

BRANDEIS UNIVERSITY
POLICY ON FINANCIAL CONFLICTS OF INTEREST IN RESEARCH
(Effective July 1, 2018)

POLICY STATEMENT

Brandeis University is committed to overseeing the conduct of Research in a manner that ensures the integrity of the Research process and maintains the public trust and that of sponsors in the integrity and credibility of its faculty, its staff, and its Research programs. This commitment requires the University to ensure that Research results are not biased by the external Financial Interests of persons who are responsible for the design, conduct, reporting, or direct administration of University Sponsored Research.

This Policy addresses actual, potential, and apparent Financial Conflicts of Interest pertaining to Sponsored Research at the University. It applies to all sponsored projects, as well as sub-awards issued by Brandeis University under the Office of Research Administration.

In accordance with this Policy, all externally funded Investigators, regardless of funding source, will report their (the sum of their own and their Family's) external Significant Financial Interests in a timely manner and actual, potential, and apparent Financial Conflicts of Interest will be identified and responsibly managed.

Note that it is the Principal Investigator's responsibility to identify all Investigators participating in the Sponsored Research project and ensure that all Investigators comply with this Policy.

PURPOSE OF POLICY

The purpose of this Policy is to identify and address Financial Conflicts of Interest to assure that they do not improperly affect the Research activities of the University. 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 Financial Conflicts of Interest and objectivity in Research.

The premise of this Policy is that each member of the Brandeis Research community has an obligation to act in the best interests of the University, and must not permit outside Financial Interests to interfere with that obligation. This Policy is intended to increase the awareness of Investigators to the potential for Financial Conflicts of Interest, and to establish a process whereby such conflicts, actual, potential, or apparent, may be properly managed or avoided.

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APPLICABILITY

This Policy applies to all Investigators (as defined below) responsible for Sponsored Research activities at the University. The University's existing Institutional Conflict of Interest Policy remains in effect and applies to all other situations involving the disclosure and resolution of conflicts that are not explicitly covered by this Policy.

All Investigators engaged in PHS funded Research or Research funded by those agencies who have adopted the PHS regulations are also subject to the additional requirements set forth in Appendix A.

All Investigators involved in research funded by HHS contracts must comply with additional requirements as explicated on the [CMS Contracts](#) webpage.

POLICY DETAILS

This Policy is predicated on the expectation that Investigators will conduct their Research in a manner that avoids or minimizes Conflicts of Interest, and will respond appropriately when Conflicts of Interest arise. To that end, this Policy informs Investigators about situations that generate Financial Conflicts of Interest related to Research and provides mechanisms for Investigators and the Institution to manage those conflicts that arise. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this Policy. If a situation raising questions of Conflict of Interest arises, an Investigator should discuss the situation with the Institutional Official.

DEFINITIONS

Conflict Management Plan means an agreement that sets out limits and restrictions on the Investigator for the purpose of reducing or eliminating a Conflict of Interest that could directly and significantly affect the design, conduct, or reporting of Institutional Research.

Conflict of Interest means a situation in which financial or other personal considerations may compromise, or have the appearance of compromising, an Investigator's judgment in conducting or reporting Research.

Family means any member of the Investigator's immediate family, specifically, any dependent children and spouse or domestic partner.

Financial Conflict of Interest means a Significant Financial Interest (or, where the Institutional Official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct, or reporting of Institutional research.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or

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paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights) upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a. salary, royalties, or other remuneration from Brandeis University;
- b. income from the authorship of academic or scholarly works;
- c. income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d. equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For PHS funded Investigators only, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her Institutional Responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. federal, state, or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Institutional Official means the individual within the Institution who is responsible for the solicitation and review of disclosures of Significant Financial Interests related to the Investigator's Institutional Responsibilities. For the purposes of this policy, the Associate Provost for Research Administration is designated as the Institutional Official.

Institutional Responsibilities means the Investigator's responsibilities associated with his or her Institutional appointment or position, such as Research, teaching, administration, and Institutional internal and external professional committee service.

Investigator means any individual who is independently responsible for the design, conduct, or reporting of Sponsored Research, or proposals for such funding. This definition is not limited to those titled or budgeted as Principal Director/Investigator, co-Principal Director/Investigator, or co-Investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students, as well as any other equivalent personnel as designated by the Principal Investigator or Institutional Official. The definition may also include collaborators or consultants as appropriate.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge, including behavioral and social-sciences Research. The term encompasses basic and applied Research (e.g., a published article, book, or book chapter).

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Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- a. if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeding \$5,000; or
- b. if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeding \$5,000; or
- c. if with a non-publicly-traded company, an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d. any income related to intellectual property rights and interests not reimbursed through the Institution.

Sponsored Research means Research, training, and instructional projects involving funds, materials, or other consideration from external sources.

1) REPORT AND DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

All Investigators are required to disclose their (the sum of their own and their Family's) outside Significant Financial Interests to the Institution prior to the Institution's submission of a Sponsored Research proposal and on an ad hoc basis as described below. The Institutional Official is responsible for the distribution, receipt, processing, review, and retention of disclosure forms. Regardless of the disclosure requirements, the Investigator, in his or her own best interest, is encouraged to disclose any Financial Interest that could be reasonably perceived to present a Conflict of Interest.

a) Initial Reporting and Disclosures

When submitting an application or proposal package for a sponsored project, investigators are required to disclose whether or not they or their Family have outside financial interests that are Significant Financial Interests. In the event a Significant Financial Interest is reported, a *Significant Financial Interest Disclosure* form must be submitted to the Institutional Official for each occurrence of Significant Financial Interest.

In addition, new Investigators joining the research team of an ongoing sponsored project must submit to the Institutional Official a *Significant Financial Interest Report* – along with any required *Significant Financial Interest Disclosure* forms – within 30 days of their initial involvement with the project.

b) Ad hoc Disclosures

All Investigators must submit to the Institutional Official an ad hoc *Significant Financial Interests Disclosure* form disclosing any Significant Financial Interest they or their Family acquire (e.g., through purchase, marriage, or inheritance) within 30 days of discovering or acquiring the Significant Financial Interest.

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2) REVIEW OF SIGNIFICANT FINANCIAL INTEREST DISCLOSURES

All disclosure forms revealing a Significant Financial Interest will be reviewed promptly by the Institutional Official or designee for a determination of whether the Significant Financial Interest constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to eliminate, reduce, or manage the conflict, as appropriate. The Institutional Official may, at his or her discretion, convene a committee for guidance in specific cases, or in the application of this Policy to particular situations.

A Financial Conflict of Interest will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of Sponsored Research. If it is determined that there is a Financial Conflict of Interest that can be managed, the Institutional Official or designee will develop a Conflict Management Plan that specifies the actions that have been, or shall be, taken to manage the Financial Conflict of Interest. The Conflict Management Plan must be approved by the Institutional Official before any related research goes forward.

To address complex situations, oversight committees may be established by the Institutional Official to periodically review the ongoing activity, to monitor the conduct of the activity, to ensure open and timely dissemination of the Research results, and to otherwise oversee compliance with the Conflict Management Plan.

In the event the Investigator is dissatisfied with the decision of the Institutional Official, the Investigator may file a petition in writing with the Institutional Official, who will review the decision in consultation with a Committee and the Investigator and make the final determination.

3) REPORTING TO AGENCY

Should any deemed conflict or non-compliance require reporting to a particular funding agency, the Institutional Official will report in accordance with applicable agency regulations. If the funding for the Research is made available from a prime awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the agency. For NSF funded research, the Institutional Official will keep the NSF's Office of the General Counsel appropriately informed if it finds the Institution is unable to satisfactorily manage a Conflict of Interest.

4) INVESTIGATOR NON-COMPLIANCE

a) Retrospective Review

In the event the Institutional Official determines that (1) a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial

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Conflict of Interest, or (2) an Investigator failed to materially comply with a Conflict Management Plan for a Financial Conflict of Interest, a committee appointed by the Institutional Official will complete a retrospective review within 120 days of the Institution's determination of noncompliance to establish whether the Research conducted during the period of non-compliance was biased in the design, conduct, or reporting of the Research.

Documentation of the retrospective review shall include the project number, project title, name of the Principal Investigator, name of the Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional Official will update any previously submitted report to the funding agency or the prime awardee relating to the Research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the report will include a mitigation report in accordance with the applicable regulations, including a description of the impact of the bias on the Research project and the plan of action to eliminate or mitigate the effect of the bias.

b) Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved.

An Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the Investigator along with the individual's right to appeal the decision.

5) SUBRECIPIENT REQUIREMENTS

Brandeis must take reasonable steps to confirm that all Investigators who are Subrecipients participating in externally funded Research are subject to Conflict of Interest rules and procedures that comply with the requirements of the applicable funder.

Each Subrecipient must provide assurances to Brandeis that it has policies and procedures that comply with the requirements of the funder or otherwise adopt this Policy as their own prior to submission of externally funded Research proposals or applications and execution of a written agreement between Brandeis and the Subrecipient. Subrecipients will complete the Brandeis *Significant Financial Interest Report for Subrecipients* if they do not have their own policy, as well as the *Significant Financial Interest Disclosure for Subrecipients*, when applicable.

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6) RECORD RETENTION

The Institutional Official will maintain a database of all disclosures of Significant Financial Interests, Conflict Management Plans, and related documents for a period of three years from the date the final expenditure report is submitted to the agency or to the prime awardee.

7) CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, Conflict Management Plans, and related information will be confidential. However, the Institution may make such information available to (1) an agency funding the research of an Investigator, (2) to a requestor of information concerning Financial Conflict of Interest related to funding, or (3) the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, Conflict Management Plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

Appendix A

ADDITIONAL REQUIREMENTS ON FINANCIAL CONFLICTS OF INTEREST RELATED TO PUBLIC HEALTH SERVICE (PHS) FUNDING (Effective 24 August 2012)

INTRODUCTION

In response to the requirements from the Public Health Service (PHS) governing the disclosure and administration of Financial Conflicts of Interest related to PHS-funded research, the University has developed this Appendix to assist with the understanding and implementation of these requirements.

This Appendix describes the Brandeis University implementation of this regulatory requirement, and its program for training Investigators, reviewing disclosures, and carrying out any necessary enforcement and reporting actions.

This Appendix sets forth the additional responsibilities for PHS funded Investigators not included in the requirements outlined in the policy above. All PHS funded Investigators must comply with this Appendix.

For purposes of this Policy, *Public Health Service* or *PHS* means the Public Health Service of the U.S. Department of Health and Human Services and any components of the PHS to which the authority of the PHS may be delegated, as well as any non-PHS agencies that have adopted the PHS regulations.

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1) ANNUAL REPORTING

All PHS funded Investigators must submit to the Institutional Official a *Significant Financial Interests Report* – along with any required *Significant Financial Interest Disclosure* forms – on an annual basis throughout the life of the sponsored project. Subsequent proposals for PHS funding will not be submitted if the Investigators are not up-to-date on their annual reports and disclosures.

2) DISCLOSURE OF FINANCIAL INTERESTS: TRAVEL

In addition to the disclosure requirements set forth in the body of this Policy, PHS funded investigators must also disclose reimbursed or sponsored travel related to their Institutional responsibilities as outlined above in the definition of Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and the monetary value (or, if unknown, a reasonable approximation). The Institutional Official will determine if additional information is needed to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's Research.

3) REPORTING TO AGENCY

Should any reported conflict or non-compliance require reporting to PHS, the Institutional Official will report in accordance with the following PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS.

Prior to the expenditure of any funds under a PHS funded Research project, the Institution shall submit to the agency a Financial Conflict of Interest report and Conflict Management Plan regarding any Investigator's Significant Financial Interest or travel disclosure which the Institution has deemed a Financial Conflict of Interest.

Upon learning of a Financial Conflict of Interest in the course of any PHS funded Research, or of a previously unreported Financial Conflict of Interest related to ongoing Research, the Institution shall submit to the agency a Financial Conflict of Interest report and Conflict Management Plan within sixty days of identification of the conflict.

All Financial Conflict of Interest reports submitted to PHS shall include the following relevant information needed for the agency to understand the nature and extent of the conflict and to assess the appropriateness of the Institution's Conflict Management Plan:

- a. Project number
- b. Name of Principal Investigator
- c. Name of Investigator with the Financial Conflict of Interest
- d. Name of the entity with which the Investigator has the Financial Conflict of Interest
- e. Nature of the Significant Financial Interest

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- f. Value of the Significant Financial Interest (as \$0-4,999, \$5K-9,999, \$10K-19,999, by increments of \$20K if between \$20K-100K, or by increments of \$50K if above \$100K) or a statement that a value cannot be readily determined through references to public prices or other reasonable measures of fair market value
- g. A description of the relationship of the Significant Financial Interest to the PHS funded research
- h. A description of the basis for the Institution's determination that the Significant Financial Interest conflicts with the research
- i. A description of the key elements of the Conflict Management Plan, including:
 - i. The role and principal duties of the conflicted Investigator in the research
 - ii. The conditions of the Conflict Management Plan
 - iii. How the Conflict Management Plan is designed to safeguard the objectivity of the Research
 - iv. Confirmation of the Investigator's agreement to the Conflict Management Plan
 - v. How the Conflict Management Plan will be monitored to ensure Investigator compliance
 - vi. Any other relevant information, as needed

For all Financial Conflict of Interests reported to PHS, the Institution will submit annual reports for the duration of the award. These reports will include (1) the status of the Financial Conflict of Interest, (2) any changes to the Conflict Management Plan, and (3) a statement of whether the Financial Conflict of Interest is still being managed or an explanation of why the Financial Conflict of Interest no longer exists.

4) TRAINING

Each Investigator must complete training on this Policy prior to engaging in research funded by PHS, and at least every four years thereafter. In the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this Policy or with a Conflict Management Plan related to their activities, this training must be repeated within a reasonable period of time as determined by the Institutional Official.

5) PUBLIC ACCESSIBILITY

In the event a written request is received from any member of the public, the following information regarding Significant Financial Interests will be disclosed within five days of the receipt of the request.

- a. Investigator's name
- b. Investigator's title
- c. Investigator's role on the project
- d. Name of any entity with which the Investigator has or has had within the past three years a Significant Financial Interest constituting a Financial Conflict of Interest

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- e. Nature of any Significant Financial Interest constituting a Financial Conflict of Interest
- j. Approximate value of the Significant Financial Interest (as \$0-4,999, \$5K-9,999, \$10K-19,999, by increments of \$20K if between \$20K-100K, or by increments of \$50K if above \$100K) or a statement that a value cannot be readily determined through references to public prices or other reasonable measures of fair market value