

## Procedures to Implement UMBC Policy III-1.11.01 Policy on Individual Conflicts of Interest in Research and Product Development

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.

- A. **Effective Date.** These Procedures shall be effective July 1, 2006.
- B. **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.
- C. **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 Act<sup>3</sup> 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.
- D. **Disclosure and Preliminary Review.** Individuals shall disclose information about their Research and their financial holdings in a Company in two cases:
  - 1. 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
  - 2. 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.

*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.*

- E. **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.
- F. **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.
- G. **COI Training.** The Provost shall make information and training regarding Conflict of Interest issues available to Individuals.
- H. **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.
- I. **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**

- A. **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:

1. **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.
2. **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.
3. **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.
4. **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.

5. **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.
  6. **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.
  7. **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.
- B. **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.

**C. Role of Department Chair or Supervisor.**

1. **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.
2. **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.
3. **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.
4. **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.
5. **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.

D. **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.

1. **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.
2. **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.
3. **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.

- 4. **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.
- 5. **Legal Review.** All COI Management Plans shall be submitted to University Counsel for review and approval.
- 6. **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.
- 7. **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.
- 8. **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.

- E. **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.
- F. **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.
- G. **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.
- H. **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.
- I. **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.
- J. **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.

1. **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.
  2. **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.
- K. **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).

L. **Reporting.**

1. **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.
  2. **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.
  3. **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.
  4. **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.
- M. **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.
- N. **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

- A. **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.*

- B. **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.
- C. **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

- A. **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.
- B. **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.