

BABSON COLLEGE

Policy on Financial Conflict of interest Related to Research

Revised Date: July 28, 2022

I Purpose and Scope

Babson College is committed to providing a research environment consistent with our values and compliant with federal regulations surrounding “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought” (42 C.F.R. Part 50, Subpart F). This policy compliments the conflict of interest policy in the Faculty Handbook. The College’s commitment to the research process requires research activities will be carried out with integrity, objectivity and consistent with regulations.

This policy applies to all projects funded, directly or indirectly through a subaward from another organization, by the Public Health Service of the U.S. Department of Health and Human Services (PHS), including all PHS agencies, other than Phase One SBIR or STTR awards. It also applies to research funded by other agencies or foundations that use PHS Financial Conflict of Interest regulations in their award terms.¹

II Definitions

Aggregate means the total of all remuneration, sponsored travel (for PHS investigators), any equity interests and all other monies from a single source.

Conflict of Interest means when there is a divergence between an individual's private interests and his or her professional obligations to the College, such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. An actual conflict of interest depends on the situation and not on the character or actions of the individual. This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs faculty and staff about situations that generate conflicts of interest related to research and sponsored projects, provides mechanisms for Investigators and the College to manage those conflicts of interest that arise, and describes situations that are prohibited. 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 Dean of the College.

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 that the College reasonably determines could directly and significantly affect the design, conduct or reporting of sponsored projects.

¹ Sentence taken from NU policy on Financial Conflict of interest related to Research chrome-extension://efaidnbmninnibpcjpcglclefindmkaj/https://cpb-us-w2.wpmucdn.com/sites.northeastern.edu/dist/b/620/files/2020/09/Policy_on_Financial_Conflict_of_Interest_Related_to_Research.pdf

Institutional responsibilities means the Investigator's responsibilities associated with his or her College appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Investigator means the PD/PI any individual who is responsible for the design, conduct, or reporting of sponsored projects or proposals for external funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Objectivity means being free from external commitments and financial interests of persons who are responsible for the design, conduct, reporting, or direct administration of university research².

Public Health Service or *PHS* means the Public Health Service of the U.S. Department of Health and Human Services, and any components of PHS to which the authority of PHS may be delegated. The components of PHS include, but are not limited to National Institutes of Health, the 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, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, and Substance Abuse and Mental Health Services Administration.

Significant Financial Interest means

- 1) any of the following financial interests held by the Investigator or the Investigator's Family that reasonably appear to be related to the Investigator's Institutional Responsibilities:
 - a. If with a publicly traded entity: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works) and any equity interest (e.g., stocks, stock options, or other ownership interests) when the aggregate value during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000;
 - b. If with a non-publicly traded entity:
 - i. any salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works) when the aggregate amount received during the 12 month period preceding the disclosure exceeds \$5,000; or
 - ii. equity interest of any value held at any point during the 12 month period preceding (or the Investigator's spouse or dependent children) or as of the date of disclosure;
 - c. Income related to intellectual property rights and interests (e.g., patents, trademarks, servicemarks, and copyrights) not reimbursed through the College over is over \$5000. Reimbursed or sponsored Travel with an over \$5000 value undertaken by the Investigator and related to his or her Institutional Responsibilities which is sponsored or reimbursed by an entity other than U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers. This includes travel that is paid on behalf of the Investigator rather than reimbursed. If the exact monetary value is not readily available, reasonable estimates should be used to determine if the travel qualifies as a Significant Financial Interest

Significant Financial Interest excludes:

- 1) salary, royalties, or other remuneration from the College;
- 2) income from the authorship of academic or scholarly works;
- 3) 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

² Sentence taken from Cornell chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://policy.cornell.edu/sites/default/files/vol1_7.pdf

- 4) 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; or
- 5) travel reimbursed by the College, regardless of the source of funds.

Sponsored Travel, for PHS Investigators, refers to travel expenses paid to or on behalf of an Investigator by a single entity in a twelve-month period; and to travel reimbursed or paid on behalf of an Investigator's Family member by a single entity within a twelve-month period if such travel reasonably appears to be related to the Investigator's Institutional responsibilities.

III Policy

The Dean of the College is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Dean of the College is implemented. Violation of any part of this policy may also constitute cause for disciplinary or other administrative action pursuant to College policy.

DISCLOSURE REQUIREMENTS:

All Investigators are required to disclose to the College on an initial, annual, and within 30 days of any discovering or acquiring a new Significant Financial Interest that are related to the Investigator's institutional responsibilities.

The Institution's designated official(s) will review the SFI to determine if it is related to the PHS/NIH - funded research (i.e., could the SFI reasonably appear to be affected by the activities funded or proposed for funding; or is the SFI in an entity whose financial interests would reasonably appear to be affected by such activities. If the designated official determines the SFI is related to the research, the DO determines if the SFI is a FCOI (i.e., the SFI could directly and significantly affect the design, conduct or reporting of the PHS/NIH-funded research. The Dean of the College is responsible for the distribution, receipt, processing, review and retention of disclosure forms and designates the Office for Sponsored Research to administer the disclosure process.

PHS (includes NIH) Investigators – responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding – must disclose **all domestic and foreign Significant Financial Interests (SFI)** to the College on an initial, annual, and ad hoc basis. Under PHS regulations, it is the College, rather than the investigator, that must determine whether a significant financial interest or entity in which the SFI is held would reasonably appear to be affected by the research funded or proposed for funding.

Regardless of the minimum disclosure requirements, the Investigator, must disclose all SFIs that are related to their institutional responsibilities for the institution's determination of FCOI. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

a) Initial Disclosures

Prior to entering into sponsored projects or applications for sponsored projects, the Investigator must submit to the Dean of the College or designee a disclosure of his or her Significant Financial Interests as described above. The College will not submit a proposal on behalf of the Investigator(s) unless the Investigator(s) have submitted such disclosures.

b) Annual and Ad Hoc Disclosures

All disclosures must be updated by investigators while they remain engaged with externally sponsored projects or proposals for such funding, either on an annual basis or within 30 days as new reportable Significant Financial Interests are discovered or acquired.

Disclosures of financial interests must include, at a minimum, the identity of the external entity, the nature of the financial interest, and the value of the financial interest. Disclosures of reimbursed or sponsored travel must include, at a minimum, the purpose of the trip, the identity of the external entity sponsoring or reimbursing the travel, the destination, the duration, and, the monetary or estimated value. The Dean of the College will determine if additional information is needed (e.g., the role of the Investigator in the sponsored project) to determine whether the financial interest constitutes a Financial Conflict of Interest with the Investigator's project.

SUBRECIPEINT REQUIREMENTS

When Babson receives funding from PHS sponsored research, Babson will require in their written agreements that sub recipients will follow the Babson FCOI policy unless the institution has its own FCOI policy that is compliant with FCOI regulation at 42 CFR Part 50 Subpart F, applicable to PHS sponsored research. Sub awardees will notify Babson of any SFI prior to the expenditure of their funds under the subaward.

REVIEW AND DECISION OF THE DEAN OF THE COLLEGE OR DESIGNEE

Disclosure forms will be reviewed promptly by the Dean of the College or designee for a determination of whether it presents a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Dean of the College will take action to eliminate, reduce, or manage the conflict, as appropriate. The Dean of the College may consult other members of the College community, including the Investigator or other faculty or staff familiar with the project and/or with the Financial Conflict of Interest regulations for guidance in specific cases, or in the application of the policy to particular situations.

A Financial Conflict of Interest will exist when the Dean of the College or designee determines that a Significant Financial Interest is related to the PHS-funded research and could directly and significantly affect the design, conduct, or reporting of externally-supported research or other sponsored activity. If the Dean of the College determines that there is a Financial Conflict of Interest that can be managed, the Dean will create a management plan, working with the Investigator that needs to be finalized and in place before any related project activity goes forward. Management of SFI may include but are not limited to modification of the research plan, change of personnel or personnel responsibilities, reduction or elimination of financial interest, or public disclosure of financial conflicts of interests.

To address complex situations, oversight committees may be established by the Dean of the College to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of results, and to otherwise oversee compliance with the management plan.

REPORTING TO SPONSORS

Should any reported conflict or non-compliance require reporting to a Federal agency or other external sponsor, the Dean of the College or designee will report in accordance with that sponsor's regulations. If the funding is made available to Babson College from a prime awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the sponsor.

INVESTIGATOR NON-COMPLIANCE

a) Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Dean of the College may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Dean of the College is implemented.

The Dean of the College'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 Dean of the College, will be described in a written explanation of the decision to the investigator, and, where applicable, the Institutional Review Board.

b) Retrospective Review

In addition, if the Dean of the College determines that 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 Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the Dean of the College or designee will complete a retrospective review of the Investigator's activities and the project within 120 days to determine whether the activity conducted during the period of non-compliance was biased in the design, conduct or reporting of the sponsored project.

Documentation of the retrospective review shall include the project number, project title, PI, name of 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 Dean of the College or designee will update any previously submitted report to the sponsoring agency or the prime awardee relating to the project, 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 sponsor regulations, including a description of the impact of the bias on the project and the plan of action to eliminate or mitigate the effect of the bias.

TRAINING

Each Investigator must complete training on this Policy prior to engaging in externally sponsored activity or proposals, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Dean of the College 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 management plan related to their activities. New PI's will be trained by the Office of Sponsored Research to familiarize them with Babson Policies, a PI's disclosure responsibilities and federal regulation.

RECORD RETENTION

The Office for Sponsored Research will retain all disclosure forms, conflict management plans, and related documents for three years from the date of the submission of the final expenditures report,

CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the College may make such information available to an agency funding

and/or publicly accessible Web Site or to a requestor of information concerning financial conflict of interest related to external funding, if requested or required. If the College is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

PUBLIC ACCESSIBILITY

The College will provide information regarding any currently held Significant Financial Interest that has been determined to be a Financial Conflict of Interest under this policy in response to any written inquiries within five business days of a request. SFI needs to meet the following criteria to be disclosed: the SFI is still held by the PI/key personnel for the NIH-funded research project identified by the Babson and was disclosed, Babson determines that the SFI is related to the NIH-funded research; and Babson determines that the SFI is a Financial Conflict of Interest. The information to be made available are the investigators name, title and role with respect to the research project, name of the entity in which the SFI is held, nature of the SFI, and the approximate dollar value of the SFI or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

REGULATORY AUTHORITY

In accordance with Federal regulations, specifically Department of Health and Human Services regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R.Part 50, Subpart F) and the National Science Foundation (NSF) Investigator Financial Disclosure Policy (NSF 60 FR 35820), the College has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an Investigator. These regulations promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research and other sponsored activities performed under external grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

IV Additional Information

Following are some examples of individual and institutional conflicts of interest. In specific cases, individuals may be able to engage in some of these activities with a suitable management plan:

Undertaking or orientation of the faculty/staff member's college research to serve the research or other needs of a private firm without disclosure of such undertaking or orientation to Babson College and to the sponsoring agency.

Purchase of major equipment, instruments, materials and supplies from a firm in which the employee has an interest without disclosure of such interest.

A company that has made a major gift to the College has requested special consideration in the bidding process as a vendor. The individual considering the bid is a consultant for the company.

Transmission to a private firm or other use for personal gain of government-sponsored work, products, results, materials, records, or information that are not made generally available to Babson College or to the public under the terms of the government award. [Does not preclude appropriate licensing arrangements.]

Use for personal gain or other unauthorized use of confidential information acquired in connection with government-sponsored research. [*Does not preclude appropriate patents, licensing or industrial agreements.*]

Negotiations, or influence upon the negotiations, of contracts relating to research between Babson College and

private organizations with which an employee has consulting or other significant relationships.

A start-up company partially owned by the College has requested a discounted rate in utilizing several College core facilities. The facilities are overseen by an individual who is the chief scientific officer of the company.

Acceptance of gratuities or other financial considerations from private organizations with which Babson College does or may conduct business in connection with a government-sponsored research project, or extension of gratuities or other financial considerations to employees of the sponsoring government agency, under circumstances which might reasonably be interpreted as an attempt to influence the recipients in the conduct of their duties. Specifically, an employee may not receive honoraria, fees for service, or a management position from a private source if that individual is involved in a *federally supported project* that is evaluating or testing a product of the private source.

When the employees engaged in Government-sponsored research also serves as a consultant to a Federal agency.

When the employee consults for one or more Government contractors, or prospective contractors, in the same technical field as their research, care must be taken to avoid giving advice that may be of questionable objectivity because of its possible bearing on other interests.

V Contact Information

Questions can be addressed to Ken Matsuno, Vice President, Academic Affairs and Dean of the College. Horn Library Room 305, Babson College, Babson Park, MA 02457. matsuno@babson.edu

Any request for current SFI at Babson can be made by emailing matsuno@babson.edu