



**Policy and Procedure Manual**

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<b>Attachments/ Forms:</b>	<b>Form 1: Financial Interest Disclosure</b> <b>Form 2: Addendum to Financial Interest Disclosure</b>
<b>Section:</b>	9.0 Compliance

**SIGNIFICANT FINANCIAL CONFLICTS OF INTEREST IN THE  
CONDUCT OF RESEARCH**

**Purpose:**

Boston Medical Center (“BMC” or “Hospital”) is committed to upholding the highest standards of objectivity in research. To that end, this policy aims to ensure that the design, conduct, and reporting of Research at the Hospital will be free from bias resulting from Investigators’ Financial Conflicts of Interest.

**Policy Statement:**

This Policy provides for procedures for Investigators to disclose to BMC through the Boston University Office of Research Compliance Conflict of Interest Unit (“BU COI Unit”) Significant Financial Interests, and a process to identify, evaluate, manage and report Financial Conflicts of Interests that may have, or may appear to have, an impact on the objectivity and integrity of Research conducted at BMC. This policy is intended to comply with the requirements set forth in the United States Department of Health and Human Services regulation at 42 CFR Part 50, Subpart F for grants or cooperative agreements (revised August 2011) and 45 CFR Part 94 (revised August 2011) for research contracts (the “PHS Regulation”) as well as the National Science Foundation (NSF) regulations found in Section 510 of its Grant Policy Manual (July 2005) (the “NSF Regulation”), to the extent applicable. In addition to complying with the requirements of this Policy, Investigators remain subject to any and all requirements (i) imposed by the reviewing Institutional Review Board (IRB) and/or (ii) contained within other applicable BMC policies and procedures, including parallel obligations to disclose financial and other information required by those policies and procedures.

**Application:**

This policy applies to all persons, regardless of title or position or employer, who are responsible for the design, conduct or reporting of Research while engaged in the performance of services or responsibilities at or for the Hospital. The Boston University Investigator Financial Conflicts of Interest Policy for Research shall apply when those responsible for the design, conduct or reporting of Research are engaged in the performance of services or responsibilities at or for Boston University.

**Exceptions:**

None

**Defined Terms:**

- A. “Financial Conflict of Interest” (or “FCOI”) means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of Research.
- B. “Designated Official” means an institutional official designated to solicit and review disclosures of significant financial interests from Investigators. The Designated Official is the Hospital President or such other individual as he or she may designate in writing.
- C. “Institutional Responsibilities” means an Investigator’s professional responsibilities on behalf of BMC or Boston University (BU), including but not limited to research, teaching, professional practice, and administration such as service on committees and panels.
- D. “Investigator” means 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 including, without limitation, residents, fellows, graduate students, post-doctoral fellows, technicians, collaborators or consultants.
- E. “Manage” means taking action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- F. “PHS” means the Public Health Service of the United States Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
- G. “PHS Awarding Component” means the organizational unit of the PHS that funds PHS-Funded Research.
- H. “PHS-Funded Research” means any Research for which funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award, and any Research for which funding is available from any organization, foundation or other

sponsor who has adopted the PHS regulation. Research funded by the National Science Foundation is not PHS-Funded Research.

- I. “Research” means 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, regardless of funding source. The term encompasses basic, sponsored, and clinical research, including applied research and product development.
- J. “Senior/key Personnel” means the PD or PI and any other person identified as senior/key personnel in the grant application, contract proposal, contract, progress report, or any other report submitted to the sponsor of the Research.
- K. “Significant Financial Interest” (or “SFI”) means:
  1. A financial interest consisting of one or more of the following interests of an Investigator (and those of the Investigator’s spouse or dependent children), that reasonably appears to be related to the Investigator’s Institutional Responsibilities:
    - a. With regard to a publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship fees). Equity interest includes any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
    - b. With regard to a non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000 or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock options, or other ownership interests); and
    - c. Intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income related to such rights and interests.
  2. For PHS-Funded Investigators only, an SFI also includes Travel, which means reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to an Investigator's Institutional Responsibilities. The disclosure of Travel will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. The disclosure requirement for Travel does not apply to any travel that is reimbursed or 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.

3. Exceptions: “Significant Financial Interest” does not include the following financial interests:
  - a. Salary, royalties, or other remuneration paid by BMC or BU to the Investigator, if the Investigator is currently employed or is otherwise appointed by the Institution making the payment;
  - b. Intellectual property rights assigned to either BMC or BU and agreements to share in royalties related to such rights.
  - c. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
  - d. Income from seminars, lectures, 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, a research institute that is affiliated with an Institution of higher education.
  - e. 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; and

## **Procedure:**

### **A. Investigator Responsibilities**

1. Investigators shall (i) disclose Significant Financial Interests (including financial interests of their spouse and dependent children), (ii) comply with the Review Process set forth in Section B, which follows; and (iii) for PHS-Funded Investigators, complete training as described in Section F, which follows.
2. **Disclosure.** Every Investigator must disclose all Significant Financial Interests, and those of their spouse and dependent children, that reasonably appear to be related to the Investigator’s Institutional Responsibilities. The Investigator is not responsible for determining whether the SFI constitutes an FCOI. That determination is made by a Designated Official in accordance with the process described below. Investigator disclosures are required to be made as follows:
  - a. **Upon Application.** Each Investigator who is planning to participate in Research must disclose their SFIs to BMC through the BU COI Unit no later than the time of application to the sponsor for funding, or if no application for funding, prior to the submission of a proposal for the Research to the Institutional Review Board.

- b. **Annually.** Each Investigator who is participating in Research must submit an updated disclosure of SFIs at least annually during the period of the award. Such disclosure shall include any information that was not disclosed initially to BMC pursuant to subparagraph a above, or in any subsequent disclosure of SFIs (e.g. any FCOI identified on Research that was transferred from another institution), and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).
- c. **New SFI.** Each Investigator who is participating in Research must submit an updated disclosure within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new SFI.
- d. For each Research proposal the PI is responsible for designating in writing any other Investigators that are required to comply with this Policy and in making sure the list of Investigators is kept current.
- e. The BMC Research Operations Department shall notify the BU COI Unit of all newly submitted Research proposals.

**B. Process for Reviewing Investigator Significant Financial Interests**

- 1. **Initial Review and Action.** Before the Hospital disburses any funds for a Research project, the Designated Official has delegated to the BU COI Unit, under the direction of the BU Associate Vice President for Research Compliance (BU AVPRC), the obligation to perform the following on behalf of BMC, directly or acting through the Review Committees as described in paragraph 2. below, and in accordance with this Section B:
  - a. Solicit and review Investigator Significant Financial Interest (“SFI”) disclosures and any other information deemed relevant (e.g. research proposal summary, IRB application, etc.). In connection with this review, the BU AVPRC may require the Investigator to provide additional information;
  - b. Using Institutional guidelines, determine (1) whether an Investigator’s SFI is related to Research, and if so, (2) whether the SFI is a Financial Conflict of Interest (“FCOI”). An Investigator's SFI is related to Research when the SFI could be reasonably affected by the Research or is in an entity whose financial interests could be reasonably affected by the Research;
  - c. Notify the BMC Research Compliance Officer and BMC Research Operations when an FCOI has been identified;
  - d. Take such actions as necessary to manage the FCOI, including development and implementation of a management plan; and assuring that all FCOIs are reviewed and managed prior to approval of the Research by the Institutional Review Board.

2. **Boston Medical Center/ Boston University Medical Campus Review Committee on Research Conflicts of Interest (“Review Committee”)**. The Review Committee shall have no fewer than seven voting members from BU and the Hospital with relevant research experience. Members of the Review Committee will be appointed by the BU AVPRC in consultation with the Boston Medical Center Compliance Office and will serve four year renewable terms. The Boston Medical Center Research Compliance Officer, Director of the Boston University Office of Technology Development and designated counsel from the Office of the General Counsel of BU or the Hospital may attend meetings as consultants and advisers as-needed but shall not be members of the Review Committee and are not entitled to vote. Only faculty members on the Review Committee hold the right to vote. The presence of a majority of the voting members of the committee shall constitute a quorum.

The Review Committee will consider the facts of each disclosure to determine (1) whether the Investigator’s Significant Financial Interest is related to the Research and, if so, (2) whether the SFI is a Financial Conflict of Interest, and in doing so may consider any initial review that was conducted by the BU COI Unit. The Review Committee may require Investigators to provide additional information.

The Review Committee will prepare a report for the BU AVPRC detailing a recommended management plan, including any proposed conditions or restrictions to manage the FCOI.

3. **Decision by BU AVPRC**. If the Review Committee determines that a FCOI exists, it will submit a report of its determination and recommended management plan to the BU AVPRC who will share the report with the BMC Research Compliance Officer. After consultation with the BMC Compliance Office, the AVPRC may return the report to the Review Committee for clarification or supplementation, and will accept, reject or modify the Review Committee determination and recommendation. The BU AVPRC in consultation with the BMC Research Compliance Officer will make a final determination in writing and specify the conditions or restrictions, if any, that should be imposed to manage the FCOI.

The BU AVPRC or other representative of the BU COI Unit will provide copies of the final decision to the Investigator, Chair of the Investigator’s department, the responsible Institutional Review Board (if human subjects’ research is involved), the BMC Compliance Office, and the BMC Research Operations.

On occasion, normally with respect to existing management plans, the BU AVPRC may provide for administrative handling, consisting of a letter issued by the BU AVPRC providing appropriate guidance and, if warranted, stating that no additional safeguards or conditions are needed.

Upon receipt of the decision, the Investigator must either acknowledge it or submit an appeal. Funding will be held until the Investigator agrees to comply with the management plan.

4. **Investigator Appeals.** The Investigator has 10 days from receipt of the BU AVPRC's final decision to submit an appeal in writing to the BMC Compliance Office who will address the appeal with the Hospital President. The appeal should include the specific provisions being challenged, the reason for the appeal, and the justification for a different outcome. The Investigator may also provide an alternative management plan and any supplemental information that might be helpful to the Hospital President in making a final determination. This decision of the Hospital President shall be final and not further appealable.
5. **Institutional Remedies.**
  - a. Investigators are required to comply with the final decision of the BU AVPRC or the Hospital President. If an Investigator fails to comply, the BU AVPRC in consultation with the BMC Compliance Office, with the aid of the appropriate Review Committee, will develop a corrective action plan for final review and approval by the Hospital President. BMC may impose sanctions for non-compliance including suspension, denial of eligibility to engage in Research, or other appropriate penalties. Such sanctions may require giving notice to professional bodies or journals, or the public.
  - b. If an Investigator fails to comply with this policy or a management plan in a way that could have biased the design, conduct, or reporting of Research, BU COI Unit, on behalf of BMC, shall promptly notify the PHS Awarding Component, or other sponsor as required, of the corrective action taken or to be taken (e.g., a mitigation report for PHS-Funded Research, as further described below), and implement corrective action.

**C. Management of Financial Conflict of Interests**

1. **Management Plans.** Each management plan shall specify the actions that have been, and shall be, taken to manage the FCOI.
2. **Conditions or Restrictions.** Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:
  - a. Public disclosure of the FCOI (e.g., when presenting or publishing the Research);
  - b. For research projects involving human subjects research, disclosure of the FCOI directly to the human subjects as approved by the Institutional Review Board;
  - c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the FCOI;
  - d. Modification of the research plan;
  - e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;

- f. Reduction or elimination of a financial interest (e.g., sale of an equity interest); and
  - g. Severance of relationships that create FCOIs.
3. **Clinical Research.** The existence of a FCOI related to a clinical research project creates a rebuttable presumption that stringent management of the FCOI is appropriate. In any case in which the United States 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 and was not managed or reported by the Institution as required, HHS may require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and in an addendum to previously published presentations.
  4. **Monitoring Compliance with the Management Plan.** The BU COI Unit will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the Research.

**D. New SFIs During Ongoing Research.**

Whenever, in the course of ongoing Research, an Investigator who is new to participating in the Research discloses an SFI or an existing Investigator discloses a new SFI, the BU COI Unit, in consultation with the BMC Compliance Office will do the following, acting directly or in conjunction with the Review Committee within sixty (60) days:

1. Review the SFI;
2. Determine whether it is related to Research;
3. Determine whether a FCOI exists or could be perceived to exist; and, if so:
4. Implement a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI.

**E. Review of Existing SFIs and Retrospective Review during Ongoing Research.**

The BU AVPRC, acting directly or in conjunction with the Review Committee, will, on behalf of BMC, take the following actions with respect to a FCOI in ongoing PHS-Funded Research:

1. **Review of Existing SFIs.** Whenever BMC identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed during ongoing PHS-Funded Research, the BU AVPRC in consultation with the BMC Compliance Department, will, within sixty (60) days, undertake the same review, determinations and management plan implementation set forth in Section D, above.

2. **Retrospective Review.** Whenever an FCOI with respect to ongoing PHS-Funded Research is not identified or managed in a timely manner, or the Investigator has failed to comply with a management plan, the BU AVPRC in consultation with the BMC Compliance Office, will, within 120 days, complete a retrospective review of the Investigator's activities and the PHS-Funded Research to determine whether any Research was biased in design, conduct, or reporting.

The BU COI Unit, on behalf of BMC, will document the retrospective review in accordance with federal requirements set forth in 42 CFR §50.605(a)(3)(ii)(B)(1)-(9), for PHS-Funded research grants or cooperative agreements, or 45 CFR §94.5(a)(3)(ii)(B)(1)-(9), for PHS-Funded research contracts, and if appropriate, will update the previously submitted FCOI report, describing the new management plan.

3. **Notification and Mitigation Report.** If the BU AVPRC finds bias, or actual harm, to the design, conduct, or reporting of PHS-Funded Research as a result of the newly discovered FCOI, the BU COI Unit, on behalf of BMC, will notify the PHS Awarding Component promptly and submit a mitigation report, as required by and including all key elements specified in 42 CFR, Part §50.605(a)(3)(iii) and 45 CFR §94.5a(3)(iii), described further in section H(3), below.

At any time, the BU AVPRC may determine in consultation with the BMC Compliance Office that interim measures are necessary with regard to the Investigator's participation in the Research.

#### **F. Training.**

Every PHS-Funded Investigator will complete training on Investigator policy responsibilities at the following times:

1. Prior to engaging in PHS- Funded Research and at least once every four years thereafter;
2. Immediately after a revision of this policy in any manner that affects the requirements of PHS-Funded Investigators;
3. When an Investigator is new to BMC, even if the PHS-Funded Research has already begun;
4. When a PHS-Funded Investigator is not in compliance with this policy or a management plan, as determined by the BU AVPRC; and
5. Any other time as reasonably determined by the Designated Official.

**G. Subrecipients.**

If BMC carries out PHS-Funded Research through a subrecipient (e.g. subcontractors or consortium members), BMC will take reasonable steps to ensure that subrecipient Investigators comply with the PHS Regulation by:

1. Incorporating as part of BMC's written agreement with the subrecipient terms that establish whether BMC's FCOI policy or that of the subrecipient will apply to the subrecipient's Investigators. The written agreement will state either that:
  - a. If the subrecipient's policy applies, the subrecipient shall certify as part of the above agreement that its policy complies with the PHS Regulation, and that the subrecipient's Investigators will comply with the subrecipient's FCOI policy or,
  - b. If the subrecipient cannot provide such certification, the agreement shall state that that subrecipient Investigators are subject to this policy for disclosing SFIs that are directly related to the subrecipient's work for BMC, as the awardee institution.
2. If the subrecipient's policy applies, the written agreement will specify the time period(s) for the subrecipient to report all identified FCOIs to the Hospital. The time period(s) will be sufficient to enable the Hospital to meet its reporting obligations to the PHS Awarding Component as required by the PHS Regulation.
3. If Hospital's policy, as awardee, applies, the agreement shall specify time period(s) for the subrecipient to submit all subrecipient Investigators disclosures of all SFIs to BMC, through the BU COI Unit, to enable BMC, as the awardee institution, to comply timely with its review, management, and reporting obligations to the PHS Awarding Component under the PHS Regulation.

**H. Reporting of Financial Conflict of Interest for Public Health Service or National Science Foundation-Funded Research**

Prior to BMC's expenditure of any Research funds, the BU COI Unit, on behalf of BMC, shall provide to the to the PHS Awarding Component, National Science Foundation, or other funding agency, as required, an FCOI report regarding any Investigator's FCOI (unless eliminated) and ensure that a management plan has been implemented. The report ("FCOI Report") to PHS will contain all the information required under federal regulations at 42 CFR §50.605(b)(3) and 45 CFR §94.5(b)(3), as applicable. Under the NSF's policy, conflicts which cannot be satisfactorily managed, reduced or eliminated must be disclosed to NSF. For newly acquired FCOIs during ongoing PHS-Funded Research, described in Section D above, the BU COI Unit shall provide to the PHS Awarding Component, within sixty (60) days, an FCOI Report ensuring that the Institution has implemented a management plan.

For FCOIs not previously disclosed, reviewed or managed during ongoing PHS-Funded Research, described in Section E above, the BU COI Unit shall, if the retrospective review results in a finding of bias in the design, conduct or reporting of the Research, promptly submit its mitigation report to the PHS Awarding Component. In accordance with 42 CFR

§50.605(a)(3)(iii) and 45 CFR §94.5a(3)(iii), the mitigation report shall include the key elements documented in the retrospective review, a description of the impact of the bias on the Research and the Institution's plan of action or actions taken to eliminate or mitigate the effects of the bias.

After the submission of any initial FCOI Report with regard to ongoing PHS-Funded Research, BU COI Unit on behalf of BMC shall provide the PHS Awarding Component with annual FCOI Reports that address the status of the FCOI and any changes to the management plan for the duration of the Research (including extensions with or without funds) at the same time as the Institution is required to submit the annual progress report or at the time of project extension.

The BU COI Unit on behalf of BMC shall, upon request of the PHS, make information available to the PHS relating to any Investigator disclosure of financial interests and the institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI. The BU COI Unit shall notify the BMC Research Compliance Officer of any requests made by PHS for information and shall provide the BMC Compliance Office with copies of any information that the BU COI Unit provides to PHS and with copies of any communications it has with PHS pursuant to this Section H.

**I. Maintenance of Records.**

The BU COI Unit will maintain, on behalf of BMC, records relating to Investigator SFI disclosures other than those related to NSF Research, including the review of and response to such disclosures (whether or not resulting in an FCOI finding), and any other action under this policy, for at least three years from the date the final expenditures report is submitted to the PHS or other funding sponsor other than NSF. For Research funded by NSF, the BU COI Unit will maintain records of all financial disclosures and of all actions taken to resolve conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any NSF action involving those records, whichever is longer.

**J. Public Accessibility.**

1. BMC will make this Policy available via a publicly available web site.
2. For PHS-Funded Research, BMC will ensure public accessibility of information concerning the FCOIs currently held by Senior/Key Personnel subject to this Policy. BMC will provide a written response within five (5) business days of receipt by the Designated Official of a complete written request for information regarding any SFI disclosed to BMC that meets the following three criteria:
  - a. The SFI was disclosed and is still held by the senior/key personnel as defined by the PHS Regulation;
  - b. BMC determines through the procedure set forth in this Policy that the SFI is related to the PHS-Funded research; and
  - c. BMC determines through the procedure set forth in this Policy that the SFI is an FCOI.

The information that BMC provides in its written response will be the minimum required by the PHS Regulation. Anyone seeking to make such requests should mail them to the attention of the Research Compliance Officer, Compliance Department, Boston Medical Center, 720 Harrison Avenue, 6<sup>th</sup> Floor, Boston, MA 02118.

In compliance with 42 CFR 50.605(a)(5)(iv), information concerning the SFIs of Senior/Key Personnel shall remain available for responses to written requests for at least three years from the date that the information was most recently updated.

**References:**

1. Promoting Objectivity in Research. 42 CFR Part 50, Subpart F. Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought
2. Responsible Prospective Contractors 42 CFR Part 94.

**Responsibility:**

All Investigators are responsible for compliance with this Policy. The BU COI Unit in consultation with the BMC Compliance Department, is responsible for overseeing the implementation of this Policy. The Review Committees are responsible for supporting implementation and compliance. BMC Research Operations is responsible for assuring that the BU COI Unit is informed of all newly submitted Research proposals.

**Forms: (available online at <http://www.bu.edu/orc/coi/forms>)**

**Financial Interest Disclosure - Form 1**

**Addendum to Financial Interest Disclosure - Form 2**

**Title: Significant Financial Conflicts of Interest in the Conduct of Research**

**Policy number: 09\_23\_000**

**Section: 09 Compliance**

**Other Related Policies:**

**Boston Medical Center**

**#39.02.456- Policies and Procedures Concerning Allegations of Misconduct in Scholarship and Research**

**#39.02.196 -Human Subjects Research**

**Initiated by: BMC Compliance Department**

**Contributing Departments:**

**Office of General Counsel**

**BMC Research Operations**

**Boston University Office of Research Compliance**