

# UMBC POLICY on Individual Conflicts of Interest in Research and Product Development UMBC Policy # 1.11.01

# I. POLICY STATEMENT

A conflict of interest in a research environment arises in a situation in which the potential exists for a secondary interest, such as financial gain, to cause undue influence over judgment associated with a primary interest such as performing research, reporting research results, or mentoring students. Since conflicts of interest are based on a situation, not an outcome, the integrity or moral character of a person involved in a conflict of interest situation is not relevant in the determination of whether or not a conflict of interest exists. Conflicts of interest, whether actual or perceived, can call into question the integrity of research performed by an investigator at an institution. For this reason, it is necessary for institutions to adopt policies and procedures that appropriately manage, reduce, or eliminate any actual or perceived conflicts of interest.

# II. PURPOSE FOR POLICY

The University of Maryland, Baltimore County ("UMBC") strives to maintain the excellence and academic integrity of a top tier research institution while also promoting the economic development activities and corporate interaction expected of a State university. The pursuit of these two missions increases the likelihood that situations involving individual conflicts of interest will arise. It is important for UMBC to adhere to policies and procedures that address conflicts of interest and also support the university's pursuit of its mission.

Maryland law encourages public 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 creative works, and the provision of technical assistance. To facilitate these purposes, the Maryland Public Ethics Law¹ ("State Ethics Law") allows for the exemption of University System of Maryland ("USM") officials and employees from some of that law's conflict of interest provisions, which otherwise preclude such activities, provided that USM adopts policies and procedures that meet the requirements specified in § 15-523 of the law, and subject to the approval of such policies and procedures by the Office of the Attorney General and the State Ethics Commission.

University System of Maryland Policy. In response to the State Ethics Law, the University System of Maryland (USM) adopted a *Policy on Conflicts of Interest* 

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in Research or Development (BOR Policy III -1.11). This UMBC Policy on Individual Conflicts of Interest in Research and Product Development and its implementing procedures have been developed in compliance with the USM policy as it applies to research and product development activities.

The Public Health Service ("PHS") and The National Science Foundation ("NSF") have taken steps to promote objectivity in research by establishing standards to ensure that there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS or NSF grants or cooperative agreements will be biased by any conflicting financial interest of an investigator<sup>2</sup>. Effective October 1, 1995, all proposals being submitted to NSF and PHS by UMBC, and all current grants from NSF and PHS, are required to include a certification by UMBC that UMBC has implemented and is enforcing a written policy on conflicts of interest. These federal agencies have promulgated regulations that require:

- 1. Individuals to disclose certain financial interests;
- 2. Institutional review of those disclosures;
- 3. Designation of a person(s) to review the disclosures and resolve actual or potential conflicts revealed;
- 4. Arrangements for informing (a) the NSF of conflicts that are not resolved to the satisfaction of UMBC, and (b) the PHS of all conflicts reported, resolved or not; and
- 5. Record retention procedures.

In addition, any subcontractors and collaborators of UMBC must either comply with this Policy or provide assurances to UMBC that they comply with their own policies that meet the PHS and/or NSF requirements, as applicable.

#### III. APPLICABILITY AND IMPACT STATEMENT

This Policy shall apply to all employees, including faculty and staff, students, fellows, visiting scholars and other individuals having a formal scholarly relationship with UMBC, whether or not employed by UMBC, who participate in research and product development activity ("Individual"). This Policy also applies to subcontractors and collaborators of UMBC unless such subcontractors and collaborators have their own policies on conflict of interest, which are acceptable to UMBC.

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# IV. CONTACTS

Direct any general questions about this University Policy first to your department's administrative office. If you have specific questions, call the following offices:

Subject	Contact	Telephone	Email
Policy Clarification	Office of Sponsored Programs	410-455-3140	ospa@umbc.edu
	Office of Technology Dev	410-455-3658	OTD@umbc.edu

# V. UNIVERSITY POLICY

In an effort (i) to preserve the public trust and the academic and research integrity of UMBC and its faculty,(ii) to support UMBC's academic research and economic development missions, and (iii) to comply with the State Ethics Law, USM Policy, and policies established by the NSF and PHS; UMBC has adopted this Policy and its implementing procedures to address situations that involve, or may be perceived to involve, a conflict of interest.

#### **GENERAL PROVISIONS**

- **A. Scope.** This Policy shall apply to all employees, including faculty and staff, students, fellows, visiting scholars and other individuals having a formal scholarly relationship with UMBC, whether or not employed by UMBC, who participate in research and product development activity ("Individual"). This Policy also applies to subcontractors and collaborators of UMBC unless such subcontractors and collaborators have their own policies on conflict of interest, which are acceptable to UMBC.
- **B.** Acceptable Conflicts of Interest. Certain relationships, including certain financial interests that would constitute a conflict of interest, or may be perceived to constitute a conflict of interest, may be permitted if such relationships are first disclosed, evaluated, and approved in accordance with this Policy and its implementing procedures. No Individual shall perform research or product development activity when an unapproved conflict of interest exists, and UMBC shall not enter into any agreement where an unapproved conflict of interest exists, or would be created, on the part of any Individual. Only the President of UMBC can approve a conflict of interest as required for an exemption under the State Ethics Law.
- C. Unacceptable Conflicts of Interest. If a disclosed conflict of interest is found by UMBC to be unmanageable, approval shall not be granted and the activity shall be prohibited. Examples of unmanageable conflicts of interest include, but are not limited to: (i) those perceived to be so influential as to impair impartiality in the conduct of the research or product development, including

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the interpretation of the results of the research or product development; (ii) those that give an unfair advantage to entities with which Individuals have a financial interest; and (iii) those that lead to misuse of the institution's students or employees for the benefit of such entities.

- D. The President and Vice Presidents. The President or a Vice President may have a relationship with an outside entity that would constitute a conflict of interest, or may be perceived to constitute a conflict of interest, only if the Board of Regents grants an exemption after finding that: (i) participation by, and the financial interest or employment of, the President or Vice President is necessary to the success of the research or product development activity; and (ii) any conflict of interest can be managed consistent with the purposes of relevant provisions of the State Ethics Law.
- **E. Reporting**. UMBC shall submit to the Chancellor in a format determined by the Chancellor a quarterly report that shall include all approvals granted under this Policy and how this Policy and the procedures adopted pursuant to it have been implemented in the preceding quarter. UMBC shall also submit to the State Ethics Commission all disclosures of conflicts of interest for which approval for an exemption is granted by the President.
- **F. Records.** UMBC shall maintain records of disclosures that required a management plan or were prohibited. All such records shall be retained for a period of three (3) years following termination of the relationships involved and shall be available to the public. Other agencies may impose longer record-keeping requirements of which UMBC should be cognizant and observant.
- G. Former Policies. This Policy and its implementing procedures replace UMBC's former policies and procedures addressing conflicts of interest UMBC Procedures on Conflict of Interest for Faculty or Employee Interest in Sponsored Research and Economic Development approved May 5, 1993; and Supplement to the UMBC Procedures on Conflict of Interest for Faculty Interest in Sponsored Research and Economic Development effective October 1, 1995.

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# IMPLEMENTATION.

- A. Institutional Procedures. UMBC shall develop implementing procedures based on this policy and the provisions of the State Ethics Law as stated at Title 15 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 Ethics Law by the State Ethics Commission. The approved procedures shall be filed with the Office of the Chancellor.
- **B.** Requirements for Implementing Procedures. The procedures developed to implement this Policy shall:
  - 1. Describe a process that requires Individuals to disclose any financial interests in a company when that company is engaged, or plans to engage, in a relationship with UMBC involving the Individual and any real or perceived conflicts of interest that could develop from such a relationship;
  - 2. Require institutional evaluation of, and action on, all disclosed real and perceived conflicts of interest, as described in this Policy;
  - 3. Ensure that financial interests do not improperly give, or could not be perceived to give, an unfair advantage to entities with which the financial interests exist, lead to misuse of UMBC students or employees for the benefit of such entities, or otherwise interfere with the duties and responsibilities of the Individual maintaining the relationship;
  - 4. Require that each activity that generates a conflict of interest be prohibited unless exempted as described in this Policy by the President, with such determination to be the final decision;
  - 5. Require that the Board of Regents approve any financial interest maintained by the President or a Vice President;
  - 6. Take into consideration relevant federal regulations such as those governing National Institutes of Health, Food and Drug Administration, and National Science Foundation awards and provide procedures that satisfy agency requirements; and
  - 7. Require that records of exemptions granted be maintained in a public file at UMBC.

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#### OTHER PROVISIONS.

- **A. COI Awareness.** UMBC shall make available to Individuals information regarding conflict of interest issues to raise awareness on the UMBC campus.
- **B.** Acknowledgement of Funding Source. Since the source of research funding is of particular interest when considering conflict of interest situations, especially when such funding is provided by a company, Individuals must include in any publications resulting from funding originating outside of UMBC, an acknowledgement of the source of such funding whether or not an actual or perceived conflict of interest exists.
- C. University Support for Investigators. When an investigator acts in good faith to comply with this Policy but requires representation in a lawsuit related to a financial conflict of interest related to his or her research, UMBC shall work with the Attorney General's Office to give support to that investigator.

# VI. DEFINITIONS

- **1. Board of Regents or BOR.** The University System of Maryland Board of Regents.
- 2. COI Committee. Shall mean a faculty, advisory committee to the Provost responsible for reviewing situations involving potential Conflicts of Interest and reviewing COI Management Plans as described in Section VI.A of these Procedures.
- 3. COI Management Plan. Shall mean the plan for managing, reducing, or eliminating a Conflict of Interest, as described in Section V.D.3. of these Procedures. Exhibit D contains an outline of a COI Management Plan.
- **4. COI Statement.** Shall mean a statement signed by an Individual in which the Individual indicates acceptance of, and agrees to abide by, the terms of a COI Management Plan, as set forth in Section V.F. of these Procedures. Exhibit E contains an example of a COI Statement.
- **5. Company** (**ies**). A for-profit entity, including, but not limited to, any form of corporation, partnership, or sole proprietorship; or any individual who is supporting research activity at UMBC for the purpose of Research and Product Development.
- **6. Conflict of Interest or COI.** Any Relevant Interest or Significant Financial Interest of an Individual or a Family Member, or any other financial or non-

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financial interest of an Individual, that could be perceived to directly affect the design, conduct, or reporting of Research, or the mentoring of students; or any Relevant Interest or Significant Financial Interest of the Individual or a Family Member (i) that could reasonably appear to be directly affected by the Research and educational activities funded, or proposed for funding, through UMBC, or (ii) Companies whose financial interests could reasonably appear to be directly and significantly affected by such activities.

- **7. Consulting.** The rendering of paid and unpaid consulting or other professional services outside of the scope of one's role as an official, employee, or faculty member of UMBC.
- **8. Family Member.** Shall mean an Individual's spouse, parent, or child.
- **9. Financial Disclosure Statement.** Shall mean a statement of financial interests as described in Section V.A. of these Procedures. Exhibit C contains a sample Financial Disclosure Form.
- **10. Gift**. Anything of economic value, regardless of form, that is transferred from one party to another without adequate and lawful consideration. A Gift shall include, but not be limited to, the payment of money or anything of value for (i) speaking at, participating in, or attending, a meeting or other function; or (ii) writing an article that has been, or is intended to be, published.
- 11. Institutional Review Board or IRB. Shall have the meaning set forth in 21 CFR 56. For the purposes of these Procedures, the term "Institutional Review Board" or "IRB" shall specifically refer to the IRB responsible for human subjects Research conducted by UMBC investigators.
- 12. Individual(s). All employees, including faculty and staff, students, fellows, visiting scholars, and other individuals having a formal scholarly relationship with UMBC, whether or not employed by UMBC, who have independent responsibility for the design, conduct, or reporting associated with Research, service, educational, Product Development, or other activities, which are funded through, proposed for funding through, or in any way supported by, UMBC.
- **13. National Science Foundation or NSF**. The National Science Foundation, an independent agency of the United States Government, established by the National Science Foundation Act of 1950, as amended.

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- **14. Public Health Service or PHS.** The Public Health Service, an operating division of the United States Department of Health and Human Services, and any components thereof to which the authority involved may be delegated.
- **15. Product Development.** Any activity related to the commercialization of technology or creative works including, but not limited to, research, technology development, licensing, sales, marketing, and the formation of companies.
- **16. Provost.** Shall mean UMBC's Provost, or a designee.
- 17. Relevant Interest(s). A financial interest or other relationship (including Consulting) with a Company that would be prohibited by the State Ethics Law when the Company has or anticipates having contracts or subcontracts with the University or otherwise seeks to do or is doing business with the University. A guideline for determining a Relevant Interest is included in the *Guidelines for Determining Conflicts of Interest in Research & Product Development* (Exhibit A).
- **18. Research.** A systematic investigation, whether or not funded by an external source, designed to develop or contribute to a body of knowledge in such fields, including but not limited to, art and science, public health, the humanities, engineering, and behavioral and social science; and any contracted service activity performed for the benefit of a Company. The term encompasses basic and applied research, service, and Product Development.
- 19. Significant Financial Interest. Anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights) as defined in 45 CFR 94.3. A guideline for determining a Significant Financial Interest is included in the *Guidelines for Determining Conflicts of Interest in Research & Product Development* (Exhibit A).
- **20. Small Business Innovation Research Program or SBIR Program**. The extramural research program for small business that was established by the awarding components of the PHS and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For the purposes of these Procedures, the term SBIR Program includes the Small Business Technology Transfer or STTR Program, which was established by Public Law 102-564.
- **21. State Ethics Law.** The law contained in the *Annotated Code of Maryland State Government Title 15 Public Ethics*.

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# VII. APPROVAL AND PROCEDURES

<u>Procedures to Implement UMBC Policy III-1.11.01 Policy On Individual Conflicts of Interest in Research and Product Development</u>

VIII.	<b>DOCUMENTATION: None</b>	
IX.	RESTRICTIONS AND EXCLUSIONS: No	ne
Х.	RELATED ADMINISTRATIVE POLICIES III-1.11.02 UMBC Interim Policy on Individ in PHS Research	
Admi	nistrator Use Only	
Policy	Number: 1.11.01	
Policy	Section: III Academic Affairs	
Respo	onsible Administrator:	(same as noted in IV above)
Respo	onsible Office: Office of Sponsored Programs	
Appro	oved by President: [date(s)]	
	nally Issued: (date)	
Revisi	on Date(s): Reformatted April 2018.	

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