

VIII-4.1 POLICY ON FINANCIAL CONFLICT OF INTEREST IN RESEARCH (FCOI)

Approved: UB UFS 3/7/18; Executive Vice President and Provost 4/2/18;
Maryland Office of Attorney General 12/10/17; President 4/20/18

Proposed Effective Date: upon approval

Periodic Review Date: Every (3) three years

Responsible Department: Office of the Provost – Office of Sponsored Research

Responsible Administrator: Margarita M. Cardona, Assistant Provost for Sponsored Research
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As required by 42 CFR Part 50 & 45 CFR Part 94 – *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50, Subpart F)*, and *Responsible Prospective Contractors (45 CFR Part 94)*, U.S. Department of Health and Human Services.

I. PURPOSE

The University of Baltimore (UB or “the Institution”) adopts this policy is to ensure compliance with all applicable Federal regulations, including the U.S. Public Health Service (“PHS”) regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50, Subpart F) and Responsible Prospective Contractors (45 CFR Part 94). The purpose of this Policy is to comply with federal regulatory requirements and their goal of promoting objectivity in federally funded research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under federal grants, cooperative agreements, and contracts will be free from bias resulting from Investigators’ Financial Conflict of Interest. This policy complements University of Baltimore policy UB VI-8.1 – Professional Commitment of Faculty, where applicable, and the University System of Maryland Policy on Professional Commitment of Faculty.

II. DEFINITIONS

- A. **“Investigator”** – means any individual who is responsible for the design, conduct, or reporting of federally sponsored research, or proposals for such 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.
- B. **“Research”** – means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge, including research relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).
- C. **“Financial Interest”** – means anything of monetary value received or held by an Investigator or an Investigator’s immediate family including domestic partners, regardless of whether the value is readily ascertainable, including, but not limited to salary or other payments for services (e.g., consulting fees, honoraria, or 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.

1. For Investigators, *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 as well as travel that is 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, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

D. “Significant Financial Interest” – Exists when an Investigator (or the Investigator’s immediate family including domestic partners) meets one of these criteria:

- a) 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 of the interest by the Investigator, and the value of any equity interest during the 12-month period preceding or as of the date of such disclosure, exceeds \$5,000; or
- b) 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 Investigator’s disclosure of the interest exceeds \$5,000; or
- c) with a non-publicly-traded company, an equity interest of any value during the 12-month period preceding or as of the date of Investigator’s interest disclosure; or
- d) intellectual property rights and interests upon receipt of income related to such rights and interests not reimbursed through the Institution, or
- e) the Investigator is reimbursed or receives sponsored travel related to his/her institutional responsibilities subject to the exclusion noted in Section II.C.1 above.

1. **Significant Financial Interest does NOT include:**

- a) salary, royalties, or other remuneration from the Institution if the Investigator is currently employed or otherwise appointed by the Institution;
- b) 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; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- c) 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.

E. “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 federally sponsored research.

III. APPLICABILITY

This Policy applies to all University faculty, staff, and student investigators who participate, or intend to participate on federally funded research projects.

IV. POLICY SCOPE

A. DISCLOSURES

1. Proposal & Award Disclosure - All Investigators must disclose their Significant Financial Interests that are related to the investigator's institutional responsibilities to the responsible administrator of this policy during the proposal routing process and/or prior to the participation on a federally funded award. Such disclosures must then be reported to the provost.

2. Ad Hoc Disclosure - In addition to the conditions outlined in IV.A.1 above, certain situations require an *ad hoc* disclosure. All Investigators must disclose their Significant Financial Interests to the responsible administrator:

- 1) Within (30) days after the individual is hired to perform work on a federally sponsored project.
- 2) Within thirty (30) days of discovering or acquiring a new or updated Significant Financial Interest

Prior to participating on federally sponsored projects or submitting applications for federally sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the disclosure or submit to the responsible administrator and President (or designee) an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

3. Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest and Significant 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, if known, the monetary value. The provost or designee will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

B. REVIEW BY THE RESPONSIBLE ADMINISTRATOR AND PRESIDENT OR DESIGNEE

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the responsible administrator of this policy and the provost or his or her designee for a determination of whether it constitutes a Financial Conflict of Interest. A Financial Conflict of Interest will exist when the responsible administrator and/or the president or his or her designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of federally sponsored research. In such cases the Investigator will work with the responsible administrator of this policy to develop and adopt a written management plan prior to the commencement of federal funded project activities.

The responsible administrator will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

V. REPORTING TO FEDERAL GOVERNMENT

The responsible administrator and the Provost (or designee) will report financial conflicts of interest or non-compliance to the federal government in accordance with the applicable federal regulations. If the funding for the Research is made available from a prime awardee of federal funds, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the federal sponsor.

VI. INVESTIGATOR NON-COMPLIANCE

In the event of an Investigator's failure to comply with this Policy, the responsible administrator of this policy and Provost (or designee) may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the President (or designee) is implemented. A decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the responsible administrator or President, will be described in a written explanation of the decision to the investigator, and, where applicable, the University's Institutional Review Board, and will include notification regarding the right to appeal the decision. The institutional official will promptly notify the Federal sponsoring agency of the action taken or to be taken. If the funding for the research is made available from a prime federal awardee, such notification shall be made promptly to the prime awardee for reporting to the federal sponsoring agency.

In addition, if the responsible administrator 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 Provost and/or the Provost' Senior Staff will complete a retrospective review of the Investigator's activities and the federally sponsored research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

VII. PUBLIC ACCESSIBILITY

Prior to the expenditure of funds, UB will respond to any requestor within five business days of the request with information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the senior and key personnel;
- b) A determination has been made that the Significant Financial Interest is related to the Federally funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of applicable federal regulations.

Enclosures:

1. Financial Conflict of Interest Disclosure Form

Conflict of Interest & Financial Conflict of Interest Disclosure

As part of its commitment to promoting objectivity in research and in compliance with applicable federal regulations, non-federal agency guidelines, and the University's Financial Conflict of Interest policy VIII-4.1, the University of Baltimore requires an Investigator to submit a conflict of interest disclosure form with the proposal routing form and to do so prior to submission of the proposal to a Public Health Service (PHS) or to any other Federal agency, including the National Science Foundation (NSF), and to other applicable private foundations/agencies to ensure the design, conduct, and reporting of sponsored program activity will not be biased by significant financial interests or obligations of any investor.

For the purposes of this disclosure form, ***Investigator means any individual who is responsible for the design, conduct, or reporting of PHS, NSF, and other applicable sponsored research/programs, or of proposals for such funding.*** This definition is not limited to those titled or budgeted principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. This definition may also include collaborators or consultants as appropriate.

A revised disclosure form must be filed with the Office of Sponsored Research (OSR) whenever an Investigator has a material change in the significant financial interests or obligations previously disclosed.

The Disclosure of Significant Financial Interests and Obligations ("Disclosure Form") is a two-section form. All Investigators meeting the definition referenced above must complete Section I of the Disclosure Form. If any answer to Section I is "yes", Section II of the Disclosure Form must also be completed. The completed and signed Disclosure Form should be included with the sponsored proposal routing package.

Applicable agency proposals will not be submitted, nor will any applicable award be accepted, until all required Disclosure Forms have been completed, signed by all Investigators, and submitted to the Office of Sponsored Research (OSR). This process will ensure that the University of Baltimore remains compliant with the U.S. Department of Health and Human Services / Public Health Services, the National Science Foundation (NSF), 42 CFR 50 Subpart F and 45 CFR 94, and the University of Baltimore's Financial Conflict of Interest policy available at <http://www.ubalt.edu/policies/>.

Once submitted, Disclosure Forms will be reviewed and maintained in the Office of Sponsored Research. Should a significant Financial Interest (SFI) be identified with the Disclosure Form, the review and subsequent recommendation for management will be conducted by the Responsible Administrator, which is the assistant provost for sponsored research. Questions concerning any research-related disclosure should be addressed to Margarita M. Cardona, Assistant Provost at mcardona@ubalt.edu.

Section I: Disclosure of Significant Financial Interests and Obligations

All University of Baltimore Investigators seeking sponsored funding from a PHS agency, NSF, and other applicable funding agencies per UB Policy VIII-4.1 are required to complete this form before a proposal can be submitted.

Instructions:

Please complete the information requested below and place a check in the appropriate column for each question. Once every question is answered, the investigator must certify the information with a signature at the bottom.

Investigator Name: _____

Department/School: _____

Sponsor/Agency: _____

Project/Program Title: _____

Questions:	Yes	No
Do you or your family member* hold a position of management, such as board member, director, officer, partner, trustee, employee, or consultant with a sponsor, a vendor, or subcontractor related to the proposed sponsored program activity?	<input type="checkbox"/>	<input type="checkbox"/>
Do you or your family member(s) have a Significant Financial Interest (SFI) in a Sponsor, Vendor, or subcontractor related to your proposed sponsored program activity?	<input type="checkbox"/>	<input type="checkbox"/>
<p><i>Significant Financial Interest</i> includes::</p> <p>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 this disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000; or</p> <p>b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month preceding the disclosure exceeds \$5,000; or</p> <p>c) if with a non-publicly traded company, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure; or</p> <p>d) is intellectual property rights and interests upon receipt of income related to such rights and interests not reimbursed through the Institution, or</p> <p>e) reimbursed or sponsored travel related to your institutional responsibilities (teaching, research, academic advising, etc.) excluding travel reimbursed or sponsored by 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</p>		
Could the value of you or your family's Significant Financial Interest reasonable affect the outcome of the proposed sponsored research/activity?	<input type="checkbox"/>	<input type="checkbox"/>

*family member includes immediate family, specifically dependent children, spouse and/or domestic partner

Section I: Disclosure of Significant Financial Interests and Obligations

If you have answered "YES" to ANY of the questions above, please continue to Section II and complete the requested information for every organization with which you have declared a Significant Financial Interest. Please return all completed forms to the Office of Sponsored Research (OSR).

Investigator Certification:

I have read and understood the University of Baltimore's policy on Conflict of Interest and Financial Conflict of Interest.

I have read and understood the Disclosure of Significant Financial Interests and Obligations form, and agree to file a new or updated Disclosure of Significant Financial Interests and Obligations form if any answers to questions above were to change and/or when I establish a Significant Financial Interest with the sponsor and/or any individual or entity related to the program referenced above.

I certify that the answers to the declaration are accurate and truthful to the best of my knowledge.

Signature: _____ Date: _____

Section II: Disclosure of Significant Financial Interests and Obligations

Complete Section II below only if you answered, "YES" to at least one of the questions in Section I.

Investigator's Name: _____

1. Name of organization with which you or your family has a Significant Financial Interest:

2. Type of Significant Financial Interest (check all that apply):
 Consultant Employee
 Equity Interest Recipient of Honoraria
 Recipient of Royalties Other (describe): _____

3. The Significant Financial Interest is between the organization and (check all that apply):
 Self Family Member

4. Have you received in the last twelve (12) months, or do you expect to receive in the next (12) months, payments for salary, director's fees, consulting, honoraria, royalties, or any other payments that, when aggregated with payments from this organization to your spouse, domestic partner, and/or dependent child(ren), will exceed \$5,000?
 Yes No

5. Have you or your family member had in the last twelve (12) months or do you anticipate having in the next (12) months, stock, stock options, or other equity interest in the organization which, when aggregated have a fair market value exceeding \$5,000?
 Yes No

6. What relationship, if any, is there between the business or activities of the organization and your current or planned areas of research or proposed sponsored activity?

I certify that the answers to the declaration are accurate and truthful to the best of my knowledge:

Signature: _____

Date: _____