



**Policy and Procedure Manual**

**Policy #:** 2.27

**Issued:** October 2004

**Reviewed/**

**Revised:**

**Section:** 2.0 Management/Administration

**POLICY ON CONFLICT OF INTEREST  
IN THE CONDUCT OF RESEARCH**

**Purpose:**

Boston Medical Center seeks to ensure the integrity of academic research conducted by its workforce consisting of Medical and Dental Staff, employees, students, and contractors to sustain public confidence in that research.

**Policy Statement:**

Since October 1, 1995, two federal agencies, the National Science Foundation and the Public Health Service, have required every institution that applies for research funding to maintain a policy designed to promote research objectivity through the management, reduction or elimination of investigators' conflicts of interest<sup>1</sup>. Thereafter, Boston Medical Center and previously its predecessor institutions and Boston University ("BU") adopted procedures which complied with these federal regulations with respect to federally funded research.

In recent years there has been heightened concern about research conflicts of interest in both clinical research. Faculty or staff start-up companies and other technology transfer arrangements have raised issues of conflict of interest that could affect basic science research. In view of these concerns, BU expanded its conflict of interest policy, effective June 5, 2001, to apply to all investigators who conduct human subject research, regardless of whether there is a federal funding source. Subsequently, effective October 31, 2003, BU expanded its Policy on Investigator Conflicts of Interest to cover all Medical Campus research. In the interest of maintaining consistent standards and administering a joint program with BU for all research on the Boston University Medical Center Campus, Boston Medical Center now issues this revised Policy on Conflicts of Interest in the Conduct of Research.

**Application:**

**A. Research Affected:**

Human subject and non-human subject) research at Boston Medical Center regardless of funding ("covered research").

**B. Individuals Affected**

All persons ("investigators") responsible for designing, conducting or reporting covered research in the course of Boston Medical Center work are governed by this policy. The term "investigator" includes all principal investigators and co-investigators, and may include others (e.g., graduate students, post-doctoral fellows, and technicians) if they have such responsibilities.

**C. Conflict of Interest**

A conflict of interest exists when an investigator, the investigator's spouse, or the investigator's dependent children have a "significant financial interest" (for definition of "significant financial interest," 2) that could directly and significantly affect the design, conduct or reporting of covered research.

**Exceptions:**

None

**Procedure:**

**A. Disclosure**

**Financial Interests to be Disclosed:**

An investigator must disclose whether he, his spouse, or any of his dependent children has a significant financial interest that could directly and significantly affect the design, conduct or reporting of covered research. (See Attachment)

The investigator is required to list all such significant financial interests and to identify (i) the nature and approximate monetary value of the interest; (ii) the person(s) having the interest; (iii) the investigator's relationship to such person(s); and (iv) whether the project will involve human subject research.

**Examples of Activities Requiring Disclosure:**

Activities that may constitute conflicts of interest, and thus must be disclosed, include the following:

1. An investigator conducting covered research the results of which have been contractually obligated to an entity<sup>3</sup> (See endnote 3 for definition of "entity") in which he and his wife own equity.
2. An investigator conducting covered research sponsored by a corporation from which her husband expects to receive more than \$10,000 in consulting fees over the next twelve months.

3. An investigator conducting covered research on a technology in which he owns a patent arising either out of externally-performed work or out of Medical Center work where the Medical Center has assigned the patent to the investigator

**Time of Disclosure and Supplemental Disclosures:**

On or before December 31, 2004 (or, thereafter, December 31 of an investigator's first year at the Medical Center), investigators must submit a comprehensive disclosure relating to all of their covered research, whether or not funded. These disclosures must be supplemented whenever there is a material change in the information previously disclosed. If the comprehensive disclosure indicates that the investigator has no significant financial interests as to which disclosure is required, then no further filings need be made, except filings of supplemental disclosures in the event of material change in information previously submitted. Conflict of Interest Disclosure Form and

**Supplements:**

Disclosure Forms will be made available by the Grants Administration Office.

The principal investigator is required to identify all other persons who will be responsible for the design, conduct or reporting of the proposed research, and to ensure that Disclosure Forms are completed by all such persons and attached to the principal investigator's Disclosure Form. Individuals whose independent responsibilities will significantly affect the integrity of these functions in Covered Research should be identified by the principal investigator as "investigators" for purposes of the disclosure requirements of the Policy.

Any activity that may involve a conflict of interest ordinarily should not be undertaken until the conflict has been disclosed and reviewed in accordance with this policy.

**B. Review of Disclosure Forms**

**Disclosures Forwarded to BMC President:**

The Grants Administration Office will forward all disclosure forms that report significant financial interests to the President of Boston Medical Center or her designee with a copy to the investigator's Chief of Service or Vice President, as appropriate. If the proposed research receives an award of external funding from the National Institutes of Health or from the National Science Foundation, the Grants Administration Office will inform the President so that, prior to Boston Medical Center's expenditure of any award funds from those federal agencies, the President may complete a review of the relevant disclosure form(s).

**Boston University Medical Center [BUMC"] Conflict of Interest Advisory Committee:**

The President of Boston Medical Center and the Provost of the BU Medical Campus will jointly appoint a Conflict of Interest Advisory Committee for the Boston University Medical Center. The Committee shall consist of between five and seven persons and shall

include individuals with experience in academic scientific research and in the transfer of technologies from academia to the commercial sector. The Committee will be provided with administrative support as needed from the office of the President. The Committee shall maintain records of its activities, including copies of all documents received and sent.

The President shall forward all Disclosure Forms and Supplemental Disclosure Forms for review and advice to the BUMC Conflict of Interest Advisory Committee.

**Committee Proceedings:**

- (a) **Review of Disclosure Forms and Other Information:** The Committee will review the Disclosure Form and may request additional information, from investigators, administrative offices of the Medical Center, Boston University, and other sources.
- (b) **Determination of Whether a Conflict of Interest Exists:** The Committee will determine whether a conflict of interest exists under the terms of this Policy. In making this determination, the Committee will consider all relevant factors and information, including but not limited to the nature of the research, the magnitude of the financial 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, the extent to which the academic programs under the supervision of the investigator may be affected by the interest, and the degree of risk to the human subjects, if any, that is inherent in the research protocol.
- (c) **Management, Reduction and Elimination of Conflicts of Interest:** If the Committee determines that a conflict of interest exists, the Committee will consider what conditions or restrictions, if any, should be imposed to manage, reduce or eliminate the conflict of interest. Prior to the recommendation of such conditions or restrictions, the Committee will give the investigator an opportunity to submit additional information and may meet with the investigator. The investigator will be encouraged to suggest procedures, protocols, or other measures designed to manage, reduce or eliminate the conflict.

**Examples of conditions or restrictions that might be imposed include:**

1. Public disclosure of a significant financial interest;
2. Monitoring of the research or other activity (such as teaching or administration related to the affected research) by independent reviewers;
3. Modification of the research plan or other activity (such as teaching or administration related to the affected research);
4. Disqualification from participation in all or a portion of the research or other activity (such as teaching or administration related to the affected research);
5. Divestiture of significant financial interests; or

6. Severance of relationships that create conflicts. If federal regulations permit, the Committee may recommend the waiver of conditions or restrictions that normally would be imposed where their imposition would be ineffective or inequitable, and where the consequences that might result from a conflict of interest are outweighed by interests of scientific progress, technology transfer, or public health and welfare.

- (d) **Human Subject Research:** If the conflict of interest affects a project involving human subject research, the Committee will normally presume that the conflict should be eliminated, unless the investigator rebuts the presumption by showing compelling circumstances that justify allowing the conflict to exist subject to conditions or restrictions designed to manage or reduce it.

**Committee Report to the President:**

The Committee will prepare a report to the President indicating its determination, the basis for its determination (applying the factors indicated in these guidelines and any other relevant factors), and its recommendation, including any proposed conditions or restrictions. The Committee's report will normally be submitted to the President within thirty (30) days after the Committee's receipt of the Disclosure Form

The President may return the report to the Committee for clarification or supplementation. The President will share the report with the investigator and his dean and provide ten (10) business days for any written response. The President may refer the response to the Committee for it to consider the response, make any revisions it deems appropriate in its report in light of the response, and submit its final report to the President.

**Decision of the President:**

The President will review the report and its recommendations, including any written response submitted by the investigator or his dean. If deemed necessary or appropriate, the President may seek additional information or advice from, or request further review by, the Committee or other sources. The President will accept, reject, or modify the determinations and recommendations of the Committee and issue a decision.

The President's decision will state whether a conflict of interest exists. If the President determines that a conflict of interest exists, the decision will state what conditions or restrictions, if any, should be imposed to manage, reduce or eliminate the conflict of interest.

The President will provide copies of the decision to the Committee, the investigator, the investigator's chief of service or Vice President, the BUMC Institutional Review Board (if human subject research is involved), and the Grants Administration Office. No NSF or PHS grant funds are to be expended prior to the President's decision and implementation of any conditions or restrictions. The Grants Administration Office will send a copy of the decision to the NSF or PHS, if such grant funds are involved.

## **E. Implementation and Enforcement**

### **Institutional Review Board:**

The BUMC Institutional Review Board will determine whether any information concerning a conflict of interest needs to be provided to the human subject to ensure appropriate informed consent.

### **Committee Implementation and Enforcement of Conditions or Restrictions:**

- a. **Implementation:** If conditions, restrictions or monitoring are imposed by the President, the Committee will oversee their implementation in accordance with the terms of the President's decision. In so doing, the Committee may use such means as are deemed appropriate and necessary under the circumstances, including but not limited to:
  - i. requiring the investigator, Chief of Service or Vice President to submit evidence of compliance with restrictions;
  - ii. requiring the investigator, Chief of Service, or Vice President to submit periodic written reports containing information in accordance with specifications of the Committee and/or President; and
  - iii. requiring the investigator, Chief of Service, or Vice President to work with any oversight panel that may be established by the President (including members of the Committee and others as appropriate), to oversee the investigator's program in order to protect against the adverse effects of bias upon the conduct of research, academic administration or training programs under the investigator's supervision. Any such oversight panel will report to the Committee, which, in turn, will report to the President
- b. **Corrective action:** If the Committee or an oversight panel receives information indicating that any investigator has failed to comply with this policy or the requirements imposed upon an investigator pursuant to this policy, the Committee or oversight panel shall attempt to resolve the matter by corrective action in an expeditious fashion.
- c. **Referral to President:** In the absence of expeditious correction, the Committee shall report the non-compliance to the appropriate President, and the Committee may recommend that a sanction be imposed pursuant to this policy.

## **F. Sanctions**

Sanctions may be imposed by the President for failure to comply with this policy.

Such failures may include the following:

1. Failure to make timely, full and accurate disclosure in a Disclosure Form;

2. Failure to update a Disclosure Form as necessary;
3. Failure to provide information requested or required by the Medical Center in enforcing this policy; or
4. Failure to comply with conditions or restrictions imposed by the President.

Sanctions may include suspension or dismissal, non-renewal of appointment, denial of eligibility to engage in research funded through Boston Medical Center, denial of merit pay, or other appropriate penalties. Such sanctions may require giving notice of relevant information to funding agencies, professional bodies or journals, or the public.

The President will determine what sanctions, if any, are to be applied. The President may refer the matter to the appropriate Chief of Service or Vice President, take action on her own, or initiate Boston Medical Center procedures governing such discipline.

#### **G. Records**

The Grants Administration Office will maintain records of all disclosures by these offices to sponsoring agencies or entities concerning a possible conflict of interest and of all decisions taken by Boston Medical Center in such an instance. These records will be kept for such time periods as are required by Boston Medical Center or the sponsoring agency.

The President and Conflict of Interest Advisory Committee will maintain records relating to their activities for such time periods as may be required by Boston Medical Center.

#### **H. Confidentiality**

Information submitted by investigators will be treated as confidential and will not be disclosed, except as is required by law or as may be necessary under this policy.

#### **I. Additional Procedures**

The President may establish additional procedures relating to the implementation of this policy, including procedures for reviewing Disclosure Forms and for managing, reducing or eliminating conflicts of interest.

#### **J. Relationship to Other Boston Medical Center Policies**

Matters may arise under this policy which involve other Boston Medical Center policies or procedures, including those governing research misconduct, animal care, human subject research, and patents. The President may refer such matters to the appropriate Boston Medical Center body.

**Responsibility:**

**Forms:** Boston Medical Center/Boston University Medical School Conflict of Interest Disclosure Form

[http://www.internal.bmc.org/grants/Forms/Pre-Award%20Forms/COI%20Form04\\_04.doc](http://www.internal.bmc.org/grants/Forms/Pre-Award%20Forms/COI%20Form04_04.doc)

**Other Related Policies:**

Section name and # 2.0 Management/Administration

**Policy No.: # 2.27**

**Title: Policy on Conflict of Interest in Research**

**Initiated by: Office of the General Counsel**

**Contributing Departments:**

- 1.
- 2.

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<sup>1</sup> See Regulations of the U.S. Public Health Service (PHS) at 42 Code of Federal Regulations Part 50; Federal Register, Vol. 60, No. 132, July 11, 1995, pages 35810-35819; and requirements of the National Science Foundation (NSF) at Federal Register, Vol. 60, No. 132, July 11, 1995, pages 35820-35823.

<sup>2</sup> "Significant financial interest" refers to anything of monetary value, including a salary, consulting fee, honorarium or other payment for service; equity interests, including stocks, stock options or other ownership interests; and intellectual property rights, including patent rights owned by the investigator or on which a clinical investigator is a named inventor (whether licensed or not), copyrights and royalties. This Conflict of Interest Policy, however, excludes from consideration the following items:

- (a) salary, or other remuneration (not including royalties) from Boston Medical Center;
- (b) income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities (for definition of "entity," see footnote 4)
- (c) income from service on advisory committees or review panels sponsored by public or non-profit entities;
- (d) salary, royalties or other payments from a single entity (or group of affiliated entities) that, when aggregated for the investigator and members of his immediate family over the next twelve months, are not expected to exceed \$10,000.

<sup>3</sup> "Entity" means any business or legal entity, including a corporation (profit or non-profit), partnership, limited partnership, joint ventures, voluntary association, sole-proprietorship, or trust.