

**At all times, Morgan State University Policy on Conflict of Interest in Research and Development will have two components: (i) Attachment A - Morgan State University Procedures on Conflict of Interest and Professional Commitment of Faculty and (ii) Attachment B - Morgan State University Procedures for Management of Financial Conflict of Interest in Public Health Service Funded Research attached hereto and posted publicly with this Policy**

**MORGAN STATE UNIVERSITY BOARD OF REGENTS POLICY ON  
CONFLICTS OF  
INTEREST IN RESEARCH AND DEVELOPMENT**

**References: Replacement for Morgan State University Board of Regents Policy on Conflict of Interest for Faculty Interest in Sponsored Research and Economic Development;** Maryland Annotated Code, Maryland Public Ethics Law, General Provisions Article §5-101 et seq., and Maryland Public-Private Partnership Act, §5-525 (Institutions of higher education.

**POLICY ON CONFLICTS OF INTEREST IN RESEARCH AND DEVELOPMENT**

**I. Introduction**

Maryland law encourages public senior higher education institutions to promote economic development in the State and to increase their financial resources through arrangements with the private sector, including collaborative research and development, commercial application of institution-owned intellectual property, and provision of technical assistance. To facilitate these purposes, the Maryland Public Ethics Law allows for the exemption of Morgan State University (“University”) personnel from some of that law's conflict of interest provisions. This policy establishes the essential elements of the procedures, to be adopted by the University, for obtaining such exemptions.

**II. Policy**

A. A present or former official or employee of a unit of the University may have a relationship (as defined herein) with an entity engaged in research or development, or an entity having a direct interest in the outcome of research or development, which relationship would otherwise be prohibited by the conflict of interest provisions of the Ethics Law, if such relationship is disclosed and approved by the President in accordance with the University's faculty conflict of interest procedures developed pursuant to this Policy.

B. The President, or a Vice President or one holding a similar such position may have such a

relationship only if the Board of Regents makes the following findings:

- 1) that participation by, and the financial interest or employment of, the official is necessary to the success of the research or development activity; and
- 2) that any conflict of interest can be managed consistent with the purposes of relevant provisions of the Public Ethics Law.

The Board shall promptly notify the State Ethics Commission in writing of any approval given under this paragraph. In the event that the Commission disagrees with any approval and provides notice to the Board within 30 days of the Commission's receipt of notice of the approval, the Board shall reexamine the matter. The Board shall adopt procedures for handling request for approval under this paragraph.

C. If the above conditions are not met, this Policy does not exempt a former or present official or employee from any of the provisions of the State Ethics Law.

D. Nothing in this Policy allows an exemption on the part of any official or employee of Morgan State University from the provisions of §5-505 ("Gifts or honoraria") of the General Provisions Article. Further, an official or employee of the University may not (1) represent a party for contingent compensation in any matter before the Board of Regents or before the State's Board of Public Works, or (2) intentionally misuse his or her position with the University for personal gain or for the gain of another person.

E. The approval of a relationship under this policy does not relieve the official or employee from the obligation to comply with other University policies, including the University Policy on Professional Commitment of Faculty.

F. The President is encouraged to consult periodically with the Maryland Department of Commerce and with Federal agencies that regulate federally-funded research concerning the implementation of this policy.

### **III. Procedures**

A. The University shall develop procedures based on the above policy and the purposes of the Maryland Public Ethics Law as stated at Section 5-102 of the General Provisions Article of the Maryland Annotated Code. The procedures shall be approved by the Office of the Attorney General and approved as to conformity with the Maryland Public-Private Partnership Act by the State Ethics Commission. The approved procedures shall be filed with the Office of the President and the Board of Regents.

#### **B. Procedures shall:**

- 1) Require timely disclosure of any relationship. The disclosure shall be filed with the State Ethics Commission, and maintained as a public record at the University.
- 2) Subject to paragraph (5), require review of all disclosed relationships by a designated official

who shall determine what further information must be disclosed and what restrictions shall be imposed in order to manage, reduce, or eliminate any actual or potential conflict of interest. The designated official shall also determine whether or not the disclosed relationship represents a harmful interest, as defined herein. If so, approval shall not be granted.

3) Include guidelines to ensure that relationships do not improperly give an advantage to entities with which the relationships exist, lead to misuse of University students or employees for the benefit of such entities, or otherwise interfere with the duties and responsibilities of the official or employee maintaining the relationship.

4) Subject to paragraph (5), require that each relationship be approved or disapproved by the President, with such determination to be the final decision.

5) Require that any relationship maintained by the President or a Vice President, and by one holding any other position designated by the Board of Regents be approved by the Board of Regents.

#### **IV. Reporting**

Divisions shall submit to the President in a format determined by the President a quarterly report which shall include all approvals granted under this Policy. The Board of Regents shall report to the Governor, the Legislative Policy Committee of the General Assembly, and the State Ethics Commission, the number of approvals granted under this Policy and how this Policy and the procedures adopted pursuant to it have been implemented in the preceding year.

#### **V. Definitions**

A. "Harmful interest" means an interest which is found to be so influential as to impair impartiality in the conduct of the research, the interpretation of the results of the research, and/or the determination of research or other professional and employment priorities.

B. "Unit" as used in this policy means any constituent unit of the University (e.g. departments, schools, etc.), centers and institutes and any other unit of the University that the President shall designate.

C. "Relationship" means any interest, service, employment, gift, or other benefit or relationship with an entity that would be prohibited by Title 5, Subtitle 5 of the State's Public Ethics Law if not disclosed and approved pursuant to this Policy and procedures adopted pursuant to it. "Relationship" includes any relationship of the spouse or other relative of an officer or employee if such relationship creates restrictions on the officer or employee under the conflict of interest provisions of the Ethics Law.

D. "Research or development" means basic or applied research or development, and includes the development or marketing of university-owned technology, the acquisition of services of an official or employee by an entity for research and development purposes, or participation in State economic development programs.

**ATTACHMENT A TO THE POLICY ON CONFLICT OF INTEREST  
IN RESEARCH AND DEVELOPMENT**

**MORGAN STATE UNIVERSITY PROCEDURES ON CONFLICT OF INTEREST  
AND PROFESSIONAL COMMITMENT OF FACULTY**

1. Purpose

These procedures implement the Board of Regents (BOR) Policy on Conflict of Interest in Research and Development and Policy on Professional Commitment of Faculty. These procedures outline the mechanisms by which the University will manage the process of identifying, assessing, and responding to potential conflicts of interest or commitment, consistent with State Ethics Law<sup>1</sup> and University policies. They are intended to guide officers, faculty, staff, and other employees at Morgan State University in reviewing and managing the disclosure and resolution of conflicts of interest and commitment, whether real, apparent, or potential.

Neither these procedures, nor the law and Board of Regents' policies under which they have been adopted, exempt any University official or employee from any provision of State Ethics Law, except as specifically provided. Approvals granted under these procedures do not affect the application of other University and BOR policies or the obligation to adhere to other provisions of State Ethics Law.

2. Definitions

- a. Designated Official: The University staff member(s) tasked with reviewing the conflict of interest disclosure form as detailed in Section 5.d.
- b. Unit Head: The role of the unit head is pivotal in these procedures. For the purposes of this document, the unit head is normally the chair or director in an academic department or a similar official (e.g. Vice President) in a non-academic unit, unless a different individual is designated by proper authority.
- c. Relationship: Restrictions on activities sometimes revolve around relationships of a faculty or

staff member with other individuals or entities. As used herein, the term "relationship" includes any interest, activity, service, employment, gift, or other benefit or relationship with an entity not part of State government that would be prohibited by State Ethics Law if not disclosed and approved pursuant to MSU and Board of Regents Policy and these Procedures. An interest or relationship of the spouse or other relative (e.g., parent, child, or sibling) of an officer or employee is included if it would create restrictions on the officer or employee under the conflict of interest provisions of the Ethics Law.

- d. Research or Development: Activities associated with research or development may receive preferential treatment. As used herein, the term "research or development" means basic or applied research or development, and includes the development or marketing of University-owned technology, the acquisition of services of an official or employee by an entity for research and development purposes, or participation in State economic development programs.

### 3. Reporting Procedures

Faculty, staff, and other employees are required to report outside activities and potential conflicts of interest or commitment in accordance with the Policies on Conflicts of Interest in Research or Development and Professional Commitment of Faculty. First, they must provide to their Unit Heads (see Definition 2.a above) timely disclosure of any significant commitment to professional activities to be undertaken outside the University or outside the unit, or situations where conflict or the perception of conflict, may occur. This disclosure should be made before any such commitment is finalized. This mechanism provides a timely opportunity to protect both the University and the individual from adverse consequences that conflicts of interest or commitment can produce. Guidelines for what constitutes a "significant" commitment will be established by each unit head, in consultation with the unit's faculty and with the approval of the Dean or the next level administrator. Second, faculty and exempt staff must complete an Annual Report on Outside Professional Activities, which provides appropriate context in which the unit head can evaluate individual conflict issues, and from which the University can gauge broader trends. In many cases, no further action is required of the individual. The following sections describe how any concerns will be resolved; the procedures are different for conflicts of interest as opposed to conflicts of commitment.

### 4. Resolving Conflicts of Commitment

In cases of potential conflicts of commitment, questions will normally be resolved at the level of the unit head, who is best prepared to judge whether the individual's commitment to institutional responsibilities is in jeopardy. If resolution cannot be made at this level, the matter should be addressed at the next higher level of supervision.

### 5. Resolving Conflicts of Interest in Research or Development

#### a. Activities Related to Research or Development

In recognition of the University's role in promoting economic and technological development in the State, the University has been given the authority (under State law) to consider and waive certain State Ethics Law conflict of interest constraints in connection with research or development activities.

Thus, certain Relationships (see definition 2.b above) that would otherwise violate conflict of

interest provisions of State Ethics Law (and/or University or federal policies) may be permitted under certain circumstances. First, they must involve entities engaged in, or having an interest in the outcome of, Research or Development (see definition 2.c above). Second, they must have been reported, reviewed, and approved in accordance with the following procedures.

Outgoing (or former) officials or employees remain subject to the post-employment restriction in State Ethics Law with respect to certain employment relationships absent an exemption obtained in accordance with these procedures.

These procedures do apply to relationships of the President or a Vice-President (or similar official designated by the Board of Regents). Such relationships must be approved by the Board of Regents in accordance with its Policy on Conflicts of Interest in Research or Development.

*b. Initial Determination by Unit Head*

Based upon the disclosure to the Unit Head (see Definition 2.a above) of an employee's intended outside professional activity or situation, and in view of the employee's existing relation to such activities, if any, the Unit Head typically will determine whether there are any concerns about possible conflict of interest.

If neither the Unit Head nor the individual identify a potential conflict of interest, no further action will typically need be taken with regard to the disclosure under these procedures.

*c. Conflict of Interest Form*

If either the Unit Head or the employee expresses a concern that the activity or relationship may involve a possible conflict of interest, the faculty or staff member must complete a Conflict of Interest Disclosure Form. The form is available from the Office of Sponsored Programs & Research (OSPR). The completed disclosure form provides information on the nature of the activity or relationship. Upon completion, the disclosure form is submitted to the unit head who forwards it for evaluation, through the appropriate dean or similar official, to the President's Advisory Committee on Conflict of Interest ("COI Committee"), a group composed of University faculty and administrators that reports to the Vice President, Research & Economic Development.

It should be noted that submission of a disclosure form may be requested by, or be advisable for the best interests of, the faculty, staff, or other employee concerned, as well as the University. In an era of increasing levels of outside professional activity and interaction with industry of productive research universities, situations can be complex with regard to possible conflicts. In some cases, review of a disclosure form may serve to guide and protect the individual faculty, staff, or other employees in pursuing outside interactions and relationships.

If an activity or relationship has been approved in accordance with the process described below, a follow-up report must be submitted in a timely manner whenever circumstances concerning the activity or relationship change significantly, including a final report when the

activity or relationship ends. The University will request annual confirmation of any activity or relationship that remains in place from year to year.

d. Review of Conflict of Interest Form

i. General Background

- a) After the disclosure form is submitted, the COI review and evaluation process may include further involvement of the faculty or staff member whose activities are being assessed, either by that person providing further information or by his or her assistance in exploring avenues to manage a conflict if one is found to exist.
- b) The COI evaluation process culminates in a written notification from the COI Committee to the faculty or staff member of approval or disapproval by the University. Copies of the completed Conflict of Interest Disclosure Forms are forwarded to the State Ethics Commission, with the original maintained as a public record at the University.
- c) Because disclosure of a significant new outside professional activity or relationship is expected to be made before commencing the activity, it is important that the faculty or staff member make the disclosure in a timely fashion to allow sufficient time for consideration by the unit head and, if necessary, the COI Committee and the President. It is also important that the unit head and the COI Committee provide timely feedback and action so as not unreasonably delay action by the individual in pursuing the new activity.

ii. Initial Review by Unit Heads

- a) Unit heads are responsible for conducting the initial review of the disclosure forms submitted by those within their unit. As part of that initial review, a unit head should attach to a disclosure form a "proposed management plan," including any mechanisms that the unit head considers to be appropriate for managing, reducing, or eliminating real or potential conflicts of interest.
- b) The unit head shall forward the disclosure form, including proposed management plan, through the appropriate dean or similar official, to the COI Committee Chair.

iii. Review by COI Committee

- a) The COI Committee Chair shall forward the disclosure form for consideration by the COI Committee. The COI Committee shall have nine voting members: six faculty members appointed by the President, a member from the Office of Academic Affairs, a member from the Office of Technology Transfer, and the Vice President, Research and Economic Development, who will serve as Committee Chair.
- b) The COI Committee may require that further information be provided and is encouraged to seek information, advice and input from appropriate University personnel, including Unit Heads, deans, University Counsel and the faculty, staff, or other employees involved. The COI Committee may also consult, as appropriate, with the Maryland Department of Commerce and federal agencies that have imposed regulatory requirements on federally funded research.

iv. Recommendation by the COI Committee

The COI Committee shall review the disclosure form and recommend to the President whether the disclosed relationship should be approved. The COI Committee may not recommend approval of any relationship that would:

- a) Give improper advantage to the entity with whom the employee has a relationship;
- b) Lead to misuse of institution students or employees for the benefit of such entities;
- c) Otherwise interfere with the duties and responsibilities of the official, faculty member, or other employee maintaining a relationship;
- d) Be so influential as to impair impartiality in conducting research, interpreting research results, or determining research or other professional and employment priorities; or
- e) Otherwise constitute a harmful interest or violate state or federal policies, or procedures, or the best interests of the University.

A recommendation for approval indicates the Committee's conclusion that any conflict or potential conflict is manageable, in accordance with these procedures and any approved management plan. A decision not to recommend approval signifies the Committee's conclusion that a conflict of interest exists that cannot be properly managed, and that the individual should refrain from participating in the activity or relationship. The COI Committee's recommendations shall be forwarded, through the Vice President, Research & Economic Development to the President.

v. Final Action by the President

Except for relationships involving the President or a Vice President (or similar official as determined by the Board of Regents), which matters shall be forwarded by the COI Committee to the Board of Regents for approval, the President shall review the recommendations of the COI Committee and make a written determination. Approval may be subject to such conditions or restrictions as the President requires. The President's determination is final. Notice of the President's decision will be provided in writing to the faculty or staff member(s), Unit Heads and deans or similar officials involved. Among other things, any notice of approval should inform faculty, staff, or other employees of their continuing obligations to:

- a) Ensure that their activities, statements, evaluations, recommendations, and judgments do not improperly give advantage to an outside entity;
- b) Ensure that unauthorized statistics, documents, reports, comparison information, and other data are not disclosed that would improperly give advantage to an outside entity;
- c) Be aware that legal restrictions regarding misusing their position for personal gain or gain of another, soliciting or accepting improper gifts, and representing a party before the Board of Regents or the Board of Public Works, or other State or local agency for a contingent fee, continue to apply notwithstanding any approval under these procedures; and
- d) Continue to adhere to other University policies and procedures, including those concerning conflicts of commitment and professional commitment of faculty.



Approval may be withdrawn if it is determined that an official, faculty member, or other employee misrepresented the nature of his or her interest in an entity, or if circumstances change in such a way as to create an unacceptable conflict of interest or a violation of University policy or applicable legal requirements. If, after an exemption is granted, a new or unforeseen conflict of interest arises not covered by the previous approval, the official, faculty member or other employee shall promptly disclose such conflict and seek an exemption following the procedures set forth herein.

e. Effect of Non-Compliance on Sponsored Projects

Non-compliance with the conflict of interest policy or these procedures may result in the suspension or termination of a sponsored project. Non-compliance could also result in restrictions on faculty, staff, or other employees with respect to future proposal submissions as well as other sanctions in accordance with University policies, State Ethics Law, or other applicable State or federal laws and regulations.

If the failure of an investigator to comply with Conflict of Interest Policies or Procedures has biased the design, conduct, or reporting of Public Health Service (PHS) funded research, the University must promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and may take, or refer the matter to PHS for, further action, which may include directions to the University on how to maintain appropriate objectivity in the funded project.

f. External Reporting Procedures and Record Retention

The President shall submit quarterly reports of all approvals granted under these procedures involving State Ethics Law to the Board of Regents for inclusion in the Board's quarterly report to the Governor, the Legislative Policy Committee of the General Assembly, and the Ethics Commission and provide supplemental information or develop additional reports or analyses needed for compliance with reporting requirements of the Ethics Law.

Upon completion of the process, copies of all disclosure forms submitted in connection with research and development relationships that are approved shall be filed with the State Ethics Commission. The University, through the COI Committee Chair, will develop and maintain a file, available for public review that will contain all approved relationships with applicable disclosure forms.

OSPR is responsible for providing the appropriate written notice to the awarding agency in those cases involving sponsored projects. As required by agency regulations, information regarding all conflicts of interest identified by MSU will be made available to NSF or HHS upon request. Conflicts that cannot be satisfactorily resolved must be disclosed to NSF and PHS. In the case of PHS awards, notice must be given for all conflict of interest.

OSPR will maintain records of all financial disclosures and of all actions taken to resolve actual or potential conflicts of interest at least three (3) years after termination or completion of the sponsored project or after resolution of any government action involving those records, or as required by applicable state and federal regulations whichever is longer.

6. Resolving Conflicts of Interest Not Involving Research or Development

a. Conflicts of Interest under State Ethics Law

When a conflict of interest not involving research or development arises in the context of State Ethics Law, the State Ethics Commission should be consulted. The State Ethics Commission has the sole authority to interpret State Ethics Law. At the request of the unit head or State Ethics Commission, consulting work or other activities may be suspended pending an opinion from the Ethics Commission. Faculty, staff, other employees, or a Unit Head may seek guidance about consulting with the Ethics Commission from the University's General Counsel's Office.

b. Conflicts of Interest under University Policy

In cases of potential conflicts of interest under University policy that do not involve Research or Development or State Ethics Law, the question will normally be resolved at the level of the unit head. If resolution cannot be made at this level, the matter should be addressed at the next higher level of supervision.

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<sup>1</sup> Among other things, State Ethics Law generally prohibits University employees from having financial interests in or employment relationships (including consulting) with entities under the authority of the University or which have or are negotiating contracts or subcontracts with the University. Other employment relationships (including consulting) prohibited under State Ethics Law include those which would impair the impartiality or independent judgment of the employee and those involving an entity which is a party to a State contract (greater than \$1000) if the employee's duties include matters which substantially relate to the subject matter of the contract. State Ethics Law also prohibits State employees from: participating in matters in which they (or certain family members or business entities) have an interest; soliciting and accepting gifts; using the prestige of their office or confidential information for private gain; and representing parties in State matters for contingent compensation. The conflict of interest provisions of Maryland State Ethics Law are codified in Title 5, Subtitle 5, of the General Provisions Article of the Annotated Code of Maryland.

## **ATTACHMENT B TO THE POLICY ON CONFLICTS OF INTEREST IN RESEARCH AND DEVELOPMENT**

### **PROCEDURES for MANAGEMENT of FINANCIAL CONFLICT OF INTEREST IN PUBLIC HEALTH SERVICE FUNDED RESEARCH**

Morgan State University (“Morgan or “University”), the State of Maryland’s Preeminent Public Urban Research University, adopts these Procedures for Management of Financial Conflicts of Interest in Public Health Service Funded Research (the “Procedures”) in order to comply with the requirements of 42 CFR 50, Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought” which establishes standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

- A. These Procedures apply to any application for or receipt of research funding from PHS, including without limitation the National Institutes of Health (NIH), whether such funding is by means of a grant, cooperative agreement, or contract. However, these Procedures shall only apply to PHS Funded Research with an issue date of the Notice of Award on or after \_\_{*approval date*\_\_}, 2021.
- B. These Procedures apply to each Investigator of PHS-Funded Research.
- C. Any Investigator conducting PHS-Funded Research is also subject to (i) the Morgan State University Board of Regents Policy on Conflicts of Interest in Research and Development approved on May 2, 2017, as may be amended from time to time (the “Policy”) and (ii) the Morgan State University Procedures on Conflict of Interest and Professional Commitment of Faculty, as may be amended from time to time.
- D. Notwithstanding anything contained herein, these Procedures do not apply to any Small Business Innovation Research Program (SBIR) or Small Business Technology Transfer (STTR) Program Phase I applications.

## Definitions

- A. **COI Administrator:** University’s Conflict of Interest Compliance Administrator, as designated by the Vice President for Research and Economic Development.
- B. **COI Committee:** The President’s Advisory Committee on Conflicts of Interest, as appointed from time to time by the University’s President, in accordance with University’s Procedures on Conflict of Interest and Conflict of Commitment.
- C. **COI Official:** University’s Vice President for Research and Economic Development.
- D. **Financial Conflict of Interest (FCOI):** A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-Funded Research.
- E. **Institutional Responsibilities:** An Investigator’s professional responsibilities on behalf of the University including, without limitation, research, education, administrative, and/or service responsibilities, and which may include for example such activities as research, research consultation, teaching, professional practice, committee memberships, and service on research compliance committees such the Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC).
- F. **Investigator:** The principal investigator or project director and any person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-Funded Research
- G. **Manage:** Taking action to address a Financial Conflicts of Interest, which may include reducing or eliminating the Financial Conflict of Interest, to ensure to the extent possible that the design, conduct, and reporting of PHS-Funded Research will be free from bias.
- H. **Management Plan:** A plan to Manage a Financial Conflict of Interest.

- I. **PHS Funded Research:** Any Research which is funded by PHS.
- J. **PHS Regulations:** PHS regulations promoting objectivity in research (set forth at 42 CFR §50.601 *et seq.* and 45 CFR §94.1 *et seq.*), as they may be amended, supplemented, or replaced from time to time, and any other similar PHS regulations that may be promulgated.
- K. **PHS Unit:** The organizational unit of the PHS that funds PHS-Funded Research. PHS Units are the agencies within the Department of Health and Human Services (HHS) designated as components of PHS, as may be changed from time to time, including: (1) the National Institutes of Health (NIH), (2) the Health Resources and Services Administration (HRSA), (3) the Agency for Healthcare Research and Quality (AHRQ), (4) the Centers for Disease Control and Prevention (CDC), (5) the Substance Abuse and Mental Health Services Administration (SAMHSA), (6) the Food and Drug Administration (FDA), (7) the Agency for Toxic Substances and Disease Registry (ATSDR), (8) the Indian Health Service (IHS), and the Office of the Inspector General (OIG).
- L. **Research:** A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge 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). The term includes any such activity for which research funding is available from a PHS Unit through a grant, cooperative agreement, or contract, including without limitation a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
- M. **Senior/Key Personnel:** This term includes the project director or principal investigator and any other personnel identified to be essential to work performance in the sponsored project proposal and award in accordance with 48 CFR §352.242–70
- N. Significant Financial Interest:
1. One or more of the following financial interests (i.e., anything of monetary value, whether or not the value is readily ascertainable) of an Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:
    - a. Remuneration of any value from any entity during the twelve (12) months preceding the disclosure, including without limitation salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship);
    - b. Any equity interest in any entity (including any stock, stock option, or other ownership interest);

- c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests;
  - d. An asset in a blind trust, (i) if the Investigator is aware that the asset is in the trust, or (ii) if the trust is not managed by an independent fiduciary; or
  - e. Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available).
2. The term “Significant Financial Interest” does not include the following:
- a. Salary, royalties, or other remuneration paid by University to the Investigator if the Investigator is currently employed or otherwise appointed by University, including intellectual property rights assigned to University and agreements to share in royalties related to such rights;
  - b. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
  - c. An asset in a blind trust, but only if (i) the asset is not known to the Investigator (e.g., it was purchased by the trust with proceeds from assets originally placed in the trust), and(ii) the trust is managed by an independent fiduciary;
  - d. Income from service on advisory committees or review panels of: a federal, state, or local government agency; an institution of higher education (as defined in 20 U.S.C. §1001(a)); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education; or
  - e. Travel that is reimbursed or sponsored by: a federal, state, or local government agency; an institution of higher education (as defined at 20 U.S.C. §1001(a)); an academic teaching hospital; a medical center; or a (research institute that is affiliated with an institution of higher education.

**O. Unit Head:** The chairperson or director in an academic department or a official in a non- academic unit, unless a different individual is designated by proper authority.

## Requirements

### Designation, etc.

1. The COI Official is designated as University’s institutional official with overall responsibility for the solicitation and review of disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in, PHS Funded Research.

2. The COI Committee is responsible for making determinations regarding Significant Financial Interests, Financial Conflicts of Interest and Management Plans, as provided herein.
3. The COI Administrator is responsible for coordinating and facilitating the processes established to implement this Policy and Procedures and shall coordinate such efforts with  
  
University's Office of Research Administration, Director of Research Compliance and/or the COI Committee, as appropriate.
4. Input and advice may be solicited throughout such processes, as appropriate, from the Office of the General Counsel (OCG), federal agencies and from others unaffiliated with Morgan State University who may have relevant expertise.

## **Training**

Each Investigator who is planning to participate in, or is participating in, PHS-Funded Research must complete training related to financial conflicts of interest (regardless of whether or not a Financial Conflict of Interest exists).

Such training must be completed:

- a. Prior to engaging in PHS-Funded Research;
- b. At least every four (4) years;
- c. If the Investigator is new to the University, within sixty (60) days of the commencement of employment (but not later than the beginning of PHS Funded Research by the Investigator);
- d. Whenever University revises the Policy and/or these Procedures in a manner that affects the requirements of Investigators; and/or
- e. When so directed as a result of an Investigator's non-compliance with the Policy and/or these Procedures or any Management Plan.

Training, or access to training, shall be provided by the University and shall include information regarding the Policy and these Procedures, PHS regulations, and the Investigator's responsibilities under the Policy and these Procedures and the PHS Regulations to disclose Significant Financial Interests of the Investigator (and of the Investigator's spouse and dependent children).

## **Disclosure of Significant Financial Interests**

Each Investigator who is planning to participate in, or who is participating in, PHS Funded Research shall disclose any Significant Financial Interest (including of the Investigator's spouse and dependent children) through his/her Unit Head to the COI Official or designee, if it reasonably appears that a Significant Financial Interest is related to the Investigator's Institutional Responsibilities. Such disclosures shall be made as part of the application submission process.

Alternatively, if no such Significant Financial Interest exists, the Investigator shall so certify as part of the application submission process.

Disclosures of Significant Financial Interests (or certifications that no such Significant Financial Interests exist) shall be made by each Investigator as follows:

- a. At or before the time of submission of an application for PHS-Funded Research;
- b. At least annually during the period of the PHS-Funded Research award;  
The annual disclosure shall include: (a) any new information that was not disclosed either initially or subsequently (e.g. any Financial Conflict of Interest identified on a PHS-Funded Research project that was transferred from another institution); and (b) updated information regarding any previously disclosed Significant Financial Interest (e.g. the updated value of a previously disclosed equity interest);

Annual updates shall be required of all Investigators participating in a PHS-Funded Research project, regardless of whether or not a Significant Financial Interest was previously disclosed.

Within thirty (30) days of the discovery or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.

The disclosures shall include without limitation the following information:

1. The nature and amount of remuneration received from any entity in the twelve (12) months preceding the disclosure;
2. The name and address of the entity;
3. If there is an equity interest in the entity, any value as of the date of disclosure; and
4. With respect to reimbursed or reimbursable travel expenses that require disclosure: the purpose of the trip; the identity of the sponsor/organizer; the destination; and the duration of the travel.

The COI Administrator shall notify the Investigator and/or Unit Head if further information is needed, including without limitation a determination or disclosure of monetary value, in order to decide whether the disclosed Significant Financial Interest constitutes a Financial Conflict of Interest with PHS-Funded Research. The Investigator and/or Unit head shall provide any such additional information, as requested.

### **Determination of Financial Conflicts of Interest**

Prior to University's expenditure of any funds under a PHS-Funded Research project, all Investigator disclosures of Significant Financial Interests shall be reviewed and the following determinations shall be made, as applicable, and



consistent with the Policy and these Procedures and the PHS Regulations.

The COI Committee shall determine, in its reasonable discretion, whether any Significant Financial Interest is related to PHS-Funded Research.

A Significant Financial Interest is related to PHS-Funded Research if (as reasonably determined by the COI Committee):

- (i) the Significant Financial Interest could be affected by the PHS-Funded Research; or
- (ii) the Significant Financial Interest is in an entity whose financial interest could be affected by the PHS Funded Research.

If the Significant Financial Interest is related to PHS-Funded Research, the COI Committee, in its reasonable discretion, shall then determine whether a Financial Conflict of Interest exists.

A Financial Conflict of Interest exists if the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-Funded Research.

The COI Official may authorize the Chair of the COI Committee to designate a Subcommittee to conduct any review and/or determination regarding whether a Significant Financial Interest is related to PHS-Funded Research and/or whether a Financial Conflict of Interest exists.

The COI Committee may involve the Investigator, Unit Head, and others, as provided herein, in the determination of whether a Significant Financial Interest is related to PHS Funded Research and/or whether a Financial Conflict of Interest exists.

If it is determined that (a) Significant Financial Interest is related to PHS-Funded Research and (b) a Financial Conflict of Interest exists, the COI Committee shall communicate the determination to the Investigator and the Unit Head.

### **Management of Financial Conflicts of Interest / Management Plan**

If it is determined that a Financial Conflict of Interest exists, University will undertake such actions as are deemed necessary to Manage the FCOI.

The COI Administrator will work with the Investigator and the Investigator's supervisor and Unit Head to develop an appropriate Management Plan. The purpose of the Management Plan is to establish rules and procedures that provide a reasonable expectation that the PHS-Funded Research associated with the Investigator's Financial Conflict of Interest will be free from bias. The Management Plan must specify the actions that have been, and shall be, taken to Manage any Financial Conflict of Interest in accordance with the Policy and these Procedures and the PHS Regulations.

The Unit Head shall forward the Management Plan, through the appropriate dean or similar official, to the COI Administrator, who shall submit it to the COI

Committee for review and recommendation as to approval. The recommendation of the COI Committee shall be subject to approval by the COI Official.

The COI Administrator, COI Committee, and/or COI Official may require additional information from the Investigator, supervisor and/or Unit Head and may seek input and advice from others, as provided herein, in connection with the development and/or implementation of a Management Plan.

Actions, conditions, or restrictions that may be required under the Management Plan may vary depending upon the nature and extent of the Financial Conflict of Interest. Examples of actions, conditions, or restrictions that might be imposed to Manage a Financial Conflict of Interest include but are not limited to:

1. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the Research);
2. For Research projects involving human subjects, disclosure of financial conflicts of interest directly to participants;
3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the Financial Conflict of Interest;
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 elimination of the Significant Financial Interest (e.g., sale of an equity interest); and/or
7. Severance of relationships that create financial conflicts.

The Investigator's Unit head is responsible for: (a) ensuring that steps set forth in the Management Plan are implemented; and (b) taking reasonable steps to ensure the Investigator's compliance with the Management Plan.

### **Reporting of Financial Conflicts of Interest**

- i. The COI Official shall be responsible for ensuring that all Financial Conflict of Interest reports and other information are submitted to the PHS Unit, as required by the PHS Regulations.
- ii. Such FCOI reports must be filed:
  1. Prior to University's expenditure of funds under a PHS-Funded Research project;
  2. Within sixty (60) days, with respect to any Significant Financial Interest that is identified as a Financial Conflict of Interest subsequent to the initial FCOI report during an ongoing PHS-Funded Research project (e.g., upon the participation of an Investigator who is new to the PHS-Funded Research project); and

3. Annually with respect to any Financial Conflict of Interest previously reported with regard to an ongoing PHS-Funded Research project.

### **New Significant Financial Interests during Ongoing PHS-Funded Research**

This Section applies: (a) whenever an Investigator discloses a Significant Financial Interest that was developed or acquired after Research under a PHS-funded award had begun; or (b) whenever, in the course of an ongoing PHS Funded Research project, an Investigator who is new to participating in the Research project discloses a Significant Financial Interest.

In any such event, within sixty (60) days of the disclosure, the COI Committee (or designated Subcommittee) shall: (a) review the disclosed interest; (b) determine whether it is related to the PHS Funded Research; and (c) if so, determine whether a Financial Conflict of Interest exists.

If a Financial Conflict of Interest exists, University shall implement, on at least an interim basis, a Management Plan that shall specify the actions that have been, and will be, taken to Manage such Financial Conflict of Interest going forward. The COI Official shall report to the PHS Unit as required by the PHS Regulations.

Depending on the nature of the disclosed interest, additional interim measures may be taken with regard to the Investigator's participation in the PHS Funded Research between the date of disclosure and the completion of the review process.

### **Retrospective Review and Mitigation Report**

If a Significant Financial Interest is not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by University during an ongoing PHS-Funded Research project (e.g., was not timely reviewed or reported by a subrecipient), the COI Committee shall, within sixty (60) days of the disclosure: (a) review the disclosed interest; (b) determine whether it is related to the PHS-Funded Research; and (c) if so, determine whether a Financial Conflict of Interest exists.

If a Financial Conflict of Interest exists, University shall implement, on at least an interim basis, a Management Plan that shall specify the actions that have been, and will be, taken to Manage such Financial Conflict of Interest going forward. The COI Official shall report to the PHS Unit as required by the PHS Regulations.

Depending on the nature of the Financial Conflict of Interest, the COI Official may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS Funded Research project between the date that the Financial Conflict of Interest or the Investigator's non-compliance is determined and the completion of the retrospective review process.

In addition, whenever a Financial Conflict of Interest is not identified or Managed in a timely manner (including failure by the Investigator to disclose a Significant Financial Interest that is determined to constitute a Financial Conflict of Interest; failure by University to review or Manage such a Financial Conflict of Interest; or

failure by the Investigator to comply with a Management Plan), the COI Official shall, within one hundred twenty (120) days of the determination of non-compliance: (a) complete a retrospective review of the Investigator's activities and the PHS-Funded Research, or portion thereof, conducted during the time period of the non-compliance; and (b) determine whether or not there was bias in the design, conduct, or reporting of the PHS-Funded Research. The COI Official shall document the retrospective review as required by the PHS Regulations.

Based on the results of the retrospective review, if appropriate, the COI Official shall update the previously submitted Financial Conflict of Interest report, specifying the actions that will be taken to Manage the Financial Conflict of Interest going forward. If bias is found, the COI Official shall notify the PHS Unit promptly and submit a mitigation report to the PHS Unit, in accordance with the PHS Regulations. Thereafter, the COI Official shall submit Financial Conflict of Interest reports annually.

### **Monitoring / Internal Reporting**

Whenever a Management Plan is implemented, the Investigator's Unit Head shall be responsible: (a) to monitor and to take reasonable steps to ensure Investigator compliance with the Management Plan on an ongoing basis until the completion of the PHS-Funded Research project; and (b) to report to the COI Official or designee any non-compliance with the Management Plan.

### **Public Accessibility**

1. Prior to University's expenditure of any funds under a PHS-Funded Research project, University shall ensure public accessibility of information concerning any disclosed Significant Financial Interest that meets the following three criteria: (a) the Significant Financial Interest was disclosed and is still held by Senior/Key Personnel; (b) University determines that the Significant Financial Interest is related to the PHS-Funded Research; and (c) University determines that the Significant Financial Interest is a Financial Conflict of Interest.
2. Such information shall be made accessible via written response to any requestor within five (5) business days of the COI Administrator's receipt of a written request. Such information shall include at a minimum the information required by the PHS Regulations. The response will note that the information provided is current as of the date of the response and is subject to updates, on at least an annual basis and within sixty (60) days of University's identification of a new Financial Conflict of Interest, and that such updates should be requested subsequently by the requestor.
3. Information concerning the Significant Financial Interests of an individual subject to this section shall remain available for responses to written requests, for at least three (3) years from the date that the information was most recently updated.

### **Subrecipient Collaborations (UNIVERSITY as Prime Recipient)**

If University carries out PHS-Funded Research through a subrecipient (e.g., subcontractors, or consortium members), University's Office of Research Administration shall be responsible to ensure that there is a written agreement with the subrecipient which contains terms that establish whether the Policy and/or these Procedures or the financial conflicts of interest policy of the subrecipient will apply to the subrecipient's Investigators.

1. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement shall require that the subrecipient certify as part of the agreement that its policy complies with the Policy, these Procedures, and the PHS Regulations. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the Policy and these Procedures for disclosing Significant Financial Interests that are directly related to the subrecipient's work for University;
2. Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to University. Such time period(s) shall be sufficient to enable MSU to provide timely Financial Conflict of Interest reports, as necessary, to the PHS Unit as required by the Policy and these Procedures and the PHS Regulations;
3. Alternatively, if the subrecipient's Investigators must comply with University's financial conflicts of interest policy, the agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to University. Such time period(s) shall be sufficient to enable University to comply timely with its review, management, and reporting obligations under the Policy, these Procedures, and the PHS Regulations.

The COI Official (in coordination with the COI Administrator and University's Office of Research Administration) shall be responsible to provide Financial Conflict of Interest reports to the PHS Unit regarding all financial conflicts of interest of all subrecipient Investigators consistent with the Policy and these Procedures and the PHS Regulations, *i.e.*, prior to the expenditure of funds and within sixty (60) days of any subsequently identified Financial Conflict of Interest.

#### **UNIVERSITY as a Subrecipient**

1. If University is a subrecipient of PHS Funded Research where another entity is the prime recipient, University's Office of Research Administration shall be responsible to ensure that there is a written agreement with the prime recipient which contains terms that establish whether the Policy, these Procedures or the financial conflicts of interest policy of the prime recipient will apply to University's Investigators.

2. If the agreement specifies that University's Investigators must comply with the prime recipient's financial conflicts of interest policy, then University's Investigators shall so comply with the prime recipient's policy, and these Procedures shall not apply.
3. If the agreement specifies that University's Investigators must comply with these Procedures, then University's Investigators shall so comply with these Procedures, and these Procedures shall apply.

### **Record Retention**

1. The COI Official shall retain all records relating to Investigator disclosures of financial interests; the review of and response to such disclosures (whether or not a disclosure resulted in the determination of a Financial Conflict of Interest); and all actions under the Policy and these Procedures or retrospective review, if applicable.
2. Such records shall be retained for at least three (3) years from the date of submission of final expenditure reports to PHS for each PHS-funded project (or where applicable from other dates specified in the PHS Regulations for different situations).
3. Such records may be destroyed within ninety (90) days following the expiration of the three (3) -year retention period, unless there is relevant pending or active administrative or legal action or otherwise required by applicable law or University policy.

### **Noncompliance**

1. It shall be considered a violation of University policy, subject to disciplinary action in accordance with applicable policies, if an Investigator fails to: disclose a Significant Financial Interest as required herein; (b) comply with an established Management Plan; (c) provide timely annual report information or other required information; or (d) comply with any other requirement of the Policy and/or these Procedures.
2. If the failure of an Investigator to comply with the Policy and/or these Procedures or a Management Plan appears (in the reasonable judgment of the COI Official) to have biased the design, conduct, or reporting of PHS-Funded Research, the COI Official shall be responsible for promptly notifying the PHS Unit regarding the corrective action taken or to be taken, as required by PHS Regulations.
3. In the event that the U.S. Department of Health and Human Services determines that a PHS-Funded Research project involving clinical Research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not Managed or reported by University in accordance with the PHS Regulations and the Policy and these Procedures, such Investigator shall be required to disclose the Financial Conflict of Interest in each public presentation of the results of the Research and to request an addendum to previously published

presentations.

Questions regarding these Procedures and their application should be directed to the Research Compliance Office in the Division of Research and Economic Development (D-RED).