

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

III-1.11(C) | **Academic Affairs** | *Approved December 21, 2023*

Responsible VP/AVP: Susan C. Buskirk, DM, MS

Revision History

Revised June 1, 2011

Purpose

The purpose of this Policy is to set forth the standards and procedures for identification, review, and management of relationships which are deemed to constitute Institutional Conflicts of Interest (“**ICOI**”) (as defined in Section IV).

The scope of an ICOI review involves the financial interests of the University of Maryland, Baltimore (“**University**”) and of those senior leaders acting within their authority on behalf of the University in matters that could (or could reasonably be perceived to) negatively impact the objectivity or integrity of the University’s core missions of research, scholarship, or teaching.

Policy Statement

The University is committed to the highest standards of conduct in its core missions of research, scholarship, and teaching. Relationships of the University and its senior officials with external entities play an important role in supporting the University’s core missions. It is recognized that financial interests arise in the normal course of the University’s operations. However, any Covered University Transaction or Covered Senior Official Relationship must not (or must not be reasonably perceived to) negatively impact the objectivity or integrity of the University’s core missions of research, scholarship, or teaching. Such transactions and relationships must be identified, reviewed, and managed if they constitute an ICOI.

This Policy authorizes the COI Officer and the COI Advisory Committee: (a) to determine whether Covered University Transactions and Covered Senior Official Relationships constitute an Institutional Conflict of Interest; and (b) if so, to mitigate risks of the Institutional Conflict of Interest by formulating ICOI Management Plans.

Definitions

A. COI Officer: The University employee who is designated to administer this Policy.

B. COI Advisory Committee: The University committee which is constituted pursuant to the University Procedures Implementing Board of Regents Policy on Conflicts of Interest in Research or Development (III-1.11(A)).

C. Covered Senior Official Relationship: A relationship of a Senior Official with an external entity: (a) if the relationship is a “*Significant External Relationship*,” and (b) if that entity:

1. Is sponsoring or proposes to sponsor research, scholarship, or teaching at the University;
2. Receives greater than \$100,000 from the University in revenue for purchases or other transactions over a 12-month period; and/or
3. Is licensing or proposes to license intellectual property from the University.

“*Significant External Relationship*” means any of the following which are also reasonably related to the Senior Official’s institutional responsibilities:

1. The Senior Official (or his/her immediate family member) has external engagements with an entity that provides greater than \$25,000 to the Senior Official (or such family member) in income in a 12-month period; *
2. The Senior Official serves as a fiduciary or other senior management role in an entity (such as President, Chief Executive Officer, Chief Operating Officer, Treasurer, Chief Scientific Officer, Chief Medical Officer); or
3. The Senior Official (or his/her immediate family member) owns an ownership interest in the entity (if the entity is privately held, any ownership interest regardless of value, and if the entity is publicly held, an ownership interest valued greater than \$25,000).

* *Significant External Relationship* does not include income from: (1) the University or University of Maryland Faculty Physicians, Inc., or its affiliates; (2) investment vehicles, such as mutual funds and retirement accounts, so long as the individual does not directly control the investment decisions made in these vehicles; or earned income from salary of an immediate family member unless the family member’s position involves a fiduciary duty to the non-University entity.

D. Covered University Transaction: Any of the following:

1. The University receives gift(s) in aggregate from a commercial entity in a 12-month period greater than \$500,000 in total cumulative value, if that entity proposes to sponsor research, scholarship, or teaching at the University.
2. The University receives payments (or has the right to receive future payments) resulting from technology transfer licensing to a commercial entity, including royalty payments, milestone payments and other fees, if the licensed technology is tested or evaluated at the University:
 - a. Using human subject research;
 - b. Using cells that are derived from or mimic human cells; and/or
 - c. Using tissues obtained from human subjects.
3. The University holds equity in a non-publicly traded company, if that entity proposes to sponsor research, scholarship, or teaching at the University.
4. The University holds equity in a publicly traded company (other than through an independent investment vehicle) valued at greater than \$100,000, if that entity proposes to sponsor research, scholarship, or teaching at the University.

E. ICOI Management Plan: A written plan to ameliorate, manage, and mitigate the potential impact of an Institutional Conflict of Interest.

F. Institutional Conflict of Interest (“ICOI”): A Covered University Transaction or Covered Senior Official Relationship which could (or could reasonably be perceived to) negatively impact the objectivity or integrity of the University’s core missions of research, scholarship, or teaching.

G. Senior Official: The President, Provost, Deans, Department Chairs, Division Chiefs, Center/Institute/Program Directors, and Vice Presidents (if they have responsibility for approval, conduct, funding, or oversight of research, scholarship, or teaching at the University).

Scope and Exceptions

This Policy applies to “Covered University Transactions” and “Covered Senior Official Relationships” (as such terms are defined in Section IV) that are determined to constitute Institutional Conflicts of Interest.

Compliance with this Policy only covers review of institutional interests and is separate from and in addition to review under state ethics laws, policies, and procedures concerning *individual* conflicts of interest and conflicts of commitment applicable to faculty and staff. Senior Officials identified in this Policy may have multiple disclosure obligations. Review of a Significant External Relationship under this

Policy is not considered approval of outside professional activities / secondary employment addressed by other policies.

Roles and Responsibilities

Guiding Principles

In the event of a Covered University Transaction or a Covered Senior Official Relationship, the following guiding principles will guide the decision-making process of the COI Officer and the COI Advisory Committee, and the formulation of Institutional ICOI Management Plans:

1. Gifts from commercial entities must not compromise (or appear to compromise) the integrity of University research, scholarship, or teaching.
2. The University's potential to receive financial gain from intellectual property that it owns must not compromise (or appear to compromise) the evaluation or testing of that intellectual property by University personnel.
3. The University's ownership interest in a commercial entity must not compromise (or appear to compromise) the testing or evaluation of the commercial entity's products by University personnel.
4. Senior Officials must not use their official University positions or influence to gain further advancement for themselves, immediate family, or other personal and business associates, at the expense of the University.
5. Significant External Relationships must not compromise (or appear to compromise) the integrity of University research, scholarship, or teaching.
6. University personnel must comply with executed ICOI Management Plans.

Procedures

Identifying Potential Institutional Conflicts of Interest

1. *Semi-Annual Reports.* At least semi-annually, the following offices shall provide information to the COI Officer, in order to enable the COI Officer and the COI Advisory Committee to identify Covered University Transactions:
 - (i) *Office of Technology Transfer:* Information regarding transactions with commercial entities

during the previous semi-annual period which satisfies the definition of Covered University Transactions.

(ii) *Office of Sponsored Programs Administration*: Information regarding research sponsored during the previous semi-annual period which satisfies the definition of Covered University Transactions.

(iii) *Office of Clinical Trials and Corporate Contracts*: Information regarding research sponsored during the previous semi-annual period which satisfies the definition of Covered University Transactions.

(iv) *Office of Philanthropy*: A list of commercial entities that donated gifts in aggregate of \$500,000 or more in the previous semi-annual period, and the University departments and administrative units that were the recipients of those gifts.

2. *Senior Official Disclosures*

(i) Senior Officials must complete and submit to the COI Officer an annual ICOI disclosure form, by May 15th each calendar year in which all Significant External Relationships must be reported.

(ii) Senior Officials who report a Significant External Relationship may be required to also submit to the COI Officer a copy of the relevant sections of the annual Financial Disclosure Statement that they file with the Maryland State Ethics Commission.

(iii) Senior Officials who have no Significant External Relationships to report must submit an attestation that they have no such relationships to report.

(iv) Senior Officials must update their disclosures during the year as emerging circumstances warrant (e.g., a new consulting agreement; appointment to a Board of a commercial entity; etc.).

Reviewing Potential Institutional Conflicts of Interest

1. The COI Officer will review each ICOI disclosure. If the disclosure sets forth a Covered Senior Official Relationship that in the judgment of the COI Officer constitutes an Institutional Conflict of Interest, then the COI Officer will make a recommendation to the COI Advisory Committee.
2. The COI Officer and the COI Advisory Committee will determine whether a Covered University Transaction or Covered Senior Official Relationship constitutes an Institutional Conflict of Interest. If so, the COI Officer and the COI Advisory Committee will recommend a course of action to manage the Institutional Conflict of Interest and formulate an ICOI Management Plan.
3. The COI Advisory Committee will provide a report with its recommendations and the ICOI Management Plan to the COI Officer and the Provost. The Provost may either approve, modify, or reject them. If the Provost approves them, he/she will forward them to the President for his/her approval.
4. If the President has an Institutional Conflict of Interest, he/she must recuse himself/herself and defer to the Chancellor of the University System of Maryland, who will create and approve an ICOI Management Plan for the President in consultation with the Provost.
5. If the Provost has a potential Institutional Conflict of Interest, he/she must recuse himself/herself from the review process. In such cases, the President will review the report and recommendations of the COI Advisory Committee and determine the course of action.

ICOI Management Plans

ICOI Management Plans may consist of one or more of the following:

1. Recusal of a Senior Official from the chain of authority over a transaction or project (including a research study) and from supervision of personnel conducting the activity, and appointment of a nonconflicted individual to assume this role.
2. For research studies, disclosure of the ICOI to all stakeholders (including all investigators conducting the study, the sponsor, and the public in presentations and publications).
3. For human subject studies, disclosure of the ICOI in consent forms and/or to applicable regulatory bodies, as well as to University and external IRB, external biostatisticians, external contract research organizations and/or an external Data Safety Monitoring Board (“DSMB”).
4. Reduction or elimination of transactions or other engagements with an external entity.
5. Recusal from decision-making or from participation in an activity that would directly or indirectly involve the person’s financial interest.
6. Declining gifts or funding for sponsored research projects or other activities.
Divestment of a financial interest.

Oversight of ICOI Management Plans.

The COI Officer and the COI Advisory Committee are responsible for verifying compliance with any ICOI Management Plans at least annually, and for modifying the plans to address any issues that arise.

Noncompliance

Senior Officials are expected to provide complete and truthful information relating to their external engagements that may give rise to the involvement of the COI Advisory Committee or an ICOI Management Plan. Noncompliance with an executed ICOI Management Plan, failure to disclose, or the submission of erroneous, misleading, or incomplete information may be the subject of disciplinary procedures and sanctions. The COI Official or the COI Advisory Committee shall refer concerns relating to noncompliance, failure to disclose, or submission of inaccurate information to the President, Provost, or other appropriate University authority for review.