

**Beth Israel Deaconess Medical Center  
BIDMC Manual**

**Title: Conflict of Interest**

**Policy #: ADM-19**

**Purpose:** BIDMC has developed this Policy on Conflict of Interest to identify, address, manage, and resolve conflicts of interest of the BIDMC Workforce and to coordinate the application of Harvard Medical School's Conflict of Interest and Commitments Policy to Faculty Members who have appointments at BIDMC as well as the requirements of Title 42 Code of Federal Regulations (CFR) Part 50, Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought*.

## **I. Introduction**

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.<sup>1</sup> All individuals who serve BIDMC and its patients are expected to put this mission first and foremost whenever conducting activities relating to BIDMC.

BIDMC encourages each member of its Workforce, including members of the Board of Directors, Trustees and Overseers, to participate in activities that might benefit not only BIDMC, but also the individual and the public at large. BIDMC acknowledges that these activities may involve complex relationships with government, academia, industry and others. However, it is important that such relationships do not create conflicts of interest and commitment. A Conflict of Interest arises when an individual has the opportunity to use his or her position for some personal advantage or gain; or where outside interests may inappropriately influence the way the individual carries out his or her responsibilities to BIDMC; or where the individual is in a position to influence a transaction or decision in such a way that it will, or might reasonably appear to, benefit the individual or his or her family.<sup>2</sup>

The purpose of this policy is to provide guidelines to address such conflicts. This policy involves two paths, a General Workforce Path and a Research Path. The General Path, set forth in Section V of this Policy, is designed to identify and manage any conflicts of members of the general BIDMC Workforce. The Research Path, set forth in Section VI of this Policy, is designed to identify and manage any conflicts that principal investigators or key personnel may have with research projects. There will be some individuals who will have to make disclosures for both the General and Research Workforce paths.

## **II. Covered Individuals**

This Policy shall apply to the BIDMC Workforce. *Workforce* means persons whose conduct, in the performance of work for BIDMC, is for the benefit of BIDMC, directly or indirectly, whether or not they are paid by BIDMC.<sup>3</sup> This shall include employees, members of the Medical and Professional Staff, consultants, agents, volunteers, trainees, members of the Board of Directors, Trustees, and Overseers, along with the officers and / or members of any related committees.

### III. Definitions

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

- A. **Conflict of Interest.** A situation in which financial, professional, or personal interests may compromise one's professional judgment or professional or business obligations.<sup>4</sup>
- B. **Financial Conflict of Interest.** A type of conflict of interest where the conflict of interest is due to a financial interest or goal.
- C. **Conflict of Interest in Research.** An interest, commonly, but not solely financial in nature, related to the design, conduct, analysis, reporting or supporting of research which does or may be reasonably expected to, create a bias stemming from that interest.<sup>5</sup>
- D. **Research.** A systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.<sup>6</sup>
- E. **Clinical Research.**<sup>7</sup>
  - 1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual. Patient oriented research includes (i) mechanisms of human disease, (ii) therapeutic interventions, (iii) clinical trials, or (iv) development of new technologies.
  - 2. Epidemiologic and behavioral studies.
  - 3. Outcomes research and health services research.
- F. **Clinical Trial.** A biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).<sup>8</sup>
- G. **Investigator.** (1) A principal investigator, and/or (2) co-principal investigator, and/or any person (3) who is independently responsible for the design, conduct, or reporting of research, and/or (4) responsible for the treatment or evaluation of research subjects and/or (5) responsible for obtaining the informed consents of research subjects.<sup>9</sup> This definition does not include students, post doctorate fellows, technicians, and other BIDMC employees whose work is directly supervised and controlled by an Investigator.
- H. **Family.** An individual's spouse, children, parents, siblings, or other persons living in the same household.<sup>10</sup>
- I. **Financial Interest.** A relationship with a business consisting of (1) stock, stock options, partnership shares, or similar ownership interests in such business, but excluding any interest rising solely by reason of investment in such business by a mutual, pension, or other institutional investment fund over which the Covered Individual does not exercise control, or (2) receipt of, or the right or expectation to receive, any income from 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.<sup>11</sup>

**J. Material Interest.**

1. Consulting fees, honoraria (including honoraria from a third party, if the original source is a financially interested company), gifts or other emoluments, or “in kind” compensation from a Materially Interested Company (or entitlement to the same), whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research, that in the aggregate exceeds \$10,000 in any twelve (12) month period.
2. Equity interests, including stock options, of any amount in a non-publicly-traded Materially Interested Company (or entitlement to same).
3. Equity interests (or entitlement to same) in a publicly-traded Materially Interested Company that in the prior calendar year exceeded \$10,000 in value or five percent (5%) ownership, or is expected to exceed those amounts in the next twelve months.
4. Royalty income or the right to receive future royalties under a patent license, trademark or copyright, where the research is directly related to the licensed technology or work.
5. Any non-royalty payments or entitlements to payment in connection with the research that are not directly related to the reasonable costs of the research. This includes any bonus or milestone payments to the investigators in excess of reasonable costs incurred, whether such payments are received from a Materially Interested Company or from BIDMC.<sup>12</sup>
6. Service as an officer, director, or in any other fiduciary role for a Materially Interested Company, whether or not remuneration is received for such service.
7. Holding an elected or appointed office or position in a branch of government or in a regulatory agency having authority or jurisdiction over providers of health care (for member of the judiciary, areas of conflict of interest will be as defined by the Code of Judicial Conduct).
8. Competing with BIDMC or an affiliate in the purchase or sale of property or any property right, interest or service.<sup>13</sup>

**Exceptions.** Material Interests shall not include the following:

1. Interests of any amount in publicly traded, diversified mutual funds.
2. Stock in a publicly-traded company that (when valued in reference to current public prices) is less than \$10,000 in value or five percent (5%) ownership interest.
3. Payments to BIDMC, or via BIDMC to an Investigator that are directly related to reasonable costs incurred in the conduct of Research as specified in the research agreement between the Sponsor and BIDMC.
4. Salary and other payments for services from BIDMC or HMFP.<sup>14</sup>

- K. **Materially Interested Individual.** A Covered Individual who holds a significant financial or other interest that would reasonably appear to be affected by the individual's research or other professional activities.<sup>15</sup>
- L. **Materially Interested Company.** A commercial entity with financial or other interests that would reasonably appear to be affected by the conduct or outcome of research or other professional activity conducted at BIDMC.<sup>16</sup>
- M. **Sponsored Research.** Research, training and instructional projects involving funds, materials, or other compensation from outside sources.<sup>17</sup>
- N. **Sponsor.** The source of funds, materials, or other compensation for Sponsored Research.
- O. **Reasonably Appear.** The test for appearance is whether a conflict of interest would create in reasonable minds a perception that the individual's ability to carry out their responsibilities or obligations to BIDMC with integrity, impartiality and competence would be impaired.

#### **IV. BIDMC Conflict of Interest Committee**

There shall be a Conflict of Interest Committee, whose charge shall be to provide guidance and recommendations to administration on BIDMC conflict of interest policies and issues. The Committee shall meet on an as needed basis, but no less than annually. The Conflict of Interest Committee shall report annually to BIDMC's Compliance Committee regarding its activities.

The Conflict of Interest Committee shall comprise the following:

**Members\*:**

- Chief Operating Officer
- General Counsel
- Chief Compliance Officer-Chair
- Corporate Director, Internal Audit
- Senior Vice President, Human Resources
- Chief Academic Officer or his/her designee
- Non-management member of the Compliance Committee
- Chair of the Committee on Clinical Investigation

\* While carrying out its duties, the Committee acting through the Chair may from time to time when specific subject matter expertise is needed call upon others to act as "ad hoc" members of the Conflict of Interest Committee, including but not limited to investigators, members of the medical staff, and the Director of Contracting.

#### **V. Annual Disclosures of Interests by the General Workforce**

**A. Who Must Make Disclosures**

The following Covered Individuals will have an affirmative duty to disclose interests that they may have on an annual basis: BIDMC Trustees/Directors, Staff and non-voting members of Board level Committees, Officers, Senior Management, Chiefs of Service, Division Chiefs,

and other workforce and professional staff categories as identified from time to time by the Chief Executive Officer and/or Directors of BIDMC, the Chief Compliance Officer. or Corporate Director for Internal Audit. <sup>18</sup> If a change in an individual's interests occurs between the time of the annual disclosures, such change must be reported to the Chief Compliance and Privacy Officer within thirty (30) days and the Conflict of Interest Committee shall be notified, if necessary.

B. Interest Disclosure Process and Management

1. At the beginning of each fiscal year the Office of Business Conduct shall notify Covered Individuals who have an affirmative obligation to report their interests as determined pursuant to Section V.A. The Covered Individuals shall provide the information to the Office of Business Conduct.. For employees of BIDMC, providing disclosure is a condition of employment and for professional staff it is a condition of appointment to the staff.
2. The Office of Business Conduct shall contact those Covered Individuals who do not return the information in a timely manner. The names of those Trustees, Directors and Overseers who do not return the disclosure information after a follow-up shall be forwarded to the Chief Operating Officer, the names of all others shall be forwarded to the Chief Compliance Officer for further action.
3. The Office of Business Conduct shall refer all those Covered Individuals who have made a disclosure to the Conflict of Interest Committee to determine the appropriate action required to respond to the information disclosed.
4. The determination of the Conflict of Interest Committee shall be communicated to the Covered Individual in writing, with a copy to either the Covered Individual's senior manager, chief of service, or Chairman of the Board of Directors as may be appropriate.
5. When appropriate as determined by the Conflict of Interest Committee, the covered Individual shall be required to respond to the determination of the Conflict of Interest Committee in writing, detailing how he or she complied with the determination. The Covered Individual's senior manager, chief of service, or Chairman of the Board, as may be appropriate, shall be responsible for ensuring that the Covered Individual's Conflict of Interest is managed consistent with the determination of the Conflict of Interest Committee.
6. The Conflict of Interest Committee shall keep minutes of all correspondence as required in this Section V.B

C. Guidelines for the Management, Reduction or Elimination of a Conflict of Interest

1. Any individual serving as a Trustee, Director or member of a Board Committee or any other BIDMC committee who is in a position to vote on or influence a particular transaction or decision when the individual or his or her Family has a Material Interest in an entity or property involved in the transaction or decision, shall without delay:
  - a. Disclose the conflict to the Board or Committee prior to any action by

BIDMC or an Affiliate;

- b. Not be present for or participate in the discussion of the transaction or decision other than to answer questions as may be requested;
  - c. Not be present for the vote, vote, or be counted in determining a quorum for purposes of the related vote.<sup>19</sup>
2. Placing interests in escrow for the term of the transaction or decision and perhaps a period beyond the end of the transaction.
  3. Reduction or divestiture of the Material Interest held by the Individual or his or her Family and restrictions on re-investment after the transaction or decision creating the Conflict of Interest is completed.

## **VI. Disclosures of Interests Related to Research**

Title 42 Code of Federal Regulations (CFR) Part 50, Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought*, was established to ensure that the design, conduct, and reporting of research will not be biased by a conflicting financial interest of an Investigator. While Subpart F only applies to federally funded research, Section VI shall apply to all research at BIDMC, regardless of the funding source.

### **A. Disclosures by Investigators**

1. Each Investigator, as part of any funding application and no less frequently than annually, shall complete the Conflicts of Interest in Research Disclosure Form and Certification and submit it to the Director for the Office of Sponsored Programs. The Director for the Office of Sponsored Programs shall be the Institutional Official pursuant to 42 CFR 50.604.
2. Investigators who are not employed by BIDMC but who conduct research at BIDMC must also disclose their interests. It shall be the responsibility of the principal investigators to ensure these individuals make the required disclosures. It shall be acceptable for non-BIDMC based investigators who serve as key personnel for a Sponsored Research project to submit copies of any disclosure forms they completed as part of their home institutions' conflict of interest review process.
3. The interests of all Investigators on a Sponsored Research project must be disclosed to BIDMC and Conflicts of Interests managed, reduced, or eliminated before any Sponsored Research funds may be expended.
4. New Investigators who intend to begin work on a project after the project has been approved and funded shall disclose any interests prior to the commencement of their work on any Sponsored Research.
5. If a change in the Investigator's interest related to the research occurs, such change must be reported to the Director for the Office of Sponsored Programs within thirty (30) days.

### **B. Process for Reviewing Disclosures and Managing Conflicts**

1. The Director for the Office of Sponsored Programs shall review the information disclosed by each Investigator to determine whether an Investigator has a Material Interest pursuant to the guidelines set forth in

Section III.C. If the Investigator does not have a Material Interest, the Director for the Office of Sponsored Programs shall process the funding application in accordance with the standard procedures.

2. In the event that the Director for the Office of Sponsored Programs determines that an Investigator has a Material Interest, he/she shall refer the matter to the Vice President, Research Operations.
3. The Vice President, Research Operations shall determine whether there is a reasonable likelihood that the Investigator's Material Interest will directly and significantly affect the design, conduct or reporting of the Sponsored Research.<sup>20</sup>
4. If so, the Vice President, Research Operations shall determine the appropriate action for the management, reduction, or elimination of the Conflict of Interest pursuant to the guidelines set forth in Section VI.C.
5. The determination of the Vice President, Research Operations shall be communicated to Investigator in writing, with a copy to the Chief of the Division or Department to whom the Investigator reports. Further, if the Investigator is involved in Clinical Research, the determination of the Vice President, Research Operations shall also be communicated to the Committee for Clinical Investigations and New Forms of Therapy.
6. The Investigator shall be required to respond in writing to the determination of the Vice President, Research Operations detailing how he or she complied with the determination. The Chief of the Department or Division to whom the Investigator reports shall be responsible for ensuring that the Conflict of Interest is managed consistent with the determination of the Vice President, Research Operations.
7. If the Sponsored Research shall be funded by the Public Health Service (PHS), National Science Foundation (NSF), or American Heart Association (AHA), the Director for the Office of Sponsored Programs shall report the existence of any Investigator's Conflict of Interest and assure that the Conflict of Interest is being managed, reduced, or eliminated to the appropriate agency before grant funding is received. In the event that an Investigator's interest changes and a Conflict of Interest arises after funding is received, the Director for the Office of Sponsored Programs shall report its management within thirty (30) days of the Investigator's notification.<sup>21</sup>
8. The Vice President, Research Operations shall consult with the Conflict of Interest Committee for guidance in the identification, management, reduction, or elimination of Conflicts of Interest from time to time as he or she deems necessary. The Vice President, Research Operations shall report regularly, but no less than once per year, to the Conflict of Interest Committee about the Conflicts of Interest identified and managed.
9. The Vice President, Research Operations shall keep records of all correspondence as detailed in this Section VI.B., and provide copies to the Conflict of Interest Committee.

C. Guidelines for the Management, Reduction or Elimination of a Conflict of Interest in Research

Resolution of any Conflicts of Interest in Research shall be based upon the

following theories:

1. No research shall be conducted at BIDMC where payments from a Sponsor are conditioned upon a particular research result or are tied to successful research outcomes. Payment for enrollment in a Clinical Trial shall only be permitted to the extent that such payments:
  - a. Are reasonably related to costs incurred, as specified in the research agreement with the Sponsor;
  - b. Reflect the fair market value of services performed; and
  - c. Are commensurate with the efforts of the individual(s) performing the research.<sup>22</sup>
2. There is a Rebuttable Presumption that, in absence of compelling circumstances, a Materially Interested Individual may not conduct human subjects research. When considering a request by a Materially Interested Individual to conduct human subjects research, the Conflict of Interest Committee should evaluate the nature of the research, the magnitude of the interest and the degree to which it is related to the research, the extent to which the interest could be directly and substantially affected by the research, and the degree of risk to human subjects involved that is inherent in the research protocol.<sup>23</sup>
3. Commercially sponsored research may give rise to financial incentives that conflict with a supervising researcher's responsibility to foster the academic development of students and trainees. Agreements with Sponsors or Materially Interested Companies that place restrictions on the activities of students or trainees or that bind students or trainees to non-disclosure provisions shall be prohibited. When such provisions are unavoidable, such agreements shall be subjected to close scrutiny by the Conflict of Interest Committee and fully disclosed to all students and trainees prior to their involvement in the Sponsored Research. Under no circumstance should a student or trainee be permitted to participate in research if the terms and conditions of participation would prevent him or her from meeting applicable institutional degree requirements (e.g. completion and public defense of a thesis or dissertation).<sup>24</sup>
4. Potential Management Solutions:
  - a. Disclosure of the Material Interest to all lab personnel and any proposed trainees.
  - b. Public disclosure of the Material Interest in publications, presentations, and, in the case of human subjects research, in the informed consent document.
  - c. Objective review by non-interested colleagues of any manuscripts or other information made available to the public based on the results of the proposed Sponsored Research project.
  - d. Revision of the Sponsored Research proposal.
  - e. Designation of a co-investigator (peer or superior) who has no Material Interest in the Sponsored Research project.

- f. Disqualification of the Investigator from participating in part or all of the proposed Sponsored Research activities.
- g. Placing interests in escrow for the term of the project and perhaps a period beyond the end of the project to provide for publication and critique of the project.
- h. Reduction or divestiture of the Material Interest held by the Investigator or his or her Family and restrictions on re-investment after the project is completed for an appropriate period to provide for publication and critique of the project.
- i. Severance of other relationships with the Sponsor or competitor that create actual or potential Conflicts of Interest.
- j. Prohibition from conducting the proposed Sponsored Research.<sup>25</sup>

#### **VII. Payments, Discounts, and Gifts**

Payments, discounts, and gifts shall only be accepted in accordance with the BIDMC Gifts Policy and related policies. Activities conducted in violation of federal, state or local law, including the offering of acceptance of a bribe or kickback, are strictly prohibited.<sup>26</sup>

#### **VIII. Use of BIDMC Name**

The proprietary names, images, and service/trademarks of BIDMC and its Affiliates must be protected from use by commercial or other outside interests or activities in such a way that the integrity and reputation of the corporation and its subsidiaries might be adversely affected. Therefore, all proposals for use of such names, images, or service/trademarks in outside activities must be reviewed and approved in advance by BIDMC's Corporate Communications Department.<sup>27</sup>

#### **IX. Confidentiality**

Information submitted by Covered Individuals and Investigators shall be treated as confidential and will not be disclosed, except as may be necessary pursuant to this Policy or as may be required by law.

#### **X. Inquiries and Investigations**

If, at any time, a member of the BIDMC workforce becomes aware of any apparent or suspected violation of the Medical Center'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 BIDMC Office of General Counsel or the BIDMC Office of Business Conduct, which have the sole authority to investigate and make findings regarding Conflict of Interest.

You can contact the BIDMC Office of Business Conduct by telephone at (617) 667-1897 or the Office of General Counsel at (617) 667-1894. You can contact either office by mail at 109 Brookline Avenue, Suite 300, Boston, MA 02215. You also can submit your questions or concerns in an e-mail to [conduct@bidmc.harvard.edu](mailto:conduct@bidmc.harvard.edu). For anonymous inquiries, you can reach the BIDMC Compliance Helpline at (888) 753-6533.

## **XI. Sanctions**

Breach of this Policy shall include but is not limited to the Covered Individual's failure to submit or submission of an incomplete, erroneous, or misleading disclosure form as required by this Policy, failure to provide additional information as may be requested, or failure to comply with the determination for management, reduction, or elimination of the Conflict of Interest. Covered Individuals who engage in such Breach shall be disciplined in accordance with BIDMC's Employee Corrective Action Policy,<sup>28</sup> Medical Staff By-Laws<sup>29</sup>, and/or the Graduate Medical Education Remediation and Disciplinary Policy<sup>30</sup> as may be applicable.

**Vice President Sponsor: Patricia McGovern, J.D., Sr. VP & Special Counsel**

### **Approved By:**

**Operations Council: 04/23/07**

**Eric Buehrens  
Chief Operating Officer**

**Research Advisory Committee: 5/8/07**

**Jeffrey S. Flier, M.D.  
Chief Academic Officer**

**Medical Executive Committee: 5/2/07**

**Mary Anne Badaracco, MD  
Chair**

**Board of Directors: 5/16/07**

**Lois Silverman  
Chair**

**Requestor Name: Leon Goldman, M.D.**

**Original Date Approved: 4/04**

**Next Review Date: 5/10**

**Revised: 04/07**

**Eliminated:**

**References:**

<sup>1</sup> Beth Israel Deaconess Medical Center Mission Statement.

<sup>2</sup> Washington University School of Medicine Conflicts of Interest Policy, at 2.

<sup>3</sup> Public Welfare and Human Services Privacy Rule, 45 CFR §160.103 (2002).

<sup>4</sup> Wash U., *supra*.

<sup>5</sup> Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection, 61 Fed. Reg. 15456, 15457 (draft proposed Mar. 31, 2003).

<sup>6</sup> Objectivity in Research Rule, 42 CFR §50.603 (1995).

<sup>7</sup> NIH Grants Management Policy (2001).

<sup>8</sup> *Id.*  
<sup>9</sup> *See supra* note 6.  
<sup>10</sup> Partners Healthcare System Code of Conduct at 12 (Sept. 1999).  
<sup>11</sup> Faculty of Medicine Harvard University Policy on Conflicts of Interest and Commitment at 16 (2000).  
<sup>12</sup> Disclosure Form to Implement the Harvard University Faculty of Medicine Policy on Conflicts of Interest and Commitment (2003); “*Protecting Subjects, Preserving Trust, Promoting Progress*” Report from Task Force on Financial Conflicts of Interest in Clinical Research for the American Association of American Medical Colleges at 11 (Dec. 2001).  
<sup>13</sup> CareGroup, Inc. and Affiliate Entities Corporate Conflict of Interest Policy at 2 (2000).  
<sup>14</sup> *See supra* note 11 at 14.  
<sup>15</sup> “*Protecting Subjects, Preserving Trust, Promoting Progress*” Report from Task Force on Financial Conflicts of Interest in Clinical Research for the American Association of American Medical Colleges at 11 (Dec. 2001).  
<sup>16</sup> *Id.*  
<sup>17</sup> *See supra* note 11.  
<sup>18</sup> *See supra* note 13, at 1.  
<sup>19</sup> *Id.* at 3-4.  
<sup>20</sup> *See supra* note 6 §50.604.  
<sup>21</sup> *Id.*  
<sup>22</sup> *See supra* note 15, at 19.  
<sup>23</sup> *Id.* at 16-17.  
<sup>24</sup> *Id.* at 20.  
<sup>25</sup> *See supra* note 6, §50.605.  
<sup>26</sup> *See supra* note 2, at 9; 42 U.S.C. §1320a-7b  
<sup>27</sup> *See supra* note 13, at 6.  
<sup>28</sup> BIDMC Policy PM-04, Employee Corrective Action  
<sup>29</sup> BIDMC Medical Staff Bylaws  
<sup>30</sup> BIDMC Policy MS-06, Graduate Medical Education Remediation and Disciplinary Policy