INSTITUTIONAL CONFLICT OF INTEREST IN RESEARCH POLICY

I. Purpose

Boston University

Boston University is a major research institution. Our faculty, staff and students engage in an objective and unbiased process of creating new knowledge through research that then benefits society through the transfer of University-developed knowledge to the public and private sectors. Increasingly, the research process leads to discoveries with financial value from which the University or its employees could potentially benefit. However, these financial interests should not compromise, or be perceived to compromise, the institution’s standards or integrity, or unduly influence, or be perceived to unduly influence, decisions in any research activity at Boston University.

The purpose of this policy is to safeguard the objectivity, integrity and credibility of research conducted by Boston University’s faculty, staff, and students by ensuring that the financial interests of the University or key employees of the University have no effect on the design, conduct or oversight of research. This policy defines the potential financial conflicts on the part of the University and key individuals, and how to identify, eliminate or manage those conflicts. ¹

II. Applicability

This policy applies to Boston University as an institution and to the financial interests held in the name of the University and over which the University has direct control.

It also applies to the financial interests of key individuals who, because of their positions, have influence over what research is or is not conducted and whose responsibilities include review or oversight of research. These individuals include the University president; provosts (including associate and assistant provosts); vice presidents (including assistant and associate vice presidents; deans (including associate and vice deans); department chairpersons; division chiefs; center and institute directors; chairpersons of the Institutional Review Board, Institutional Biosafety Committee, Institutional Animal Care and Use Committee, Stem Cell Research Committee, and Patent Committees; and technology transfer officers.

This policy also applies to institutional conflicts of interest that are already in existence at the time this policy takes effect.

¹ Financial conflicts of interest on the part of the researchers themselves are dealt with in a separate policy.
III. Definitions

“Intellectual Property” means all legally protected intellectual property, including patent rights (under applications or issued patents, whether filed by the institution or another), copyrights and trademarks (whether owned by the institution or another).

“Reporting” means informing the appropriate internal institutional officials of the existence of a financial or fiduciary interest.

“Disclosing” means informing persons or external entities about the existence of conflict of interest.

“For the University, reportable financial interests include the following:
• Equity in a publicly-owned company that proposes to sponsor research at the University when that ownership represents more than or equal to 5% of the value of the company or where the equity has a value of more than or equal to $1 million dollars;
• Any equity in a privately owned company that proposes to sponsor research at the University;
• Any ownership of Intellectual Property in a technology that is proposed to be studied at the University;
• Any current or potential royalty income to the University paid by an entity that proposes to sponsor research at the University;
• Any gift (any amount) within the previous three years from an entity that proposes to sponsor research at the University.

For key individuals, reportable financial interests include any of the following, whether held in name of the key individual or in the name an immediate family member including 1) a spouse; 2) a domestic partner; 3) a child, grandchild, parent, grandparent, sibling, uncle, aunt, nephew, or niece, or the spouse of any such person; 4) a person having a step-relationship described in (3) above; 5) a parent-in-law or a brother- or sister-in-law; or 6) any other person who resides in the same household as the key individual”:
• Any amount of equity in an entity that has sponsored research at the University within the previous 2 years;
• Any financial interest in Intellectual Property that will be studied in research at the University;
• Any compensation within the previous 12 months from an entity that proposes to sponsor research at the University;
• Any previous or current position in an official capacity (including, but not limited to, serving as a Board member, President, Vice President, Chief
Technology or Science Officer, Treasurer, Secretary, director, or manager) at
an entity that proposes to sponsor research at the University.

“Reportable Financial interests” do not include the following financial interests:
• ownership in any publicly traded, diversified mutual fund;
• salary or other non-royalty payments from Boston University); or
• honoraria from government or academic institutions for reviewing grants
  or academic activities such as seminars or grand rounds, provided the
direct source of these honoraria is not a commercially interested entity.

“Research” means a systematic investigation, including research development, testing
and evaluation, designed to develop or contribute to generalizable knowledge, or the
study of Intellectual Property. Activities which meet this definition constitute research for
purposes of this policy, whether or not they are conducted or supported under a program
which is considered research for other purposes. For example, some demonstration and
service programs may include research activities.

IV. Roles and Responsibilities
For the University, and solely for purposes under this policy, the Investment Office is
responsible for confirming ownership of any equity in a public or private company held
in the name of the University; the Office of Technology Development will be responsible
for reporting information on ownership of Intellectual Property, royalty income, or other
financial interest; and the Office of Development will be responsible for providing
information on unrestricted gifts.

Key individuals are responsible for accurately reporting their financial interests as
required by this policy.

The Offices of Sponsored Programs (OSP-CRC and OSP-MED) are responsible for
providing an up-to-date list of research sponsors.

The Office of Research Compliance (ORC) is responsible for identifying potential
conflicting financial interests held by the University or key officials (as outlined in
section III above under “Reportable Financial Interests”). Whenever a new industry-
sponsored research project is proposed, the ORC will review the financial holdings of
the University and its key individuals to identify possible financial conflicts of interest. The
ORC will notify the Office for the Advisory Committees on Research Conflict of Interest
whenever a potential conflict is identified.

The Office for the Advisory Committees on Research Conflict of Interest (which reports
to the Associate Vice President for Research Compliance) is responsible for:
• administratively reviewing actual or potential financial conflicts identified by the
  Office of Research Compliance;
• collecting additional relevant information from the University or key individuals;
• administratively managing conflict situations within the authority delegated to it
  by the Advisory Committees(s) on Research Conflict of Interest;

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- for conflicts beyond that delegated authority, forwarding the potential conflict and related information to the appropriate Advisory Committee(s) on Research Conflict of Interest for review assessment, and disposition;
- forwarding the recommendations from the Advisory Committee(s) on Research Conflict of Interest to the Associate Vice President for Research Compliance;
- communicating the final decision from the Associate Vice President for Research Compliance, as approved by the provosts, to appropriate University officials or to the key individual involved, and to other parties on a need to know basis;
- providing administrative and technical support to the Advisory Committee(s) on Research Conflict of Interest;
- monitoring compliance with approved management or divestiture plans and providing periodic (at least annual) reports on noncompliance to the Advisory Committee(s) on Research Conflict of Interest;
- recommending corrective action with respect to non-compliance with the management plans;
- maintaining minutes and records of the meetings and recommendations of the Advisory Committees on Research Conflict of Interest.

The Associate Vice President for Research Compliance shall assure compliance with this policy and is responsible, subject to oversight by the Provosts of each campus, for:
- providing institutional oversight of compliance with and implementation of this policy and related regulations and laws related to conflicts of interest affecting research, scholarly, and educational activities;
- requesting and reviewing periodic reports from the Advisory Committee(s) on Research Conflict of Interest concerning overall precedents contained in the recommendations of those Committees, results of monitoring management plans, and other aspects of the program;
- issuing implementing procedures under this policy, after consultation with the OSP, ORA, Investment Office, OTD, and the Advisory Committees on Research Conflict of Interest;
- reviewing and, in consultation with the Provosts, approving or requesting reconsideration of the Committees’ recommendations;
- reviewing and acting on reports of non-compliance with approved recommendations of the Committees

The Advisory Committee on Research Conflict of Interest is responsible for:
- investigating both individual researcher conflicts of interest and institutional conflicts of interest; if a research proposal involves both individual and institutional conflicts, the Committee will investigate both simultaneously;
- issuing guidelines for investigators concerning Committee requirements, expectations, and frequently asked questions, subject to approval by the Associate Vice President for Research Compliance;
- deciding what conflicts can be administratively managed by the Office of Advisory Committee for Research Conflict of Interest;
- reviewing reports of financial or fiduciary interests and other related information collected from investigators and others;
• determining whether a conflict of interest or potential conflict of interest exists;
• determining the Committee’s level of concern (e.g. low, medium, or high) with respect to the conflict of interest;
• determining what conditions, if any, should be imposed to manage, reduce or eliminate the conflict of interest;
• forwarding its recommendations to the Associate Vice President for Research Compliance for review;
• making recommendations to the Associate Vice President for Research Compliance regarding instances where the University or key individuals have failed to comply with conflict management decisions;
• providing information and consultation to the Vice President for Research when a management plan is appealed.

The Vice President for Research is responsible for:
• considering appeals of the decisions on managing, reducing, or eliminating institutional conflicts of interest;
• making recommendations to the Provosts (or to the President if the Provosts are involved in the conflict of interest) who will make the final decision on appeals.

V. Formation and Make-up of the Advisory Committee on Research Conflict of Interest

The Provosts will appoint the Advisory Committee(s) on Research Conflict of Interest. The number of Committees will be sufficient to efficiently handle the number of conflicts that appear. The Committees will manage both institutional and individual researcher conflicts of interest.

Each Committee will consist of no fewer than seven voting members from the faculty and staff with relevant research experience as well as at least one representative from the community who is neither a researcher nor a Boston University employee. The Office of the General Counsel provides counsel to each Committee.

VI. Principles Regarding the Management or Elimination of Institutional Conflict of Interest in Research

• Boston University takes very seriously all potential conflicts involving research, related to financial interests in companies, conflicts of commitment by its researchers or key individuals, and any other conflicted situations which may affect or be perceived to affect the integrity of research by its faculty, students or research staff. No conflicted situation will be permitted unless, upon review, it is deemed manageable through a management plan that is transparent, principled and can withstand the highest level of ethical and scholarly scrutiny.

• The risk (or perceived risk) that a financial interest may affect the integrity of research depends on the nature of the research and the magnitude of the financial interest. On the basis of an assessment of the level of risk, the Advisory Committee
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on Research Conflict of Interest will determine whether (a) the conflict must be eliminated (for high levels of risk); (b) the conflict can be managed (for “manageable” levels of risk); or (c) the research can proceed unencumbered (for sufficiently low levels of risk).

- Conflicts of interest connected with research directly involving human subjects will be given especially close scrutiny. Because of the potential danger to the welfare of human subjects resulting from any compromises of standards or objectivity in the course of human-subjects research, this policy presumes that any existing conflict must be eliminated before the research activity can be carried out under the auspices of the University. However, under especially compelling circumstances, the Advisory Committee on Research Conflict of Interest may recommend that human research could be allowed to proceed despite the existence of a conflict of interest. The “compelling circumstances” include:
  - The research constitutes very low risk to the subjects;
  - The investigator is uniquely qualified to conduct the research;
  - The University is uniquely qualified to be the location of the research;
  - There is a minimal likelihood that the conflict of interest would increase the risk to the human subjects.

- The factors to be considered in assessing a conflict of interest and determining an appropriate management plan include (but are not limited to):
  - Could the conflicting financial interest affect the research;
  - Is there potential for the outcome of the research to affect the value of the financial interest driving the conflict (e.g., stock value, consulting income, etc.);
  - Does the research involve human subjects;
  - Does the research involve implications for trainees;
  - Does the research involve implications for supervisees and their academic advancement;
  - Are there compelling reasons that the research should proceed at Boston University.

- Examples of management techniques include (but are not limited to):
  - Disclosure of the presence of a conflict (e.g., in publications, to fellow researchers, to the research sponsor, to research subjects, etc.);
  - Periodic systematic scientific reviews involving unbiased subject matter experts both from within and from outside of the University;
  - Limiting the involvement of the conflicted key individual in the research approval and oversight process;
  - Reducing or eliminating the financial interest;
  - Modifying any position held by the key individual at the research sponsor’s “entity” (e.g., resign from Board position, line officer, etc.).

- In general, if a key individual has a financial conflict of interest with proposed research, the individual will either divest himself/herself, within a reasonable period
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of time, of the conflicted holdings or will recuse himself/herself from any decision-making regarding the research. If the person’s position is such that he/she cannot be realistically recused from the research process, then divestiture of the holdings or resignation from his/her position are the most suitable management approaches.

- The Advisory Committee on Research Conflict of Interest is authorized to decide that certain conflicts are sufficiently low risk that they can be administratively managed by the Office of the Advisory Committee for Research Conflict of Interest. Identifying the situations that can be delegated will be at the discretion of the Advisory Committee on Research Conflict of Interest.

- Research that may involve an institutional conflict of interest cannot be undertaken until the financial interest has been reviewed and a decision rendered with respect to disposition (management, reduction, or elimination) of the conflict in accordance with this policy. The Advisory Committee on Research Conflict of Interest will communicate regularly with the Institutional Review Board, Institutional Biosafety Committee, Institutional Animal Care and Use Committee, and any other committees that review and approve research to assure that research approvals are not granted until financial conflicts have been dealt with.

- If a potential institutional financial conflict of interest has been identified, no research support funds are to be expended on a project until a decision has been rendered by the Advisory Committee on Research Conflict of Interest and communicated to the investigator in writing. The Advisory Committee on Research Conflict of Interest will communicate regularly with the Offices of Sponsored Programs and the Boston Medical Center Office of Research Administration to assure that research funds are not released until financial conflicts have been dealt with.

VII. Right to appeal; Policy Compliance

Decisions on managing, reducing, or eliminating institutional conflicts of interest may be appealed by the affected party, in writing, to the Vice President for Research. The Vice President for Research will review the appeal in consultation with the Advisory Committee on Research Conflict of Interest, and his recommendation will be provided to the Provosts (or to the President if the Provosts are involved in the conflict of interest). A researcher can also appeal a decision on institutional conflict of interest if that decision prevents that researcher from pursuing his/her research.

Periodically, audits will be conducted to assure that the required information is being reported by the institution and key individuals, that the process for indentifying conflicts is effective, and that management plans are being adhered to. Failure to comply with this policy or decisions approved under this policy shall be addressed by the Associate Vice President for Research Compliance, the Provosts, or President, as appropriate, who will determine any corrective action.
Appendix: Examples of Institutional Conflicts of Interest and Their Management

Sample #1
Dr. Milhouse, the Chairman of the Institutional Animal Use and Care Committee (IACUC) and a faculty member in the College of Arts and Sciences, is a University-designated “key individual.” She has reported that she owns stock in Polygon Pharmaceuticals (a publicly-traded company) valued at $20,000.

Polygon Pharmaceuticals proposes to sponsor a clinical trial of a new drug at Boston University School of Medicine. The proposed principal investigator is Dr. Wood, a faculty member in the Department of Anesthesia.

The Office of Research Compliance identifies Dr. Milhouse’s potential conflict of interest and refers it to the Office of the Advisory Committees on Research Conflict of Interest. A review of the potential conflict determines that Dr. Milhouse who owns Polygon stock has no professional relationship with Dr. Wood, and, in her role as Chair of IACUC, she would have no oversight authority for the clinical research that Polygon would be sponsoring. Consequently, even though the proposed research involves human subjects, the research would be allowed, and Dr. Milhouse would not be required to reduce or eliminate her financial holdings.

In situations like these, where the chance for financial interests to influence research is remote, the Advisory Committee on Research Conflict of Interest could choose to delegate authority to decide such situations to the Office of the Advisory Committee on Conflict of Interest.

Sample #2
Crosswalk, Inc. is a manufacturer of therapeutic footwear. Dr. Wilson, a faculty member in the Department of Orthopedics, had developed a shoe insert to help older people maintain better balance. With the assistance of the University’s Office of Technology Development, Dr. Wilson has successfully obtained a patent on this technology. Ownership of the patent and revenues from licensing fees will be distributed according to the University patent policy, with shares going to the University, to Dr. Wilson (inventor) and to Dr. Wilson’s department, the Department of Orthopedics, which Dr. Bard chairs. In addition, Dr. Bard consults for Crosswalk.

Crosswalk proposes to license the technology and also to sponsor clinical research testing the technology at the University with Dr. Wilson, the inventor, as the principal investigator.

This scenario includes COI considerations for both the individual investigator and the institution.
University policy does not permit researchers to conduct human research on their own inventions, unless a compelling case can be made that risk to subjects is low, the research is valuable, and that the investigator is uniquely qualified to conduct the research. If, in this case, the researcher makes a compelling argument and is permitted to conduct the research, then the institutional COI must be dealt with.

The institutional COI here is that the University owns the shoe insert technology and could benefit if the research shows that the insert has commercial value. In addition, Dr. Bard, a University “key individual,” has a financial relationship with Crosswalk, the research sponsor, and is also Dr. Wilson’s supervisor. In this role, Dr. Bard could influence the way Dr. Wilson conducts his research to benefit both Crosswalk and himself. In making its recommendations, the Advisory Committee on Research Conflict of Interest must consider the level of risk to the research subjects, to what extent the outcome of the research could affect the University’s and Dr. Bard’s financial interests, and any compelling reasons why the research should be conducted at Boston University. If the Committee decides the research can be conducted at the University, the Committee could recommend managing the COI by appointing an objective overseer to supervise the research and/or substitute another qualified individual as Dr. Wilson’s research supervisor if that is feasible. If the Committee feels that the conflict cannot be reasonably and meaningfully managed, they could recommend that the COI should be eliminated either by requiring that Dr. Bard resign his consulting role with Crosswalk or that the research should be conducted elsewhere.

Sample #3
Dr. Martin, the University’s Vice President for Research, is a founder and equity-holder of the start-up company, Biofilm Inc. She also serves as the company’s vice president. Biofilm has developed a new drug-eluting polymer and desires to rigorously characterize the rate of drug release from the polymer.

_Biofilm Inc. proposes to award a research grant to the University to study its technology in the laboratory of Dr. Landry in the College of Engineering who is an expert in this area. The proposed research does not involve human subjects, and Dr. Landry has no financial associations with Biofilm Inc._

Because Dr. Landry has no financial interest in the sponsor, there is no individual researcher conflict of interest here.

The institutional conflict of interest in this situation is that Dr. Martin, as Vice President for Research at the University, has a financial interest in the sponsor, Biofilm Inc. If the research is successful, the financial value of her holdings in Biofilm Inc. could increase substantially. Because she is responsible for overseeing research at the University at multiple levels, it would be highly unlikely that a management plan could be designed which would effectively eliminate the potential that Dr. Martin could influence the conduct or outcome of the research. In this situation, either the research should be conducted at another institution, or Dr. Martin should divest her financial interest in
Biofilm and resign her vice president position, or Dr. Martin should resign from her position as Vice President for Research at the University.