Boston University
Policy on Investigator’s Conflicts of Interest

Policy on Investigator’s Conflicts of Interest (October 31, 2003)
Addendum to Policy on Investigator’s Conflicts of Interest (For PHS-Funded Research) (August 24, 2012)

Boston University seeks to ensure the integrity of academic research conducted by its faculty members and students and to sustain public confidence in that research. 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 (for citation to these federal regulations see footnote*). The University adopted procedures which complied with these federal regulations with respect to federally funded research.

Thereafter, financial conflicts of interest on the part of investigators conducting human subject research came under close scrutiny by the public and by the U.S. Office for Human Research Protection. Draft guidance published on January 10, 2001 by that Office, and republished in revised form on March 31, 2003 by the Office of Public Health and Science of the U.S. Department of Health and Human Services, warns that such conflicts of interest in human subject research may not only introduce biases that compromise the results of the research but also put the safety and informed consent of the human subjects at risk. In recent years, faculty 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, the University 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. In light of the University’s experience to date, and a review of policy guidance from governmental and private sources, the University now issues a revised Policy on Investigator Conflicts of Interest which applies on the Medical Campus to all research and on the Charles River Campus to all externally-funded research and all human subject research (regardless of funding) (“covered research”). This policy is effective October 31, 2003 and replaces the prior policy and President’s Westling’s letter amending the prior policy.

Conflict of Interest Policy

A. Individuals Affected

All persons (“investigators”) responsible for designing, conducting or reporting covered research in the course of Boston University 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.

B. Conflicts 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,” see footnote **) that could directly and significantly affect the design, conduct or reporting of covered research.

C. 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. 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.
D. **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 (for definition of “entity,” see footnote ***) 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 University work where the University has assigned the patent to the investigator.

E. **Time of Disclosure and Supplemental Disclosure**

1. Whenever a principal investigator files a new, continuation or renewal application or other non-federal proposal for covered research, all investigators on the research must make disclosure These disclosures must be supplemented whenever there is a material change in the information previously disclosed.

2. Whenever the principal investigator files an application with the Institutional Review Board for initial review, all investigators on the research must make disclosure. These disclosures must be supplemented whenever there is a material change in the information previously disclosed. If both (1) and (2) apply to the research, disclosure need be made only under (1).

3. On the Medical Campus, on or before December 31, 2003 (or, thereafter, December 31 of an investigator’s first year at the University), 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 under (1) and (2) above and filings of supplemental disclosures in the event of material change in information previously submitted.

F. **Supplements**

Disclosure Forms will be made available by the offices to which disclosure is due to be submitted. 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.

G. **Review of Disclosure Forms Disclosures Forwarded to the Associate Vice President for Research Compliance**

The Office of Sponsored Programs or the Office of Research Administration will forward all disclosure forms that report significant financial interests to the Associate Vice President for Research Compliance (“AVPRC”), in association with the appropriate Provost, with a copy to the dean of the investigator’s school or college. If the proposed research receives an award of external funding from the National Institutes of Health or from the National Science Foundation, the Office of Sponsored Programs or the Office of Research Administration will inform the AVPRC and the Dean so that, prior to the University’s expenditure of any award funds from those federal agencies, the AVPRC may complete a review of the relevant disclosure form(s).
H. Conflict of Interest Advisory Committees

The Associate Vice President for Research Compliance ("AVPRC"), in association with the Provost of the University and the Provost of the Medical Campus will appoint a Conflict of Interest Advisory Committee, for the Charles River Campus and the Medical Campus, respectively. The Committee for the Medical Campus may be appointed jointly with the President of Boston Medical Center Corporation. Each 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. Each Committee will be provided with administrative support as needed from the AVPRC. Each Committee shall maintain records of its activities, including copies of all documents received and sent.

I. Committee Proceedings

1. 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 University and other sources.

2. 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.

3. 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:

a. Public disclosure of a significant financial interest;
b. Monitoring of the research or other activity (such as teaching or administration related to the affected research) by independent reviewers;
c. Modification of the research plan or other activity (such as teaching or administration related to the affected research);
d. Disqualification from participation in all or a portion of the research or other activity (such as teaching or administration related to the affected research);
e. Divestiture of significant financial interests; or
f. 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.
4. **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.

5. **Committee Report to the Associate Vice President for Research Compliance**

The Committee will prepare a report to the AVPRC, in association with the appropriate Provost, 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 AVPRC within thirty (30) days after the Committee’s receipt of the Disclosure Form. The AVPRC may return the report to the Committee for clarification or supplementation. The AVPRC will share the report with the investigator and his dean and provide ten (10) business days for any written response. The AVPRC 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 AVPRC.

J. **Decision of the Associate Vice President for Research Compliance**

The Associate Vice President for Research Compliance (“AVPRC”), in association with appropriate Provost, will review the report and its recommendations, including any written response submitted by the investigator or his dean. If deemed necessary or appropriate, the AVPRC may seek additional information or advice from, or request further review by, the Committee or other sources. The AVPRC will accept, reject, or modify the determinations and recommendations of the Committee and issue a decision. The AVPRC’s decision will state whether a conflict of interest exists. If the AVPRC 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 AVPRC will provide copies of the decision to the Committee, the investigator, the investigator’s dean, the responsible Institutional Review Board (if human subject research is involved), and the Office of Sponsored Programs or the Office of Research Administration, as appropriate. No NSF or PHS grant funds are to be expended prior to the AVPRC’s decision and implementation of any conditions or restrictions. The Office of Sponsored Programs or the Office of Research Administration, as appropriate, will send a copy of the decision to the NSF or PHS, if such grant funds are involved.

K. **Implementation and Enforcement Institutional Review Board**

The responsible appropriate 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.

L. **Committee Implementation and Enforcement of Conditions or Restrictions**

1. **Implementation:** If conditions, restrictions or monitoring are imposed by the Associate Vice President for Research Compliance (“AVPRC”), in association with appropriate Provost, the Committee will oversee their implementation in accordance with the terms of the AVPRC’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:

   a. requiring the investigator, chairman or dean to submit evidence of compliance with restrictions;
b. requiring the investigator, chairman or dean to submit periodic written reports containing information in accordance with specifications of the Committee and/or AVPRC; and

c. requiring the investigator, chairman or dean to work with any oversight panel that may be established by the AVPRC (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 AVPRC.

2. **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.

3. **Referral to the AVPRC:** In the absence of expeditious correction, the Committee shall report the non-compliance to the AVPRC, and the Committee may recommend that a sanction be imposed pursuant to this policy.

M. **Sanctions**

Sanctions may be imposed by the Associate Vice President for Research Compliance (“AVPRC”), in association with appropriate Provost, 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 University in enforcing this policy; or
4. Failure to comply with conditions or restrictions imposed by the AVPRC.

Sanctions may include suspension or dismissal, non-renewal of appointment, denial of eligibility to engage in research funded through the University, 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 AVPRC will determine what sanctions, if any, are to be applied. The AVPRC may refer the matter to the appropriate dean, take action on his own, or initiate University procedures governing such discipline.

N. **Records**

The Office of Sponsored Programs or the Office of Research Administration, as appropriate, 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 the University in such an instance. These records will be kept for such time periods as are required by the University or the sponsoring agency. The AVPRC and Conflict of Interest Advisory Committees will maintain records relating to their activities for such time periods as may be required by the University.

O. **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.
P. Additional Procedures

The Associate Vice President for Research Compliance, in association with appropriate Provost, 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.

Q. Relationship to Other University Policies

Matters may arise under this policy which involve other University procedures, including those governing research misconduct, animal care, human subject research, and patents. The Associate Vice President for Research Compliance in association with appropriate Provost, may refer such matters to the appropriate University body.


** “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 University;
b. income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities (for definition of “entity,” see footnote ***)
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.

*** “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.
Boston University
Addendum to
Policy on Investigator’s Conflicts of Interest

August 24, 2012

I. Purpose

This Addendum applies to all research funded or proposed for funding by the Public Health Service of the U.S. Department of Health and Human Services ("PHS"), including the National Institutes of Health ("NIH"). The purpose of this Addendum is to implement the requirements of the federal regulations set forth in 42 CFR Part 50 and 45 CFR Part 94, and any additional regulations that may be in effect from time to time, governing investigators’ responsibilities for promoting objectivity in PHS-Funded Research. This Addendum shall be construed in accordance with such regulations and shall be deemed to include any requirements set forth in such regulations that are not expressly set forth below.

II. Covered Parties

This Addendum applies to all persons responsible for designing, conducting or reporting PHS-Funded Research under the auspices of Boston University.

III. Defined Terms

A. “Financial Conflict of Interest” ("FCOI") means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS-Funded Research.

B. “Designated Official” means an institutional official designated to solicit and review disclosures of Significant Financial Interests from Investigators. The Designated Official shall be the Boston University ("BU") and Boston Medical Center ("BMC") Associate Vice President for Research Compliance ("AVPRC") and/or such other individual(s) as the Institution may designate in writing. All references herein to the AVPRC shall be deemed to refer to such other Designated Official(s) as appropriate.

C. “Institutional Responsibilities” means an Investigator’s professional responsibilities on behalf of BU or BMC including but not limited to research, research consultation, teaching, professional practice, and administration such as service on committees, boards and panels.

D. “Investigator” means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-Funded Research. This may include, for example, graduate students, post-doctoral fellows, technicians, collaborators or consultants if they have such responsibilities.

E. “Manage” means taking action to address a Financial Conflict of Interest, which can include reducing or eliminating the Financial Conflict of Interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

F. “PHS-Funded Research” means Research funded by or proposed to be funded by the PHS, including without limitation NIH awards. The term includes 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. For purposes of
this Addendum, the term shall not include Phase 1 Small Business Innovative Research ("SBIR") or Small Business Technology Transfer ("STTR") applications or awards.

G. "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. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

H. "Senior/key personnel" means the project director or principal investigator 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 PHS for PHS-Funded Research.

I. “Significant Financial Interest” ("SFI") means:
   1. A financial interest consisting of one or more of the following interests of an Investigator, or 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 from the entity in the 12 months preceding the disclosure of the SFI and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5000. 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 nonpublicly traded entity, a significant financial interest exists if the value of any remuneration, as described above, received from the entity in the 12 months preceding the disclosure of the SFI, when aggregated, exceeds $5000 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).
      c. Intellectual property rights and interests (e.g. patents, copyrights) upon receipt of royalties or other income related to such rights and interests that exceed $5000.
      d. Reimbursed or sponsored travel (sponsored travel being 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.

   2. Exceptions: “Significant Financial Interest” does not include:
      a. Salary, royalties, or other remuneration paid by BU or BMC to the Investigator, if the Investigator is currently employed or otherwise currently holding an appointment at such institution;
      b. Intellectual property rights assigned to BU or BMC and agreements to share in royalties related to such rights (e.g., an Investigator’s royalties received under the relevant Patent Policy.)
      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; and
      d. Income from seminars, lectures, teaching engagements, service on advisory committees or review panels, or travel expenses that are 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, a research institute that is affiliated with an institution of higher education.

IV. Policy

   A. Investigator Responsibilities
This Addendum requires Investigators to (i) disclose Significant Financial Interests (including financial interests of the Investigator’s spouse and dependent children), (ii) comply with the Review Process, and (iii) complete training with respect to PHS-Funded Research. (Training is dealt with in section F below.)

1. Disclosure. Every Investigator must disclose all of his or her Significant Financial Interests (“SFIs”), and those of the Investigator’s spouse and dependent children, that reasonably appear to be related to the Investigator’s Institutional Responsibilities. The Investigator is not charged with making a determination as to whether the SFI constitutes a conflict of interest or could affect the design, conduct or reporting of the PHS-Funded Research. That determination is made by a Designated Official as is further described below. Investigator disclosures are required as follows:

   a. Upon Application. Each Investigator who is planning to participate in PHS-Funded Research must disclose SFIs to the Conflicts of Interest Unit of the Boston University Office of Research Compliance no later than the time of application or submission of a formal proposal for the PHS-Funded Research. With respect to SFIs of reimbursed or sponsored travel, disclosures will include, at minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

   b. Annually. Each Investigator who is participating in PHS-Funded 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 the Institution pursuant to paragraph “a” above, or in any subsequent disclosure of SFIs, 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 PHS-Funded Research must submit a disclosure within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new SFI.

B. Process for Reviewing Investigator Significant Financial Interests

1. Initial Review and Action. Before BU disburses any funds for a PHS-Funded Research project, the Designated Official will do the following directly or acting through the Office of Research Compliance or the duly appointed faculty Review Committees (the latter described in more detail in B(3), below):

   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 Designated Official may require the Investigator to provide additional information;

   b. Using Institutional guidelines, determine (1) whether an Investigator’s SFI is related to PHS-Funded Research, and if it is, (2) whether the SFI is a Financial Conflict of Interest (“FCOI”); and

   c. Take such actions as necessary to Manage the FCOI, including development and implementation of a management plan.

2. Financial Conflict of Interest. An Investigator's SFI is related to PHS-Funded Research when the Institution, through its Designated Official, reasonably determines that the SFI could be affected by the PHS-Funded Research or is in an entity whose financial interests could be affected by the PHS-Funded Research. A Financial Conflict of Interest exists when the Institution, through its Designated Official, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-Funded Research.

3. Review Committees on Research Conflicts of Interest (“Review Committees”). The Review Committees will be composed of a Charles River Campus Committee and a Boston University Medical Center Committee, each having no fewer than seven voting members from the faculty with relevant research experience. Members of the Review
Committees will be appointed by the Associate Vice President for Research Compliance and serve four year renewable terms. The Director of the Office of Technology Development (OTD) and designated counsel from the Office of the General Counsel of BU or BMC will be involved on an as-needed basis but will not be members of the Review Committee. Only faculty members on the Review Committee hold the right to vote. A majority of the committee members must be present to constitute a quorum. The Committees are empowered to act by majority vote of the members present at a meeting at which a quorum is present, or by written or electronic consent of a majority of all members.

The appropriate Review Committee will review the facts and on a case-by-case basis determine (1) whether the Investigator’s Significant Financial Interest is related to PHS-Funded Research and, if it is, (2) whether the SFI is a Financial Conflict of Interest, confirming the initial review conducted by the Office of Research Administration Conflict of Interest Unit. Investigators may be required to provide additional information.

The Review Committee will prepare a report for the Associate Vice President for Research Compliance detailing a recommended management plan, including any proposed conditions or restrictions to Manage the FCOI.

4. Decision by Associate Vice President for Research Compliance (“AVPRC”). If the Review Committee determines that a Financial Conflict of Interest exists, it will submit a report of its determination and recommended management plan to the Associate Vice President for Research Compliance. The AVPRC may return the report to the Review Committee for clarification or supplementation, and will accept, reject or modify the Review Committee’s determination and recommendation. The AVPRC will make a final determination in writing and specify the conditions or restrictions, if any, that should be imposed to Manage the Financial Conflict of Interest.

The AVPRC or the Office of Research Compliance Conflict of Interest Unit will provide copies of the final decision to the Investigator, the Dean at the Investigator’s school or college, Chair of the Investigator’s department, the responsible Institutional Review Board (if human subjects research is involved), and the BU Office of Sponsored Programs.

On occasion, normally with respect to existing management plans, the AVPRC may provide for administrative handling, consisting of a letter issued by the Office of Research Compliance 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.

5. Investigator Appeals. The Investigator has 10 days from receipt of the AVPRC’s final decision to submit an appeal in writing to the University Provost or the Provost of the Medical Campus, as applicable. 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 University Provost or the Provost of the Medical Campus in making a final determination. This decision shall be final and not further appealable.

6. Submission of the Research Application. The Institution will certify in the application to the Institution’s effective, implemented policy and full compliance with the federal regulations at 42 CFR Part 50 and 45 CFR Part 94, as specifically enumerated in 42 CFR §50.604(k)(1)-(5) and 45 CFR §94.4(k) (1)-(5).

7. Institutional Remedies.

a. Investigators are required to comply with the final decision of the Associate Vice President for Research Compliance (“AVPRC”) or University Provost or the Provost of the Medical Campus. If an Investigator fails to comply, the AVPRC, with the aid of the appropriate Review Committee, will develop a corrective action plan for final review and approval by the University Provost or the Provost of the Medical Campus.
b. The Institution 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.

c. If an Investigator fails to comply with this Addendum or a management plan in a way that could have biased the design, conduct, or reporting of PHS-Funded Research, the Institution shall promptly notify the PHS awarding component of the corrective action taken or to be taken (e.g., a mitigation report for the 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 Financial Conflict of Interest (“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 PHS-Funded 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 PHS-Funded 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 PHS-Funded Research;

   f. Reduction or elimination of a financial interest (e.g., sale of an equity interest); and

   g. Severance of relationships that create the Financial Conflict of Interest.

3. Clinical Research. The existence of a Financial Conflict of Interest (“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 U.S. Department of Health and Human Services (“HHS”) determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required, the Institution shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

4. Monitoring Compliance with the Management Plan. The Office of Research Compliance will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-Funded Research.

D. New SFIs during ongoing PHS-Funded Research.
Whenever, in the course of ongoing PHS-Funded Research, an Investigator who is new to participating in the PHS-Funded Research discloses an SFI or an existing Investigator discloses a new SFI, the Designated Official will do the following, acting directly or in conjunction with the Review Committee, within sixty (60) days:

1. review the Significant Financial Interest;
2. determine whether it is related to PHS-Funded Research;
3. determine whether a Financial Conflict of Interest exists, and, if so;
4. implement a management plan that shall specify the actions that have been, and will be, taken to Manage such Financial Conflict of Interest.

E. Review of Existing SFIs and Retrospective Review during ongoing PHS-Funded Research.

The Designated Official, acting directly or in conjunction with the Review Committee, will take the following actions with respect to a Financial Conflict of Interest in ongoing PHS-Funded Research:

1. **Review of Existing SFIs.** Whenever BU identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed during ongoing PHS-Funded Research (e.g. was not timely reviewed or reported by a subrecipient), the Designated Official will, within sixty (60) days, undertake the same review, determinations and management plan implementation set forth in Section IV. D, above.

2. **Retrospective Review.** Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI that is determined by the Institution to constitute an FCOI, failure by the Institution to review or manage such an FCOI, or failure by the Investigator to comply with an FCOI management plan, the Designated Official will, within 120 days of the Institution’s determination of noncompliance, complete a retrospective review of the Investigator’s activities and the PHS-Funded Research to determine whether any PHS-Funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in design, conduct, or reporting of such Research.

The Office of Research Compliance will document the retrospective review in accordance with federal requirements set in 42 CFR, Part 50, Subpart F, §50.605(a)(3)(ii)(B)(1)-(9), for PHS-funded research grants or cooperative agreements, or 45 CFR Part 94, §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 Designated Official finds bias in the design, conduct, or reporting of PHS-Funded Research, the Office of Research Compliance 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, Subpart F, § 50.605(a)(3)(iii) and 45 CFR, Part 94, § 94.5(a)(3)(iii), described further in section H(3), below.

4. **Interim Measures.** At any time, the Designated Official may determine that interim measures are necessary with regard to the Investigator’s participation in the PHS-Funded Research.

F. Training. Every 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. When this Addendum is revised in any manner that affects the requirements of Investigators;
3. When an Investigator is new to BU, even if the PHS-Funded Research has already begun;
4. When an Investigator is not in compliance with this Addendum or a management plan, as determined by the Designated Official.

G. Subrecipients

If BU is the awardee and conducts PHS-Funded Research through a subrecipient (e.g. subcontractors or consortium members), the Designated Official will take reasonable steps to ensure that subrecipient Investigators comply with this Addendum, as follows:

1. BU’s written agreement with the subrecipient will establish whether this Addendum or the subrecipient’s Financial Conflicts of Interest policy will apply to the subrecipient’s Investigators. The written agreement will state either that:

   a. The subrecipient certifies that its Financial Conflicts of Interest policy complies with the applicable federal regulations, and that the subrecipient’s Investigators will comply with the subrecipient’s policy or,

   b. if the subrecipient cannot provide such certification, that subrecipient Investigators are subject to this Addendum.

2. If the subrecipient’s policy applies, the written agreement will specify the time period(s) for the subrecipient to report all identified FCOIs initially and annually thereafter to BU. The time period(s) will be sufficient to enable BU to provide FCOI reports to the PHS prior to the expenditure of funds and within 60 days of finding any additional FCOI.

3. If BU’s policy, as awardee, applies, the subrecipient Investigators will disclose all Significant Financial Interests that are directly related to the subrecipient’s work for BU. The written agreement with the subrecipient will specify the time period in which to comply, sufficiently allowing BU enough time to comply timely with its review, management and reporting obligations, e.g., to provide FCOI reports to the PHS prior to the expenditure of funds, within 60 days of finding any additional FCOI and annually thereafter.

H. Reporting of Financial Conflict of Interest

1. Prior to the Institution’s expenditure of any funds under PHS-Funded Research, the Designated Official shall provide to the PHS, 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, Part 50, Subpart F, § 50.605(b)(3) and 45 CFR, Part 94, § 94.5(b)(3), as applicable.

2. For newly acquired FCOIs during ongoing PHS-Funded Research, described in Section IV.D above, the Designated Official shall provide to the PHS awarding component, within sixty (60) days, an FCOI Report ensuring that the Institution has implemented a management plan.

3. For FCOIs not previously disclosed, reviewed or managed during ongoing PHS-Funded Research, described in Section IV.E above, the Designated Official shall, if the retrospective review results in a finding of bias in the design, conduct or reporting of the PHS-Funded Research, promptly submit its mitigation report to the PHS awarding component. In accordance with 42 CFR, Part 50, Subpart F, § 50.605(a)(3)(iii) and 45 CFR, Part 94, § 94.5a)(3)(iii), the mitigation report shall include the key elements documented in the retrospective review and a description of the impact of the bias on the PHS-Funded Research and the Institution’s plan of action or actions taken to eliminate or mitigate the effects of the bias.

4. After the submission of any initial FCOI Report with regard to ongoing PHS-Funded Research, the Designated Official shall provide the PHS awarding component with annual FCOI Reports that address the status of the Financial
Conflict of Interest and any changes to the management plan for the duration of the PHS-Funded Research (including extensions with or without funds) in the time and manner specified by the PHS awarding component.

5. The Office of Research Compliance Conflict of Interest Unit on behalf of BU 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 a financial conflict of interest.

I. Maintenance of Records.

The Office of Research Compliance Conflicts of Interest Unit will maintain records relating to all Investigator SFI disclosures, including the review of and response to such disclosures (whether or not resulting in an FCOI finding), and any other action under this Addendum, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b), relating to records retention.

J. Public Accessibility.

1. This Addendum and all related forms shall be made publicly available on Boston University’s website (currently at http://www.bu.edu/orc/coi).

2. Upon written request to Boston University’s Office of Research Compliance Conflict of Interest Unit, information will be provided including, at a minimum, that specified in 42 CFR, Part 50, Subpart F, §50.605(a)(5)(ii) and 45 CFR, Part 94, § 94.5(a)(5)(ii), concerning a specific SFI disclosed to BU or BMC and meeting the following criteria:

   a. The SFI was disclosed and is still held by the Senior/Key Personnel;

   b. The Institution has determined that the SFI is related to the PHS-Funded Research; and

   c. The Institution has determined that the SFI is an FCOI.

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.

When the PHS-Funded Research is conducted by a subrecipient Investigator, and under their written agreement the subrecipient is required to comply with the subrecipient’s FCOI policy, the subrecipient will have the responsibility of making such information publicly accessible.

Responses will be returned within five (5) business days from when the BU Office of Research Compliance Conflict of Interest Unit receives the request.

V. Responsible Parties

The Boston University Office of Research Compliance Conflict of Interest Unit is responsible for overseeing implementation of and ensuring compliance with this Addendum. The Review Committees are responsible for supporting implementation and compliance. More information about the Office of Research Compliance, including contact information, can be found online at http://www.bu.edu/orc/coi/.

VI. Related Policies and References

A. Related Boston University Policies
1. Boston Medical Center Responsibility of Investigators for Promoting Objectivity in Research (2012)
2. Boston University Institutional Conflicts of Interest in Research Policy
3. Policy for Interactions with Industry by Faculty/Clinicians at the Boston University School of Medicine (10/20/2010)
4. Boston University Policy on External Compensated Activity
5. Boston University Patent Policy (Boston University Medical Center)
6. Boston University Patent Policy (Charles River Campus)
7. Boston University Conflict of Interest Policy – This policy has a similar title but is outside the jurisdiction of the BU Office of Research Compliance and is separate from the Investigator’s Conflicts of Interest Policy, which is centered on Financial Conflicts of Interest in Research.

B. References
   1. Promoting Objectivity in Research. 42 CFR, Part 50, Subpart F.
   2. Responsible Prospective Contractors. 45 CFR, Part 94.

VII. Policy History. This Addendum is effective starting August 24, 2012 and supersedes the prior Policies below with respect to PHS-Funded Research:
   1. Boston University Policy on Investigators’ Conflicts of Interest, June 1997