

Effective Date: June 1, 2011

**University of Maryland
Policy on Identifying and Addressing
Institutional Conflicts of Interest
to Preserve Integrity of Research
and Other Academic Activity**

I. Purpose: The University of Maryland Baltimore adopts this Policy to preserve and enhance integrity of research and other academic activity that could be subject to intentional or unintentional bias as a result of real or perceived Institutional Conflict of Interest (ICOI).

II. Applicability: This Policy applies to all University research and other academic activity, regardless of the internal or external funding sources for the activity.

III. Definitions:

A. Institutional Conflict of Interest (ICOI) – A Significant Financial Interest or Significant Relationship which may compromise University Academic Activity. ICOI may be present or be perceived to be present when the University, its senior leadership, or its investigators and scientists involved in specific University Academic Activity have a Significant Financial Interest.¹ ICOI may be present or may be perceived to be present when the University has a Significant Relationship with persons who are identified with entities (1) that are sponsors of Academic Activity or (2) that have an interest in the outcome of Academic Activity.

B. Academic Activity -- Research (see definition below), including proposed research; also any other activity undertaken by faculty or staff on behalf of the University, including but not limited to: teaching students; participating in continuing education courses; and management of University fiscal, personnel and other resources in support of Academic Activity.

¹ The UMB Procedures Implementing Board of Regents Policy On Conflicts of Interest In Research or Development ("COI Procedures") do not apply to ICOI. In situations involving Individual COI as well as ICOI, disclosure and request for exemption of an Individual COI would proceed as defined in the COI Procedures. The process could be conducted concurrent with, or subsequent to, the review for ICOI. If a matter involves both institutional and individual conflicts, approval of the ICOI and exemption by the President for the Individual COI would both be required before the Academic Activity could begin.

- C. Research** – Systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge or specific knowledge.
- D. University** – (1) University of Maryland Baltimore or any of its administrative or academic units, including without limitation schools, institutes, departments, centers, and programs. (2) University of Maryland Baltimore Foundation, Inc., University of Maryland Foundation, Inc., alumni associations, practice plan organizations, affiliated business entities, and other foundations established by the University pursuant to Board of Regents policies.
- E. Sponsor** – Any person or non-governmental entity (or that entity's subsidiary or affiliate) that is a party to a current grant, contract or other agreement with the University for Academic Activity.
- F. COI Advisory Committee** – The committee of faculty and administrators that advises the President concerning questions of ICOI and individual conflicts of interest.
- G. COI Officer** -- The University official who has responsibility for administration of this Policy.
- H. Individual COI** -- An individual conflict of interest as defined under the Maryland State Public Ethics Law, or federal or state laws or regulations, and managed under the University's COI Procedures.
- I. Significant Financial Interest** -- A Significant Financial Interest that requires an ICOI review is:
1. The University's receipt, or the reasonable expectation of receipt or anticipation of receipt, from a Sponsor or donor, of: more than \$1 million in payment (or pledge or contract for such payment) for, or in support of, Academic Activity, or a comparable amount in any other form of consideration, including a gift, for any purpose. In either case, the Significant Financial Interest occurs only if such payment or consideration is expected to be received: in a fiscal year during which the Academic Activity will occur; within 12 months before the Academic Activity begins; or within 12 months after the Academic Activity terminates.
 2. The University's receipt, reasonable expectation of receipt or anticipation of receipt, from a Sponsor of payment (or pledge or contract for such payment) for Academic Activity and any other consideration for any purpose in a fiscal year, the total of which

is more than 1% of the University's total Sponsored awards for Research and other Academic Activity received for the most recently completed fiscal year. The 1% threshold test shall be applied to the portfolio of the University school, institute, department, center, or program in which the Academic Activity will occur. Pledges of payment shall be counted at present value. Consideration other than cash shall be evaluated at fair market value as of the date of the proposed receipt of consideration.

3. The University's ownership, reasonable expectation of ownership, or anticipation of ownership, of an equity or investment interest in a Sponsor that is greater than 5% of the Sponsor's total equity or investment shares.
4. The University's receipt, or reasonable expectation of receipt or anticipation of receipt (or pledge or contract), from a Sponsor of greater than \$100,000 in gross licensing income, including royalty payments, in a fiscal year.
5. Any University ownership interest in a company, or any payments from a company, including but not limited to licensing income or anticipation of such interest or payments (or pledge or contract for such interest or payments), if the company is marketing or seeks to market a drug, device or technology that is the subject of Academic Activity, or would compete with a drug, device or technology that is the subject of Academic Activity.
6. *This section applies only to University officers and employees who have responsibility for approval, conduct or oversight of Academic Activity supported by or related to a Sponsor, and to members of the COI Advisory Committee. A University officer's or employee's: receipt of more than \$10,000 in cash or other form of consideration from a Sponsor for any purpose, in a fiscal year; financial interest in a drug, device or technology that is the subject (or that is a competitor of the subject) of Academic Activity at the University; ownership of greater than \$10,000 in equity or investment interest in a Sponsor or greater than 5% of the total equity or investment interests of a Sponsor; or employment or membership on the Board of Directors or board of scientific advisers of a Sponsor.² "Financial interest" includes inventorship and authorship unless all claims to licensing*

²In some cases (such as for the President and certain other institutional officials) University System of Maryland policy USM III 1.11 Policy on Conflicts of Interest in Research or Development also will apply.

revenues have been assigned to the University or another third party unrelated to the employee. The interest or compensation received by the spouse, children, siblings and parents of an officer or employee are considered interests or compensation of the officer or employee.

- J. Significant Relationship** – A Significant Relationship is the University’s formal association with a person who represents, or is perceived to represent, a person or entity that sponsors Academic Activity, or that is likely to be affected by the outcomes and findings of Academic Activity, and might benefit from influencing the conduct or reporting of Academic Activity. For this definition, “formal association” refers to a relationship between the University and a person who is a member of one or more of the following: (1) the University System of Maryland Board of Regents, (2) the University of Maryland Baltimore Foundation board of trustees, (3) the University System of Maryland Foundation board of trustees, (4) the board of visitors or advisors of any University school, academic unit or clinical unit, or (5) the governing board or advisory board of any entity that sponsors Academic Activity or has a contractual relationship with the University that gives rise to an interest in the outcome of Academic Activity (e.g., a licensee of University patent rights).

IV. Principles:

- A. University officers or employees (as specified in Section III.I.6. above), employees in the Office of Research and Development, including employees in the Office of Technology Transfer, and University development officers will identify and report to the COI Officer Significant Financial Interests and Significant Relationships relating to Academic Activity at the University. The COI Officer will determine whether or not the matters reported are subject to review and management of ICOI under this Policy and will monitor the development and implementation of management plans for interests and relationships that are subject to this Policy.
- B. The Dean of a school proposing Academic Activity will determine whether or not the school supports the Academic Activity, with or without revisions or conditions to manage the ICOI³, and will identify a funding source, if required, for implementing an ICOI management

³ In cases where the ICOI involves a Significant Financial Interest of any University employee who is not associated with the School in which the Academic Activity is to be conducted, the Deans of the schools involved shall share the Dean’s responsibilities under this Policy. If they bring the President a joint recommendation, the President will consider the ICOI. In cases involving more than one school, the VPAA shall coordinate a joint recommendation, if requested by the Deans involved.

plan. If the Dean does not support the activity or fund the management plan, then no further action is taken and the Academic Activity is not approved.

- C. The COI Advisory Committee will consider the possible effects of ICOI on Academic Activity and recommend an ICOI management plan. In this role, the COI Advisory Committee will defer to the IRB with respect to plans relating to Academic Activity involving human subjects research. The COI Advisory Committee may make recommendations in such cases, but ultimately the IRB will determine whether the ICOI can be managed in a manner that protects human subjects and what management plan is required for approved Academic Activity.
- D. The President will determine whether or not to grant final approval for the Academic Activity, if it is supported by the Dean. For approved Academic Activity, the President shall establish in an ICOI management plan any conditions under which the Academic Activity must be conducted. If the Academic Activity involves human subjects research reviewed by the IRB, any requirements for ICOI management that are established by the IRB will be incorporated in the management plan.
- E. An ICOI management plan may include any or all of the following requirements, or other provisions: public disclosure of approved Academic Activity and the related ICOI, including posting on the University's Research Integrity Office web site; publication of related research results; separating decision-making authority regarding the Academic Activity from decision-making authority regarding any Significant Financial Interest(s) involved in ICOI; and disclosing any Significant Relationships and measures taken to prevent them affecting Academic Activity.
- F. In situations involving ICOI arising from (1) a Significant Financial Interest arising from the relationship between a Sponsor and a specific officer or employee, or (2) a Significant Relationship between the University and individuals associated with the Sponsor, no proposals for Academic Activity at the University may be submitted to that Sponsor without prior approval of the proposed Academic Activity by a Dean or the President, as appropriate. Academic Activity may not begin without the approval of the President of an ICOI management plan and, for research involving human subjects, approval by the IRB.
- G. Approved Academic Activity and the related Significant Financial Interests or Significant Relationships will be reviewed whenever a significant change in the Academic Activity, the Significant Financial Interest, or the Significant Relationship occurs or is anticipated, or

when the Academic Activity is required to be reviewed for continuation or renewal. All such changes must be reported to the COI Officer for review. Unless stated otherwise in the original written determination of the President, the President will also determine whether or not to allow an approved ICOI to continue. The President may request the COI Advisory Committee to review and make recommendations on continuations.

- H. Human subjects research may not be conducted without being reviewed and approved by the Institutional Review Board. The President may not approve human subjects research that the IRB does not allow. The IRB is not required to approve human subjects research that the President has approved.
- I. Sponsors (e.g., the National Institutes of Health) may have requirements regarding the reporting and management of ICOI. In such cases, the requirements of the Sponsor shall be observed.
- J. Where the Academic Activity or ICOI involves another USM institution, the COI Officer will coordinate the determinations of the University and the other USM institution.

V. Procedures:

- A. The Human Research Protections Office and the Office of Research and Development will include appropriate questions to identify ICOI in forms used for routing and approval of proposals for Academic Activity. If ICOI is disclosed to the IRB or to ORD, the office receiving the disclosure will forward the information to the COI Officer for review under this Policy. Independent of disclosures through routing, the COI Officer will routinely gather information related to identification of persons and entities that having Significant Financial Interests or Significant Relationships as discussed above.
- B. When potential ICOI has been identified by, or reported to, the COI Officer, the COI Officer will contact the Principal Investigator (for Research) or faculty or staff member primarily involved (for other Academic Activity), and other persons as appropriate, to discuss the potential ICOI and request all relevant information. The persons contacted by the COI Officer are "ICOI Contacts".
- C. ICOI Contacts must provide relevant information to the COI Officer in a timely manner. This information must include details of the Significant Financial Interest or Significant Relationship, a description of all potentially related Academic Activity, and any proposed ICOI

management plan, including identifying the funding source for any costs of an ICOI management plan. The COI Officer will determine if the Academic Activity is subject to this Policy and will review the information for completeness.

- D. If the Academic Activity is subject to this Policy, the COI Officer will notify the Office of Research and Development (if Sponsored Academic Activity is involved), the IRB (if proposed academic activity involves human subjects), and the relevant Department Chair's and Dean's Offices, informing them of a pending submission for review of ICOI. The COI Officer will present the information to the relevant Department Chair(s) and Dean(s) for review, or, if the ICOI issues involve decision makers at that level, to the President or his designee for review. The Dean, if the reviewer, shall determine whether or not to support the Academic Activity, with or without revisions to manage the ICOI. If the Dean does not support the activity, then no further action is taken and the activity is not approved. If the Dean has a Significant Financial Interest or the Dean's decisions might be affected by a Significant Relationship, the President or designee will make the determination after consulting the Dean. If the President does not approve the activity, then no further action is taken and the activity is not approved.
- E. If the President has a Significant Financial Interest or the President's decisions might be affected by a Significant Relationship, the President will consult the Chancellor, and ask the Chancellor to name a designee to make a determination after consulting the Dean. If the President or designee does not approve the activity, then no further action is taken and the activity is not approved.
- F. If the Dean (or President or designee) supports the Academic Activity, the COI Officer will assemble and prepare relevant materials, including documentation of the Dean's support, and present the matter to the COI Advisory Committee for consideration.
- G. The COI Advisory Committee shall review the information reported by the COI Officer as well as the relevant Academic Activity proposal to determine whether to recommend 1) approving the Academic Activity as described in the proposal and the proposed ICOI management plan; or 2) modifications of the proposal or the management plan which would be necessary for the COI Advisory Committee to recommend approval of the ICOI; or 3) disapproval of the Academic Activity described in the proposal because no adequate ICOI management plan has been proposed or can be developed by the COI Advisory Committee.

- H. The COI Advisory Committee's recommendations will be forwarded by the COI Officer to the ICOI Contact, the Dean of the School in which the Academic Activity is being proposed, and the President.
- I. The President shall determine whether or not to approve the proposed Academic Activity, with or without revisions and/or conditions in an ICOI management plan. The President may consult with the Dean, the COI Advisory Committee, the COI Officer, and the Vice President for Academic Affairs, as well as University administrators and outside advisers, as necessary in order to determine the President's decision concerning ICOI. The President's determination shall be made in writing and shall be forwarded to the Dean of the School and Chair of the Department in which the Academic Activity is proposed to take place, the IRB (if research involving human subjects is involved), the ICOI Contact, and the COI Officer for implementation and monitoring and for posting on the University's Research Integrity Office web site.
- J. If the facts presented by an ICOI also require disclosure and/or exemption for an Individual COI under the Maryland Public Ethics Law, then the COI Officer will assist the individuals involved in the Academic Activity and those having the Significant Financial Interest in disclosing the COI and either requesting an exemption from the President, as provided in the Maryland Public Ethics Law and related policies and procedures of USM and the University, or requesting advice or an opinion from the State Ethics Commission. The COI Officer will coordinate concurrent review of the Individual COI(s) and the ICOI. The President will decide whether or not a proposed Academic Activity will be allowed to proceed concurrently with the Significant Financial Interest based on the circumstances of and recommendations concerning both the Individual COI(s) and the ICOI and will determine the ICOI management plan.
- K. Any administrator or member of the COI Advisory Committee who would be involved in the proposed Academic Activity, or who has any personal financial interest in any entity that would be involved, shall recuse himself from participation in review of the ICOI issue.


VI. Summary of Responsibilities

This Policy assigns the following responsibilities:

Responsibility	Responsible Party
Identify and report to the COI Officer potential ICOI for evaluation	Anyone with access to relevant information

<p>Identify entities and individuals with Significant Financial Interests or Significant Relationships; identify potential ICOI; review reports and information gathered and determine whether or not a potential ICOI falls within the scope of this Policy; refer matters for disposition under other policies as appropriate</p>	<p>COI Officer</p>
<p>Organize information regarding the Academic Activity, the ICOI issues, and the proposed ICOI management plan for review by the Dean, the COI Advisory Committee and the President.</p>	<p>COI Officer</p>
<p>Review the Academic Activity and the related ICOI, and determine whether or not to support the activity, with or without revisions and/or conditions to manage the ICOI.</p>	<p>Dean (or the Vice President for Academic Affairs, if the Dean is conflicted)</p>
<p>Review the Academic Activity and the information relative to ICOI and make recommendations regarding feasibility of management of the ICOI and a proposed ICOI management plan.</p>	<p>COI Advisory Committee</p>
<p>Review the Academic Activity and information related to ICOI, including recommendations of the Dean (or Vice President for Academic Affairs) and the COI Advisory Committee, and determine whether or not to grant final approval for the activity, with or without revisions and/or an ICOI management plan.</p>	<p>President</p>
<p>Monitor the status of the ICOI and compliance with conditions set by the President in the ICOI management plan. Assure that ICOI findings and management plans are provided to the IRB as required by this Policy.</p>	<p>COI Officer</p>

APPROVED:



Jay A. Perman, M.D.
President

DATE:

May 16, 2011