



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*

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 investigator². 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.

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 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.

IMPLEMENTATION.

- B. 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.
- C. 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.

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-

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.

- 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*.

VII. APPROVAL AND PROCEDURES

These Procedures have been established to implement *UMBC's Policy on Individual Conflicts of Interest in Research and Product Development* consistent with (i) the USM *Policy on Conflicts of Interest in Research and Development* (BOR Policy III – 1.11), (ii) the State Ethics Law, and (iii) regulations promulgated by the Public Health Service and National Science Foundation.

EFFECTIVE DATE

These Procedures shall be effective July 1, 2006.

Purpose. The purpose of these Procedures is to set forth the terms, conditions, and procedures by which UMBC and Individuals may engage in Research and Product Development activities that may have the appearance of a Conflict of Interest or that may be prohibited under the State Ethics Law in the absence of these Procedures. Moreover, the purpose of these Procedures is to identify activities that could be perceived to involve a Conflict of Interest and to manage, reduce, or eliminate such conflicts to preserve the integrity of UMBC's Research, service, Product Development, and educational activities. It is not the intent of these Procedures to supplement or reinforce UMBC's Policy on Conflict of Commitment nor to limit the amount of consulting that an Individual might perform in the absence of a Conflict of Interest.

Applicability. All Individuals shall comply with these Procedures. These Procedures serve to implement the USM policies and the State Ethics Law including, but not limited to, the Public-Private Partnership Act³ as they apply to Research and Product Development activities associated with UMBC. Any situation not addressed by these Procedures may still be subject to the USM Policies and/or the State Ethics Law. These Procedures shall be included in UMBC's *Faculty Handbook*, as directed in Board of Regents Policy II - 1.00, Section I.B.2., and shall be made accessible to all UMBC employees by posting to a Web site where other University policies and procedures are included.

Disclosure and Preliminary Review. Individuals shall disclose information about their Research and their financial holdings in a Company in two cases:

When an Individual is in any way engaged in Research or Product Development with a Company, or anticipates such an engagement, and that Individual or a Family Member to the extent known by the Individual has any financial interest in the Company (excluding stock held as part of a mutual fund); or

When an Individual, or Family Member to the extent known by the Individual, has or anticipates having a financial interest in a Company and the Company, or the Individual's or Family Member's financial interests in the Company, could reasonably appear to be affected by Research or Product Development activities in which the Individual is engaged.

³ State Ethics Law - § 15-523

In either case, the Individual shall disclose in writing information about their Research or Product Development activities with the Company, any financial interests held in the Company by the Individual or a Family Member to the extent known by the Individual, and any potential Conflicts of Interest to the Individual's department chair, supervisor, or the Provost, for review as set forth in these Procedures. Department chairs, supervisors, or the Provost, in consultation with the University Counsel and/or the *Guidelines for Determining Conflicts of Interest in Research & Product Development* (Exhibit A) as appropriate, shall make a determination of whether or not a Conflict of Interest might exist.

COI Review and Management. When it is determined that a Conflict of Interest might exist or at the request of an Individual or a department chair or supervisor, the Provost and University Counsel shall have the responsibility for reviewing the disclosure for any potential Conflicts of Interest; developing plans for managing, reducing, or eliminating any disclosed Conflicts of Interest; and making a recommendation for approval of such plans to the President, when appropriate. The President, or the Board of Regents when an Individual is the President or a Vice President, shall have the ultimate authority to allow or disallow activity that may involve a Conflict of Interest taking into consideration any proposed COI Management Plan. A Conflict of Interest Committee may review Conflict of Interest situations to assist the Provost with making a recommendation to the President. The committee's decisions shall establish precedents for determining, managing, reducing, or eliminating Conflicts of Interest and such precedents shall be documented in the guidelines set forth in Exhibits A and B of these Procedures, as applicable.

Prohibited Activities. Any activity that would constitute a Conflict of Interest under the USM policies addressing Conflicts of Interest or the State Ethics Law, for which UMBC's President or the Board of Regents in the case the Individual, is the President or a Vice President, has not granted approval pursuant to these Procedures, and shall be prohibited.

COI Training. The Provost shall make information and training regarding Conflict of Interest issues available to Individuals.

Acknowledgement of Funding Source in Publications. Notwithstanding any other obligation to legend publications as may be required by a COI Management Plan, Individuals shall acknowledge the source(s) of any funding used to support Research in all publications resulting from that Research.

Use of Facilities. UMBC's facilities, equipment, and other resources may not be used for research benefiting a Company in which an Individual has a financial interest unless subject to a sponsored research agreement, facilities-use agreement, or other appropriate contractual arrangement with UMBC that has been reviewed for Conflict of Interest issues.

PROCEDURES TO ADDRESS INDIVIDUAL COI

Financial Disclosure Statements. When an Individual is required to disclose information about their Research and their financial holdings in a Company as set forth in Paragraph IV.C, above, the Individual shall submit a written Financial Disclosure Statement to his or her department chair or supervisor, or to the Provost, as set forth below. The Financial Disclosure Statement shall contain the following information as it relates to the Company:

Consulting. All Consulting performed in the past year and any active consulting relationships with the Company including, (i) the total consulting fees or other consideration received from the Company, (ii) the amount of time spent consulting with the Company, and (iii) the general nature of the work performed for the Company.

Corporate Research. All active Research or Product Development projects with the Company and any that took place during the past year, whether formal or informal, including without limitation, corporate funded research, and corporate collaborations. For each Research project listed, Individuals shall list (i) the total funding, if any, (ii) the nature of the work, , and (iii) whether or not the Research involves the use of human subjects.

Gifts. All cash, Gifts, honoraria, or other items of monetary value, other than consideration received for Consulting as described in Paragraph V.A.1, and Research funding described in Paragraph V.A.2, above, received directly or indirectly by an Individual, his or her Family Member to the extent known by the Individual, or his or her laboratory from the Company during the past year that exceeded \$1,000 in value. For such Gifts, Individuals shall provide (i) a description of the Gift, and (ii) the amount or value of the Gift.

Corporate Financial Interests. Individuals must list all financial interests in the Company (excluding stock held as part of a mutual fund) including stock or options to purchase stock, licensing agreements involving licensing fees and/or royalties, and any other interest in the Company.

Federal Grants. Individuals must list any federal funding for Research (including, but not limited to, funding from the PHS and NSF) for situations in which (i) the Company may reasonably appear to be affected by the federally funded Research, or (ii) the Individual's financial interests in the Company, if any, may reasonably appear to be affected by the federally funded Research. For such grants, Individuals shall provide (i) the federal granting agency and grant number, (ii) the name of the Company in which a financial interest is held, (iii) a description of how the Company could benefit from the Research, (iv) the value of the financial holdings in the Company, and (v) whether or not the Research involves the use of human subjects.

Conflicts of Interest. Using the *Guidelines for Determining a Conflict of Interest* (Exhibit A), consultation with their department chair, supervisor, or the Provost, and their own best judgment, Individuals must list any potential Conflicts of Interest in which they are involved, including any situations that are the subject of a COI Management Plan or any situation for which they otherwise have received, or would like to receive, an exemption under the State Ethics Law.

Signature block. The submitting Individual, (i) attesting that he or she has completed the form accurately and completely to the best of their knowledge, and (ii) attesting that he or she has read and understood UMBC's Policy on Conflict of Interest and is in compliance with the policy, shall sign the Financial Disclosure Statement.

Timing of Reporting Obligations. Individuals shall always keep their department chair or supervisor informed in adequate detail and in timely fashion regarding all relevant outside professional activities including consulting, service on boards, and other activities; however, when an Individual is required to disclose in writing information about their Research and their financial holdings in a Company as set forth in Paragraph IV.C, above, the Individual shall submit a current Financial Disclosure Statement to their department chair, supervisor (which may be a dean when the Individual is a department chair), or the Provost prior to entering into Research, Product Development, or any other relationship with a Company that would trigger an obligation to disclose pursuant to Paragraph IV.C, above, or at a minimum, on an annual basis by the first of September. Individuals shall submit a Financial Disclosure Statement directly to the Provost as requested by administrative staff when the University is anticipating the completion of a sponsored research, license or other agreement with a Company that involves the Individual.

Role of Department Chair or Supervisor.

Compliance. The department chair or supervisor shall ensure that all direct-report Individuals are aware of their obligations to be familiar with UMBC's *Policy on Conflict of Interest in Research and Product Development* and these Procedures, and that such Individuals – faculty and non-faculty – are aware of their obligations to make the financial disclosures required by these Procedures.

Preliminary Review of Financial Disclosure Statements. The department chair, supervisor, or Provost shall review Financial Disclosure Statements from direct-report Individuals and in consultation with the University Counsel and/or the *Guidelines for Determining Conflicts of Interest in Research & Product Development* (Exhibit A) as appropriate, and shall make a determination whether or not a Conflict of Interest might exist.

When Conflicts of Interest Exist. In the event that a department chair or supervisor determines that a Conflict of Interest might exist, he or she shall so notify the Provost and provide copies of the Individual's Financial Disclosure Statement with a request for a more detailed review and recommendations for a COI Management Plan.

Monitoring of COI Management Plan. The department chair or supervisor shall provide general oversight for direct-report Individuals who have agreed to comply with a COI Management Plan. Department chairs or supervisors shall notify the Provost through the appropriate dean of any discovered noncompliance with a COI Management Plan by an Individual.

Records. The department chair, supervisor, or Provost shall retain copies of direct-report Individual's Financial Disclosure Forms that were deemed not to involve a Conflict of Interest for a period of three (3) years at which time the department chair, supervisor, or Provost shall destroy such documentation. Such Financial Disclosure Forms shall be considered confidential.

Provost's Role. The Provost, in consultation with University Counsel, shall be the institutional official ultimately responsible for reviewing situations involving Conflicts of Interest and developing a COI Management Plan to manage, reduce, or eliminate any such conflicts.

Review of Financial Disclosure Statements. The Provost and University Counsel shall review Financial Disclosure Statements (i) at the request of an Individual, (ii) when forwarded by department chairs or supervisors because a Conflict of Interest situation is suspected, (iii) at the request of department chairs or supervisors when they are unable to make an appropriate assessment due to the complexity of the situation, or (iv) prior to UMBC entering into a research agreement, license agreement, or other contract that warrants a conflict of interest review.

Development of a COI Management Plan. For Financial Disclosure Statements that list a Conflict of Interest or those that are determined by the Provost to have the potential for an actual or perceived Conflict of Interest, the Provost shall develop a COI Management Plan to manage, reduce or eliminate the Conflict of Interest. The Provost shall use the *Guidelines for Determining Conflicts of Interest in Research & Product Development* (Exhibit A), and/or his/her own judgment to determine if a Conflict of Interest exists. The Provost shall use the *Guidelines for Managing Conflicts of Interest in Research & Product Development* (Exhibit B), his/her own judgment, and/or any recommendations made by an Individual's department chair or supervisor to determine how to manage, reduce, or eliminate any potential Conflicts of Interest. When Research involves human subjects, the Provost will incorporate into a COI Management Plan any recommendations made by the IRB (See Section V.D.5, below). The Provost may also decide that certain activities may be prohibited when potential Conflicts of Interest are too difficult to manage, reduce, or eliminate.

COI Management Plan. COI Management Plans shall contain the following sections:

- a. Description of the Relevant Interest and/or Significant Financial Interest.** The COI Management Plan shall contain a detailed description of the Conflict of Interest including (i) all existing and any proposed Relevant Interests or Significant Financial Interests held by the Individual in the Company, and (ii) the Company's current or proposed association with the Individual's Research.

- b. Plan for Management of the Conflict.** The COI Management Plan shall recommend steps to be taken to manage, reduce, or eliminate the Conflict of Interest. The *Guidelines for Managing COI in Research and Product Development* (Exhibit B) contain precedents for managing, reducing, or eliminating Conflicts of Interest established by the COI Committee that should be used to address standard situations involving a Conflict of Interest.
- c. Request for COI Exemption.** When a Conflict of Interest exists for an Individual, a request for an exemption under the Maryland State Ethics Law must be made. The COI Management Plan shall contain a provision requesting approval from the President for such an exemption, as required by the State Ethics Law.

Conflict of Interest Committee. At the discretion of the Provost or at the request of an Individual as set forth in Section V.D.7, below, any COI Management Plan may be submitted to the COI Committee for review. The COI Committee shall meet on an as needed basis at the request of the Provost. The COI Committee shall advise the Provost regarding the approval, approval with modifications, or rejection of a COI Management Plan.

Legal Review. All COI Management Plans shall be submitted to University Counsel for review and approval.

IRB Review. When Research involves human subjects, COI Management Plans must be reviewed and approved by the IRB. The IRB may require additional conditions for performing the Research, which shall be included in such COI Management Plans.

Review by Individual. Once the Provost has developed an appropriate COI Management Plan, a copy shall be provided to the involved Individual and his or her department chair or supervisor for review and comment. At the request of the Individual, the COI Committee shall review the COI Management Plan and any comments provided by the Individual.

Recommendation by the Provost. After taking into consideration all of the information associated with a COI Management Plan, the Provost shall make a recommendation to the President for approval or rejection of the COI Management Plan and shall make such recommendation known to the Individual and his or her department chair or supervisor.

Approval by the President. The President shall make a final decision to accept or reject a COI Management Plan. Approval of a COI Management Plan by the President shall be deemed the approval of an exemption under the State Ethics Law to conduct the activities described in the COI Management Plan. The President's decision shall be final and may not be appealed.

Conflict of Interest Statement. Upon approval of a COI Management Plan by the President, the Provost shall draft a COI Statement (Exhibit E) for signature by the relevant Individual. The COI Statement shall indicate the University's approval of the COI Management Plan and shall contain a statement indicating that the Individual agrees to abide by the terms of the approved COI Management Plan.

Oversight of COI Management Plan. The Provost shall provide copies of approved COI Management Plans and COI Statements to the Individual's department chair or supervisor, and the appropriate academic dean. The Individual's department chair or supervisor shall provide general oversight for direct-report Individuals who have agreed to comply with a COI Management Plan. In addition, the Provost may appoint other individuals to have oversight responsibility for a COI Management Plan. Any suspicion that an Individual is not complying with an approved COI Management Plan must be promptly reported to the Provost. The Provost shall notify the Individual, his/her department chair or supervisor, the appropriate academic dean, and the Vice President for Research of any non-compliance with a COI Management Plan.

Withdraw of Approval. Any approval of a COI Management Plan made by the President may be withdrawn at any time upon the recommendation of the Provost if it is determined that an Individual has knowingly misrepresented or excluded relevant information on a Financial Disclosure Statement or violated the terms of a COI Management Plan, or if it is determined that the best interests of UMBC are not being served by a situation involving a Conflict of Interest.

Conflicts of Interest involving Federal Funding. The Provost shall forward Financial Disclosure Statements and approved COI Management Plans to the Vice President for Research when a Conflict of Interest may be associated with (i) federally funded Research and (ii) Research involving human subjects, including, but not limited to, Research funded by the PHS and NSF. The Provost shall also notify the Vice President for Research of any non-compliance with these Procedures by an Individual or any non-compliance of an approved COI Management Plan by an Individual.

University Contracts. UMBC will not approve any research contracts, including but not limited to, grants, contracts, or cooperative agreements with the NSF and

PHS; license agreements; or other arrangements (i) that may be perceived to involve a Conflict of Interest until an appropriate COI Management Plan has been approved or a determination has been made that a Conflict of Interest does not exist, or (ii) for Individuals who have not complied with these Procedures.

Grant Proposals. Proposals, which might involve a Conflict of Interest, may be submitted to the appropriate funding agency, such as the NSF and PHS, provided that a COI Management Plan has been submitted and reviewed by the Provost; however, account numbers will not be issued until the President has approved said COI Management Plan and a COI Statement has been signed by the Individual. If the President does not approve an appropriate COI Management Plan, UMBC reserves the right to withdraw the grant proposal, refuse the award, or hold any award in abeyance until relevant Conflicts of Interest can be managed, reduced, or eliminated. For ongoing projects in which a Conflict of Interest is disclosed subsequent to UMBC's initial report to NSF or PHS, the Individual must have a COI Management Plan approved by the President, at least on an interim basis, within sixty (60) days after identification to UMBC of the potential Conflict of Interest.

License Agreements and Other Arrangements. Any license agreements or other arrangements that might create a Conflict of Interest, as set forth in the *Guidelines for Determining a Conflict of Interest*, shall require the President's approval of an appropriate COI Management Plan addressing the Conflict of Interest before UMBC will execute the agreement or enter into such other arrangements.

Conflicts of Interest Involving the Provost, a Vice President, or the President. In the event that the President or a Vice President is considered an Individual as set forth in these procedures, he or she shall submit a Financial Disclosure Statement to the Board of Regents, which shall have the responsibility for ensuring that any Conflict of Interest is appropriately managed, reduced, or eliminated. In addition, any Conflicts of Interest involving the President or a Vice President shall be addressed in accordance with the University System of Maryland *Policy on Conflicts of Interest in Research or Development* (BOR Policy III – 1.11).

Reporting.

State Ethics Commission. The President shall be responsible for submitting all approved Conflict of Interest exemptions and associated COI Management plans that involve an exemption under the State Ethics Law to the State Ethics Commission as required by the State Ethics Law.

USM Chancellor. The President or a designee shall submit on a quarterly basis to the USM Chancellor a report outlining all exemption approvals granted by the President under these Procedures and general information as to how the USM policy and these Procedures have been implemented during the reporting quarter.

PHS and NSF. The Vice President for Research, or a designee, shall be responsible for reporting any Conflicts of Interest existing under a PHS proposal or award, including those that could not be resolved. The Vice President for Research, or a designee, shall also have the responsibility to report to NSF or PHS any non-compliance with a COI Management Plan or COI Statement by an Individual under an NSF or PHS award. Any information regarding a NSF or PHS grant related Conflict of Interest identified to or by UMBC will be made available to the Federal Government upon request.

Institutional Review Board. The Vice President for Research, or a designee, shall be responsible for forwarding to UMBC's Institutional Review Board any Financial Disclosure Statements and COI Management Plans when a Conflict of Interest may be associated with Research involving the use of human subjects.

Records. The Provost shall maintain a file of all COI Management Plans, COI Statements, and any related supporting documentation. Such files shall be available to the public in accordance with Maryland's public access to information laws. All COI Management Plans, COI Statements, and any related supporting documentation shall be kept for a minimum of three (3) years following completion of the relevant activity or as may be otherwise required by law.

Research Administration. UMBC employees responsible for approving contracts and other activities associated with Research (including, but not limited to, the Vice President for Research, IRB members, the Associate Vice President for Research, Director of the Office of Sponsored Programs, and the Director of the Office of Technology Development) shall be considered Individuals for the purposes of this Section V. The Vice President for Research shall submit Financial Disclosure Statements to the Provost for review.

ADMINISTRATION

Conflict of Interest Committee. A committee shall be formed to review Conflicts of Interest and make recommendations to the Provost regarding appropriate ways to manage, reduce, or eliminate any Conflicts of Interest. The committee shall be comprised of eight UMBC faculty members who shall be appointed by the Provost and shall serve renewable, staggered, three-year terms. The committee members shall elect a Chair for the committee who shall serve for a term of one year. The Chair may be elected to serve consecutive terms. The Vice President for Research shall be included as an additional voting member of the committee. University Counsel, the Director of the Office of Technology

Development, the Associate Vice President for Research, and one administrative representative from each of UMBC's colleges shall serve as *ex officio*, nonvoting members of the committee.

Review of Procedures. UMBC's Research Council may review these Procedures and recommend changes as deemed necessary, provided however, that changes shall not be made to these Procedures more often than once per year.

Review of Guidelines. The *Guidelines for Determining Conflicts of Interest in Research & Product Development* and the *Guidelines for Managing Conflicts of Interest in Research & Product Development* may change from time to time at the discretion of the Provost subject to the Provost's consultation with the Research Council.

MISCELLANEOUS

Compliance and Sanctions. As set forth in the NSF and PHS guidelines, failure to comply with these Procedures and the underlying Federal regulations may result in the termination of the sponsored activity by the sponsor and/or restrictions on the Individual with respect to future proposal submissions. In addition, failure to comply with these Procedures could lead to sanctions authorized and available under USM and UMBC policies and procedures including, but not limited to, UMBC's Scientific Misconduct Policy or Policy on the Responsible Conduct of Research. Noncompliance with these Procedures may also be a violation of the Maryland State Ethics Law, and other applicable federal laws and regulations.

Policy Conflicts. In the event of a conflict between these Procedures and the State Ethics Law or USM Policy, said Law and/or policy shall take precedence.

VIII. DOCUMENTATION: None

IX. RESTRICTIONS AND EXCLUSIONS: None

X. RELATED ADMINISTRATIVE POLICIES AND PROCEDURES: UMBC III-1.11.02 UMBC Interim Policy on Individual Financial Conflicts of Interest in PHS Research

Administrator Use Only

Policy Number: 1.11.01

Policy Section: III Academic Affairs

Responsible Administrator: _____ (same as noted in IV above)

Responsible Office: Office of Sponsored Programs

Approved by President: _____ [date(s)]

Originally Issued: _____ (date)

Revision Date(s): _____ (date)