

Beth Israel Deaconess Medical Center Policy Manual

Title: Conflict of Interest Policy for Institutional Transactions

Policy #: ADM-18

Purpose:

The purpose of this policy is to identify, address, manage, and resolve conflicts of interest that may affect, or appear to affect, the decisions, transactions, and operations of Beth Israel Deaconess Medical Center, Inc.

This policy applies to all members of the “Workforce,” which means persons working for the benefit of BIDMC, whether or not they are paid by BIDMC. This includes employees, officers, members of the professional staff, and also includes consultants, agents, volunteers, trainees and members of the Board of Directors and Board Committees when they are acting in a BIDMC capacity. Members of the Workforce who are participating in research at or under the auspices of BIDMC are also required to comply with [ADM-19 Conflict of Interest Policy for Research](#).

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

Each member of the Workforce is encouraged to participate in activities that might benefit not only BIDMC, but also the individual and the public at large. These activities might involve relationships with government, academia, industry and others. However, it is important that outside relationships do not create conflicts of interest and commitment that might undermine the integrity of our business decisions or the fulfillment of our mission. These concerns arise when an individual’s own interests (financial or professional) have the potential to inappropriately affect the way they carry out their responsibilities to BIDMC; or when an individual has the opportunity to use his or her position for some personal advantage, or to influence a transaction or decision in such a way that it will, or might reasonably appear to, benefit themselves or their family.

For these reasons, BIDMC has established the following Conflict of Interest Policy for Institutional Transactions. The Policy outlines unacceptable practices, and guides members of the Workforce in identifying and disclosing certain relationships with outside entities. The disclosures will assist BIDMC in identifying and managing conflicts so that institutional decisions can be undertaken with integrity.

All members of the Workforce, including consultants, agents, and members of the Board of Directors and Board Committees when they are acting in a BIDMC capacity, are required to comply with this Policy, with and any associated procedures and guidelines as amended from time to time, and with any additional requirements imposed by the BIDMC Conflicts of Interest Committee (COIC). 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.

When situations are not specifically addressed in this policy, decisions should be guided by the BIDMC [Code of Conduct](#), always keeping in mind that our patients and their welfare come first, and that we are committed to ethical and compliant conduct. When in doubt, please ask for advice from your supervisor, or from the Office of Compliance and Business Conduct (617-667-1897).

Other related policies:

- [ADM-19 Conflict of Interest Policy for Research](#)
- [ADM-17A Personal Gifts, Travel, Meals, and Entertainment](#)
- [ADM-17B Industry-Supported Speaking, Programs, Fellowships, and Preceptorships](#)
- [ADM-15 Supplier Contact and Negotiation](#)

I. Definitions

For the purposes of this policy, the following definitions shall apply:

Organization. Any legal entity organized for profit or non-profit purposes. This term includes but is not limited to: corporations, partnerships, sole proprietorships, associations, holding companies, and business or real estate trusts. Excluded from this definition are BIDMC and HMFP, any BIDMC or HMFP affiliate, any private medical practice, and any other entity controlled by, controlling, or under common control with BIDMC.

Equity Interest. Any type of ownership interest in an Organization, such as owning stock or stock options (vested and unvested), warrants, partnership shares, or similar ownership interests, 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 member of the Workforce 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 Member. A Workforce member's spouse or domestic partner, child, parent, sibling, or any person living in the same household.

Fiduciary Role. Includes service as an officer, member of a board of directors, manager or member of a limited liability company, partner in a partnership, or in any other fiduciary role for an outside Organization, whether or not remuneration is received for such service.

Government or Regulatory Agency Role. 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.

Income Interest. The receipt of, or the right or expectation to receive, any income or other tangible personal benefit from an Organization. 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 include, but are not limited to, consulting or expert opinion/witness fees, salary, speaking honoraria or other payments for services, gifts or emoluments or other "in kind" compensation, forbearance, forgiveness of debt, interest in real or

personal property, dividends, rent, or any other form of compensation.

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

Workforce. Persons working for the benefit of BIDMC, whether or not they are paid by BIDMC, including but not limited to

- a. officers, members of the Board of Directors, Trustees, Overseers, and Board Committees, when they are acting in a BIDMC capacity;
- b. full or part-time professional staff members and employees of BIDMC; and
- c. any consultants, agents, volunteers, or trainees when they are acting in a BIDMC capacity.

Members of the Workforce who, alone or together with one or more members of their Family, exercise a controlling interest in any trust, organization or enterprise other than BIDMC 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 "Workforce."

II. Policy Requirements for Individual Conflicts of Interest in Institutional Transactions

Members of the Workforce must ensure that their personal financial interests and other outside relationships which may conflict with the best interests of patients and BIDMC are disclosed and addressed to maintain the integrity of decision-making in institutional transactions.

A. Conflicts of interest may arise when BIDMC enters into, or considers entering into, a transaction with any of the following:

1. a member of the Workforce;
2. a Family Member; or
3. an Organization in which a member of the Workforce or a Family Member has a Significant Financial Interest or Relationship.

B. Significant Financial Interest or Relationship. The financial interests or other relationships listed below are considered to be a Significant Financial Interest or Relationship with an Organization:

1. the individual or a Family Member has an Income Interest with the Organization that in the aggregate exceeds \$10,000 in any twelve (12) month period;
2. the individual or a Family Member has an Equity Interest in a *publicly-traded* Organization that exceeds either \$10,000 or five percent (5%) ownership. If the Organization is *not publicly-traded*, an Equity Interest of any value in the Organization;
3. the individual or a Family Member has a Fiduciary Role or Executive Position with the Organization, whether for-profit or non-profit;
4. the individual or a Family Member has a Government or Regulatory Agency Role;
5. the individual or a Family Member is competing with BIDMC in the

purchase or sale of services, property, or property right in interest; or

6. the Organization employs or is about to employ the individual or a Family Member.

C. Recusal Requirement. A member of the Workforce who has, or whose Family Member has, a Significant Financial Interest or Relationship with an Organization may not:

1. participate in discussions on or recommendations regarding, act upon, or otherwise participate in the decision making regarding a transaction with that Organization, or take any administrative action on behalf of BIDMC that is beneficial to that Organization, or
2. engage in the selection, award, or administration of a contract supported by a Federal award¹.
3. Limited Allowable Participation. The Workforce member may participate in discussions and/or recommendations about a transaction, but not in the final decision-making, provided that the person with authority for final decision-making or the chairperson of a committee determines that involvement of the member is appropriate, and others involved in the discussion and/or recommendation are aware of the financial Interest or relationship held by the member, and the member possesses particular expertise or knowledge that would be beneficial to the final decision.

D. Disclosure Requirement for Transactions. When a member of the Workforce, or their Family Member, or an Organization in whom they have a Significant Financial Interest or Relationship has a pending transaction with BIDMC, the member of the Workforce shall without delay:

1. disclose the conflict to his/her supervisor and any applicable board or committee prior to any action by it;
2. not be present for or participate in the discussion of the transaction or decision other than to answer questions as may be requested; and
3. not vote, be present for the vote, or be counted in determining a quorum for purposes of the related vote.

E. Transactions Involving Contracts to Purchase Goods and Services. In addition, all members of the Workforce who are involved in vendor contact or negotiation for transactions involving contracts for goods and services are required to follow the procedures for disclosing conflicts of interest set forth in ADM-15, [Supplier Contact and Negotiation](#). This policy sets the process for the approval of BIDMC business decisions and transactions by non-interested decision makers. No significant purchasing transactions may be entered into by the Purchasing Office unless the decision-maker has determined, by collecting the disclosures required in ADM-15, whether any members of the Workforce have a relationship with or financial interest in the Business involved that is relevant to the transaction. When this occurs, the basis

¹OMB Guidance Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards 2 CFR §200.318(c) (1).

for proceeding with the transaction must be documented in accordance with criteria established by that policy.

F. Individual Royalties and Clinical Care. A Workforce member may not receive royalties that are derived from the sale to BIDMC of products used to treat BIDMC patients, and incorporating the Workforce member's licensed Technology, unless the Conflicts of Interest Committee approves an arrangement under which all such royalties will be donated to a specific charitable organization. License agreements under which a Workforce member's Technology is licensed to an Organization must include this provision.

G. Annual Disclosure Requirement. In addition to making any necessary transactional disclosures, the following institutional leaders and others in positions of authority are required to make annual disclosures of their financial interests and other relationships:

1. members of the Board of Directors,
2. officers, senior management,
3. chiefs of service, division chiefs,
4. members of the Pharmacy and Therapeutics (P&T) Committee and the Clinical Quality Value Analysis (CQVA) Committees, and
5. other categories as identified from time to time by the Board of Directors, the Chief Executive Officer, the Senior Vice President for Compliance, Audit, and Risk, or the Conflicts of Interest Committee.

H. Collection and Review of Disclosures. BIDMC will collect and review annual disclosures as described in the COI Guidelines for Institutional Transactions, which may be amended from time to time.

III. Policy Requirements for Organizational Conflicts of Interest

BIDMC must ensure that certain financial interests and outside relationships which may conflict with the best interests of patients and program sponsors are addressed to maintain the integrity of decision-making in clinical and institutional decisions.

A. BIDMC Royalties and Clinical Care. BIDMC may not receive royalties that are derived from the sale to BIDMC of products used to treat BIDMC patients, and 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.

B. Certain Federal Awards. Where circumstances raise a concern, that because of relationships with a parent company, an affiliate, or a subsidiary organization, BIDMC is unable or appears to be unable to be impartial in conducting a procurement transaction with a related organization that will result in a charge to a Federal award as defined in 42 CFR §200.38, the responsible individual may refer the matter to the

Conflict of Interest Committee for review and reporting under any applicable federal agency standards.²

- C. Research.** For standards of conduct covering organizational conflicts of interest potentially affecting or appearing to affect clinical research, see [ADM-19, Conflict of Interest Policy for Research](#), section entitled, “Institutional Interests Related to Clinical Research”.

IV. 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 Harvard Medical School for review when it has jurisdiction over a faculty member or trainee, as well as with supervisors, division chiefs, or department chairs in the chain of authority over the individual. Information will also be shared as may be required by law and other applicable regulations that may require an individual’s relationship with an Organization to be made publicly available.

V. Sanctions

BIDMC has wide discretion to impose a variety of sanctions in the event of noncompliance with any aspect of this policy, the [COI Guidelines for Institutional Transactions](#), or any other implementing standard operating procedures or 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 Workforce member’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 meted out, 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 for an identified conflict of interest that is not otherwise prohibited by this policy.

Individuals who do not comply with this policy may be disciplined in accordance with BIDMC’s [Corrective Action Policy](#), [Medical Staff By-Laws](#), and/or the Graduate Medical Education [Remediation and Disciplinary Policy](#) as may be applicable.

² OMB Guidance Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards 2 CFR §200.318(c) (2).

VI. Inquiries and Investigations

If, at any time, a member of the BIDMC's Workforce becomes aware of any apparent or suspected violation of the 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 Compliance and Business Conduct, which shall investigate and make findings regarding conflict of interest.

You can contact the BIDMC Office of Compliance and Business Conduct by telephone at (617) 667-1897, or 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.

Vice President Sponsor:

**Eileen McCarthy, RN, CHC
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Approved By:

Medical Executive Committee: 10/21/15

**Jonathan Kruskal, MD
Chair, MEC**

Operations Council: 12/7/15

**Nancy Formella, RN
Chief Operating Officer**

Requestor Name:

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

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Next Review Date: 12/18

References:

ADM-02 [Industry Representative Code of Conduct](#)

ADM-15 [Supplier Contact and Negotiation](#)

ADM-17A [Personal Gifts, Travel, Meals, and Entertainment](#)

ADM-17B [Industry-Supported Speaking, Programs, Fellowships, and Preceptorships](#)

ADM-19 [Conflict of Interest Policy for Research](#)

PSM-400-320 [Industry Representatives in the Perioperative Setting](#)

PM-04 [Corrective Action](#)