meets with the approval of designated BIDMC officials who may impose additional prohibitions and/or

³⁴ BIDMC Policy ADM-64, Gift Acceptance Policy.

restrictions in view of potential conflicts, as deemed warranted.

Technology.³⁵ Any compound, drug, device, diagnostic, medical or surgical procedure intended for use in health care or health care delivery.

- A Technology “belongs” to an Organization in a way that implicates the Clinical Research Rule if the Organization:
 - manufactures the Technology (or contracts with another entity to manufacture the Technology under its direction); or
 - owns or has licensing rights to the Technology.

An exception to this general rule, however, may be granted if, the COIC determines after a review of the specific facts, that a Technology is:

- off-patent and manufactured as a generic;
- non-exclusively licensed to multiple companies; or
- manufactured by multiple companies;

and, as a result, there is a sufficiently dilutive market for the Technology to conclude that the Technology does not belong to any one Organization.

- For more information on whether a Technology is being “investigated” or having Research conducted “on” it in a way that would implicate the Research Rules in this policy, please see the website of the [Office of Academic and Research Integrity](http://ari.hms.harvard.edu) for guidance (ari.hms.harvard.edu).

Travel. Any travel that is reimbursed (i.e., the Investigator is made whole for the financial outlay required) or sponsored (i.e., the costs are paid on behalf of the Investigator such that the exact monetary value may not be readily available) by an Organization other than by BIDMC, a federal, state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Vice President Sponsors:

**Jamie Katz
General Counsel and Interim Compliance
Officer**

**Randall Mason, Vice President of
Research Operations**

Approved By:

Operations Council: 3/6/17

**Peter Healy
President**

Medical Exec. Committee: 2/15/17

**Jonathan Kruskal, MD,
Chair of Medical Executive Committee**

Requestor Name:

**Melissa Anderson, JD, Director, Conflicts and
Industry Interactions**

Original Date Approved: 04/2004

³⁵ [HMS COI Policy](#) (2016).

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