

**CONFLICTS OF INTEREST IN RESEARCH POLICY AND PROCEDURES
BOSTON COLLEGE
OFFICE OF RESEARCH INTEGRITY**

PURPOSE OF POLICY

The University and its Investigators are committed to conducting themselves and University activities in accordance with the highest standards of integrity and ethics and in compliance with applicable state and federal laws related to conflict of interest and objectivity in scholarly projects.

It is the purpose of this policy to set forth the principles for identifying the potential for conflicts and the procedures for reviewing and addressing actual and potential conflicts to assure that they do not improperly affect University research and other sponsored activities. In addition, the intent of this policy is to assist Investigators to more effectively manage real or potential conflicts of interest and commitment. By reporting and managing conflicts from the start, the University and the Investigator can work together to prevent outcomes that may be harmful to either the Investigator or the University at large.

This policy addresses actual and potential Investigator conflicts of interest and commitment pertaining to research. This includes all Sponsored Projects, as well as purchase orders, sub awards, and subject matter expert agreements issued by Boston College under its Sponsored Projects. It also addresses Investigator involvement in startup companies (newly formed, privately held, for-profit companies based on University intellectual property).

This policy is divided into the following sections:

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This policy applies to Investigators and others conducting research at the University when, on behalf of the University, they are responsible for or in a position to influence the design, conduct, or reporting of research or other scholarly activity. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy.

DEFINITIONS

Associated Entity means any trust, organization, or enterprise with which the Investigator, alone or together with Family Member(s), engages in any Outside Professional Activities. This applies to any domestic or foreign, public or private, for profit, non-profit or governmental organization.

Business means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other nongovernmental legal entity organized for profit, non-profit, or charitable purposes.

Business Interest means membership on a board or holding any position that includes responsibilities for a significant segment of the operation or management of any Business regardless of compensation. Please refer to the section of the policy captioned "Conflict of Interest."

Conflict Avoidance Statement is defined as a document to be executed by the Investigator, the Office of Research Integrity, and the Office of Technology Transfer and Licensing, which describes how the Investigator will adhere to University conflict of interest policies in the face of a pending license agreement. The statement will reflect the Investigator's understanding of potential conflicts and lay out steps to be taken in the event that a future conflict should arise.

Conflict of Interest exists in any situation in which an Investigator's personal considerations or other outside interests (including without limitation an Investigator's Significant Financial Interest, Business Interest, or Familial Conflict of Interest) affect, or appear to affect, the Investigator's judgment when conducting research or in the performance of other Institutional Responsibilities. Examples of a Conflict of Interest include a Significant Financial Interest, Business Interest, or a Familial Conflict of Interest, each of which is described in this Policy.

Conflict of Interest Officer is the University employee responsible for implementing and administering this policy as designated by the Vice Provost for Research. This is typically the Director, Office of Research Integrity.

Equity Interest includes any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measure of fair market value.

Institutional Responsibilities are the responsibilities associated with the Investigator's University appointment or position, such as research, teaching, administration, conference attendance, research presentations or lectures at other universities, uncompensated publication review, and service on University committees.

Investigator means: any person possessing either a full-time or part-time appointment at the University, including faculty and staff, who on behalf of the University are responsible for, or in a position to influence the design, conduct, or reporting of the research or other scholarly activity.

Family Member includes a spouse, a domestic partner, child, brother, sister, financial dependent, or any of their spouses.

Outside Professional Activities means compensated and uncompensated activities undertaken outside of an Investigator's Institutional Responsibilities

Familial Conflict of Interest means the involvement of a Family Member in an Investigator's research. Please refer to the section of the policy captioned "Conflict of Interest."

Remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship, income from intellectual property rights and interests).

Significant Financial Interest means a financial interest meeting one or more of the three criteria outlined in the section of this policy captioned "Conflict of Interest."

Sponsored Project means research, training, and other projects involving funds, materials, or other consideration from outside sources under agreements that bind the University and/or an affiliated institution to one or more of the following:

- A line of scholarly or scientific inquiry specified to a substantial level of detail;
- A line-item budget;
- Financial reporting;
- Reporting of research results;
- External audit;
- The return of unexpended funds to the sponsor at the conclusion of the project; or,
- The disposition of either tangible or intangible properties that may result from the activity.

Sponsored Travel means travel expenses reimbursed to an Investigator or travel paid on an Investigator's behalf, by a single entity in any 12-month period if such travel reasonably appears to be related to the Investigator's Institutional Responsibilities.

GUIDING PRINCIPLES

The University and its Investigators often benefit from Investigators' participation in both public and private outside activities. The University has no interest in unreasonably interfering with Investigators' legitimate outside interests. University Investigators, in turn, have an obligation to ensure that their outside obligations, financial interests, and activities do not conflict or interfere with their commitment to conduct University research and other sponsored activity without improper influence, and to disclose to the University all actual or potential Conflicts of Interest. A number of guiding principles inform our approach to identifying and addressing Conflicts of Interest. These include:

1. An Investigator's first and primary responsibility is to support and advance the University's mission, rather than to advance his or her personal or financial interests.
2. Research must be undertaken to advance scholarship and new knowledge and not an Investigator's or Family Member's personal financial interest.
3. Professional external activities conducted by a faculty member should improve effectiveness as a teacher or contributor to scholarly achievements, or should in some manner serve the interests of the University or of the University community.
4. External activities must not distract significantly from an Investigator's primary responsibilities and must not require such extensive absence as to cause an Investigator to neglect course obligations or to become unavailable to students and colleagues.

5. Conflicts of Interest must be identified and either managed or eliminated.
 6. Disclosure of Significant Financial Interests, Business Interests, Familial Conflicts of Interest, and Outside Professional Activities is integral to identification of Conflicts of Interest.
 7. An Investigator must not attempt to influence the activities of colleagues and subordinates with the intent of enhancing the Investigator's financial, business, or personal interests.
 8. Research results must not be withheld or provided on a preferential basis for the benefit of an Investigator's financial, business, or personal interests.
 9. The University's resources, names and trademarks may only be used in connection with University activities, not for personal benefit.
 10. Investigators must disclose any actual Conflicts of Interests and any activities that may appear to give rise to a Conflict of Interest to students and staff who participate in their research.
 11. Extra scrutiny must be given to potential Conflicts of Interest in research involving human subjects.
 12. An Investigator may not supervise directly or indirectly any Family Member nor may an Investigator assume the role of advocate or judge regarding a Family Member's employment, salary, or promotion.
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APPLICATION OF GUIDING PRINCIPLES

Investigators may not:

1. Accept research sponsorship or gifts in support of the Investigator's Institutional Responsibilities from a for-profit privately held Associated Entity;
2. Subcontract to a for-profit privately held Associated Entity;
3. Negotiate with the University on behalf of an Associated Entity, or negotiate with the Associated Entity on behalf of the University;
4. Involve a student or postdoctoral fellow for whom the Investigator mentors/supervises in the Investigator's Outside Professional Activities;
5. Divert research opportunities to an Associated Entity, which are more appropriately undertaken at the University, such as research sponsorship or other projects;
6. Use University resources, including facilities, personnel, or equipment in connection with personal business, or for any other purposes that are unrelated to the education, research, scholarship, and public service missions of the University. All non-university external activities are to be performed strictly as a personal matter using personal or non-university resources;

7. Promote the use of products or services of an Associated Entity in the course of the Investigator's Institutional Responsibilities;
8. Provide preferential access to research results, materials or products generated from University teaching or research activities, or University owned equipment to an Associated Entity; or
9. Engage in research involving human subjects that could reasonably be expected to affect the financial condition of an Associated Entity.

The following situations are generally prohibited:

1. Accepting research sponsorship or gifts, in support of the Investigator's Institutional Responsibilities from a publicly held or non-profit Associated Entity;
2. Accepting an in-kind gift from a publicly held or non-profit Associated Entity for use in his or her Institutional Responsibilities;
3. Accepting research sponsorship from an Associated Entity from which the Employee receives Remuneration;
4. Purchasing goods or services from an Associated Entity;
5. Providing goods, services, or access to facilities to an Associated Entity;
6. Involving a student for whom the Investigator is not a thesis supervisor in his or her Outside Professional Activities, as an employee or consultant or in any other capacity;
7. Involving University staff in the Investigator's Associated Entity's activities;
8. Requesting an appointment for an individual from an Associated Entity to participate in research at the University.

These situations may be permitted if, after notification, the Vice Provost for Research or his/her designee deems the scope of the Investigator's University research is separate and distinct from his/her Outside Professional Activities and that engaging in these activities will not endanger or interfere with the University's interests. The Investigator must obtain prior written approval from the Vice Provost for Research or his/her designee and in appropriate cases, enter into a management plan.

CONFLICT OF INTEREST

A conflict of Interest exists in any situation in which an Investigator's personal considerations or other outside interests (including without limitation an Investigator's Significant Financial Interest, Business Interest, or Familial Conflict of Interest) affect, or appear to affect, the Investigator's judgment when conducting research or in the performance of other Institutional Responsibilities. Examples of a Conflict of Interest include a Significant Financial Interest, Business Interest, or a Familial Conflict of Interest, each of which is described in this Policy.

Significant Financial Interest

A Significant Financial Interest is a financial interest held or received by the Investigator or Family

Member in the preceding twelve months from an entity whose interests could reasonably appear to be related to the Investigator's Institutional Responsibilities and meets one or more of the following criteria:

1. For **publicly traded** entities, Equity Interests whose value as of the date of disclosure when aggregated with any remuneration exceeds \$5,000;
2. For **non-publicly traded** entities, any Equity Interests regardless of value;
3. Remuneration from an entity in excess of \$5,000;
4. Intellectual property rights and interests (e.g. patents, copyrights) that are not assigned to Boston College;
5. Travel reimbursement or sponsored travel if such travel reasonably appears to be related to the Investigator's Institutional Responsibilities. This does not apply to travel reimbursement or sponsored travel paid by a U.S. federal, U.S. state, U.S. local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, or a U.S. research institute that is affiliated with an institution of higher education.

The following do not constitute a Significant Financial Interest:

1. Salary, royalties, or other remuneration received from Boston College;
2. Royalties generated by intellectual property rights arising out of university employment that are assigned to Boston College;
3. Remuneration from authorship of academic or scholarly works;
4. Interests of any amount in investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not control the investment decisions made in these vehicles.
5. Income from a U.S. government agency, a U.S. university, a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a university for engaging in the following activities: seminars, lectures, teaching, service on advisory committees or review panels

These exceptions to Significant Financial Interest apply ONLY to U.S. sources. All income, remuneration, reimbursement, intellectual property rights and interests, and sponsored travel from foreign sources MUST be disclosed.

Business Interest

Business Interest means membership on a board or holding any position that includes responsibilities for a significant segment of the operation or management of any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other nongovernmental legal entity organized for profit, nonprofit, or charitable purposes, regardless of compensation.

Familial Conflict of Interest

A Familial Conflict of Interest, or the perception of one, may arise when an Investigator involves a Family Member in his or her research. Conducting research with one's Family Member is not permitted if the Investigator and Family Member are in supervisory and subordinate roles in relation to each other or in a situation where influence could be exerted, directly or indirectly, on future decisions concerning the status of employment, promotion, or compensation.

The following situations are generally prohibited:

1. An Investigator directly supervising the Family Member's research.

2. An Investigator evaluating the Family Member's research if the Investigator is in a decision-making position regarding the research (e.g. an Investigator may not serve as a grant reviewer for a Family Member's grant proposal, but may review a Family Member's manuscript as a co-author).
3. An Investigator providing remuneration for the Family Member's research activities.
4. An Investigator conducting research on one's Family Member. Please refer to the Standard Operating Procedures for Researchers Using Human Participants in Research policy for additional information.

Research collaborations between an Investigator and a Family Members are generally permitted as long as they do not violate the above prohibitions.

Family relationships are not always widely known and must be disclosed in accordance with normal disclosure procedures and may necessitate a conflict of interest management plan.

DISCLOSURE REQUIREMENTS

Full and prompt disclosure of Significant Financial Interests, Business Interests, and Familial Conflicts of Interests is critical to Boston College's ability to identify, manage, and eliminate Conflicts of Interest. Each Investigator who is responsible for or in a position to influence the design, conduct, or reporting of research or other scholarly activity must disclose whether or not he or she has Outside Professional Activities that may constitute a Conflict of Interest.

Upon disclosure, Investigators must describe an Associated Entity's business focus, their work or role with the Associated Entity, and any relationship to their Institutional Responsibilities. The Investigator must disclose and review these disclosures with the following frequency:

1. Prior to the University's submission of each Sponsored Project proposal or issuance of a purchase order or subcontract or agreement for the acquisition of goods and services. When an Investigator joins a research project already in progress, the Investigator must disclose to the University his or her Conflict of Interest prior to the Investigator commencing participation in the research project.
 2. Upon acquisition of a new Conflict of Interest. This must be done within 30 days following the date on which the Conflict of Interest is acquired or arises.
 3. For faculty, at least annually, as part of completing his or her Faculty Annual Report. Any disclosures will be reported in the External Activities and Conflict of Commitment, Significant Financial Conflict of Interest, and Additional Activities for Funded Research in Interfolio (system for reporting Faculty Annual Report).
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REVIEW AND EVALUATION OF DISCLOSURES

All disclosures of Conflict of Interest will be reviewed by the COI Officer and when possible, he or she makes a preliminary determination whether further action is needed. If it is determined that the Conflict of Interest is related to the Investigator's research, the COI Officer will work with the Investigator to clarify details and draft a management plan.

The goals of a management plan are to ensure open and timely dissemination of research results, protect students, and preserve the objectivity of the research. Examples of conditions or restrictions

that may be imposed by a management plan include:

1. Public disclosure of Conflict of Interest (e.g., when presenting or publishing research);
2. Disclosure of Conflicts of Interest directly to participants in human subjects research;
3. Appointment of an independent monitor or oversight committee capable of taking measures to protect the design, conduct, and reporting of research against bias;
4. Modification of the research plan;
5. Change of personnel or personnel responsibilities or disqualification of personnel from participation in all or a portion of the research;
6. Reduction or gradual elimination of the Conflict of Interest (e.g., sale of an Equity Interest);
7. Severance of the relationship that is the source of the Conflict of Interest;
8. Expedited dissemination of research results so that the Associated Entity does not receive preferential access; and
9. Monitoring of involvement of students and postdoctoral appointees by independent reviewers or oversight committees.

The disclosure and management plan draft will be submitted to the COI Review Committee. The COI Review Committee shall consist of the Vice Provost for Research; the Director, Office for Sponsored Programs; the Director, Office for Research Integrity; and the University General Counsel. Additional members may be added on an ad hoc basis as deemed appropriate by the Vice Provost for Research.

The COI Review Committee will review all management plan drafts. In conducting its review, the COI Review Committee shall:

1. Consider the nature and extent of the actual or potential Conflict of Interest in the relationship of the Investigator and the Associated Entity;
2. Consult with and obtain additional information from the Investigator as either the COI Review Committee or the Investigator feel may be helpful in resolving actual or potential conflicts; and
3. Act in a timely manner so as not to delay unduly the conduct of the research;
4. Give special consideration to the terms and conditions of any relevant Sponsored Project agreements that may mitigate or complicate the given situation.

Following its review, the COI Review Committee shall either accept or modify the draft of the management plan. Once the COI Review Committee and Investigator approve the management plan, the Investigator shall sign the management plan. The COI Review Committee and all relevant individuals, administrative offices and other units as required by the conditions of the plan shall receive signed copies of the management plan. Investigator compliance with the management plan is subject to monitoring and review by the Office of Research Integrity.

If the Investigator is dissatisfied with the COI Review Committee's conclusion, the Investigator may appeal to the Provost who will consult with the Investigator and the COI Review Committee as the Provost deems necessary and appropriate to the particular circumstance. The decision of the Provost shall be final.

The Investigator may not commence or participate in the research that gives rise to the Conflict of Interest or the appearance thereof until all approvals are obtained.

RETENTION OF RECORDS

The COI Officer shall maintain records pertaining to the resolution of positive disclosures of Conflicts of Interest as well as those situations involving the creation and maintenance of conflict of interest management plans. Access to such records will be limited to the Investigator, the COI Review Committee, the Provost, and others who have a legal right to review the records.

Management plans will be maintained by the COI Officer and updated annually.

All disclosures, management plans, and related documents will be retained for a period of at least three years following submission of the final expenditure report for the applicable project that gives rise to the conflict of interest, unless any litigation, claim or negotiation, audit, or other action involving the records is commenced before expiration of the three-year period, in which case, records will be retained until completion of the action and resolution of all issues.

REPORTING REQUIREMENTS TO THIRD PARTIES

Boston College may be required, by law or by conditions imposed by a sponsor, to report an Investigator's Conflict of Interest, activities that appear to be a Conflict of Interest or other external activities (and also any failure to report any such conflicts or activities), to the affected project sponsors. The Office for Sponsored Programs shall report this prior to the expenditure of research funds or as required by law or conditions imposed by a sponsor.

Sponsors may require additional Conflict of Interest or other external activities disclosures from Investigators. Investigators must comply with any disclosures requested by sponsor.

SPECIAL REQUIREMENTS FOR INVESTIGATORS CONDUCTING PHS RESEARCH

The 2011 Public Health Service (PHS) regulations on "*Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought*" impose special reporting requirements on investigators funded by PHS.¹ These PHS COI regulations are overseen by the U.S. Department of Health and Human Services and are federal law. As a recipient of federal research monies, Boston College must comply with these regulations.

The PHS COI regulations impose additional training, reporting, and public accessibility requirements with which Boston College and this policy adhere. Investigators receiving PHS monies are expected to be familiar with and comply with the PHS COI regulations. The PHS COI regulations may be found here: [42 C.F.R. Part 50, Subpart F](#)

For Investigators conducting research on a PHS funded project or any of the foundations that follow the PHS COI regulations, COI training is required prior to engaging in the research project or when the Investigator is new to Boston College. The training must be refreshed every four years for the duration

¹ The following are the agencies within the Public Health Service: Administration for Children and Families; Administration on Aging; Agency for Healthcare Research and Quality; Agency for Toxic Substances and Disease Registry; Centers for Disease Control and Prevention; Centers for Medicare & Medicaid Services; Federal Occupational Health; Food and Drug Administration; Health Resources and Services Administration; Indian Health Service; National Institutes of Health; Substance Abuse and Mental Health Services Administration

of the research project.

The COI Officer shall create and maintain a database of information contained in positive disclosures. This information shall be made available within 5 days of the receipt of a written request from any member of the public. The database shall be updated annually at a minimum. The information shall be maintained in the database for three years from the most recent update of the information pertaining to the project. The database shall be updated within 60 days of the receipt of a positive disclosure.

DISCIPLINARY ACTION

Violations of this policy, such as willful concealment of a Conflict of Interest or other information required to be disclosed pursuant to this Policy, or failure to abide by a conflict of interest management plan, may result in sanctions being imposed upon the violating individual. Disciplinary actions may include, but are not limited to, a reprimand, oral or written, private or public; a period of suspension with or without pay; a reduction in salary; removal of privileges; or dismissal in accordance with Boston College policies and procedures.

The COI Review Committee will review allegations of violations and will make recommendations regarding the imposition of sanctions to the Provost. The decision of the Provost with regard to the imposition of sanctions shall be final.

ADDRESSING CONFLICT OF INTEREST SITUATIONS THAT MAY NOT INVOLVE SPONSORED PROJECTS

Disclosures Pertaining to Technology Transfer

An Investigator involved with transferring technology through licensing patents or other technologies to a Business in which the Investigator has (1) a Conflict of Interest or (2) holds a position on the Business's scientific board of advisors or similar body must disclose the Conflict of Interest or such position or relationship to the COI Officer. This disclosure must be made prior to the negotiation of a license or any other business arrangement by the Office of Technology Transfer and Licensing (OTTL) with the Associated Entity.

In all instances, the Investigator is to disclose to the OTTL any existing or proposed agreements between the Investigator and the prospective licensee, or any other agreements with other entities that have potential for Conflicts of Interest. If it is determined that a Conflict of Interest exists, the University may impose limitations on any associated sponsored research agreement, any consulting agreement between the Investigator and the licensee, or other agreements. OTTL is to work directly with the Office of Research Integrity and with the Investigator to confirm that potential conflicts of interest shall be avoided or managed. This is to be illustrated by an executed Conflict Avoidance Statement and, as appropriate, by a conflict of interest management plan. These conflict of interest discussions are to take place at the earliest possible stages of the licensing discussions. OTTL shall present this executed Conflict Avoidance Statement together with a summary of the terms of the license agreement to the VPR at the time the license is prepared for execution. The VPR shall execute the license agreement as evidence that the Conflict Avoidance Statement was prepared and executed.

If, after the license or other business arrangement is executed, the Investigator is offered either (1) a Business Interest or a Significant Financial Interest in the Associated Entity or (2) a position on the Business's scientific board of advisors or similar body, this offer must be reported to the COI Officer. This

disclosure must be made prior to the Investigator's oral or written acceptance of such an offer from the Business and will trigger the preparation of a conflict of interest management plan.

Disclosures for Projects Involving Human Participants

When an Investigator submits a disclosure that indicates that human participants are involved in the research and a Conflict of Interest is also disclosed, the COI Review Committee will report the positive disclosure to the Office for Research Protections which shall report the disclosure to the Boston College Institutional Review Board (BCIRB). In the event a Conflict of Interest is disclosed in the Protocol Application, the Office for Research Protections will immediately report this to the COI Officer.

Immediately after the COI Review Committee has resolved the disclosed conflict, it will report the final resolution to the Office for Research Protections, which shall report the resolution to the BCIRB. The BCIRB may specify special conditions to the informed consent process or other aspects of the conduct of the project as it deems necessary to protect the welfare of the human participants involved in the research. The BCIRB is not authorized to impose additional requirements on the project's Principal Investigator concerning the management of the Conflict of Interest.

Conflict of Commitment Policy for Faculty

All faculty members are expected to devote their primary professional time and energy to their teaching, research and other scholarly works, service on University committees, assistance for students, performance of necessary administrative duties, and, where applicable, patient care. Although a specific work week is not defined for faculty members, it is expected that such membership constitutes a full-time obligation during the academic year and that, with the exceptions explicitly permitted by University policies on external activities, they will not engage in other employment. Accordingly, external activities must be arranged so as not to interfere with their primary commitments.

Guidance on time permitted for faculty members engaging in external activities can be found in the University Statutes, which state in part, "professional service outside the University shall not exceed the equivalent of one day per week, and any work of a continuing or regular nature, whether compensated or not, must be approved annually by the Provost."

Boston College may be required, by law or by conditions imposed by a sponsor, to report an Investigator's Conflict of Interest, activities that appear to be a Conflict of Interest, or other external activities (and also any failure to report any such conflicts or activities), to the affected project sponsors. Sponsors may require additional Conflict of Interest or other external activities disclosures from Investigators. Investigators must comply with any disclosures requested by sponsor.

Conflict of Interest Policy for Non-faculty Investigators

Specific requirements for Investigators holding non-faculty positions can be found in Professional Standards and Business Conduct – Conflict of Interest and Commitment. This policy applies to all University non-faculty employees.