

Conflict of Interest in Research & Development

Educational Slide Deck

**Prepared by the Conflict of Interest Committee
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Conflict of Interest in R&D: Topics

Background

- A. Conflict of Interest (COI), and COI in R&D
- B. The Maryland Public Ethics Law
- C. Maryland Law Allowing “COI Exemptions in Research and Development”
- D. Role of the State Ethics Commission
- E. Sponsored Research and COI

COI At Morgan

- A. How is the COI in R&D Process Managed at Morgan?
- B. Who May Apply for COI Exemptions for R&D?
- C. What is the Process?
- D. What is Morgan’s COI Committee’s Role?
- E. Where can I find the COI Application Form and other resource information?

Conflict of Interest in R&D

Conflict of Interest

A potential conflict of interest exists when there is a possibility for an individual's outside financial interests to directly and/or significantly affect the individual's professional actions or decisions.

Where can a conflict of interest occur?

- Purchasing and other business relationships
- Gifts
- Employment
- Technology licensing
- Activities of family members
- **Research (Conflict of Interest in R&D)**

Maryland Public Ethics Law

Maryland's Public Ethics Law

- The Law was enacted to:
 - 1) Assure the people of the impartiality and independent judgment of State officials and employees;
 - 2) Avoid improper influence or even the appearance of improper influence; and
 - 3) Require officials and employees to disclose financial affairs and to meet minimum standards of ethical conduct. The State Ethics Commission (SEC) administers the Public Ethics Law to guard against improper influence on public officials or the appearance of conflict of interest.

Maryland Public Ethics Law

Five Examples of COI: An official or employee may not:

- Hold any employment relationship that would impair their impartiality or judgment.
- Participate in a matter in which they have an interest. This prohibition also applies where an official's or employee's relatives have such a relationship.
- Participate in a matter when one of the parties is a business entity in which they have an employment, contractual or creditor relationship.
- Solicit any gift for themselves or for others.
- Intentionally use the prestige of their office for personal gain, or that of another.

If an official or employee anticipates engaging in some activity that may raise an issue under the Ethics Law, they should contact the State Ethics Commission (SEC) staff. Often the issue can be resolved by guidance at the staff level, or on an informal basis by the SEC.

For additional information <https://ethics.maryland.gov/public-ethics-law/>

Then click on “Public Ethics Law Summary”

Exemptions for Conflict of Interest in R&D

- **Maryland law encourages public senior 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 provision of technical assistance.
- To facilitate these purposes, the Maryland Public Ethics Law allows for the exemption of Morgan State University personnel from some of that law's conflict of interest provisions.
- **The University Board of Regents** has approved a Policy for Conflicts of Interest in Research and Development. The Policy and Procedures for obtaining exemptions, are approved by the State Ethics Commission.

Morgan's Conflict of Interest Policy

Morgan COI in R&D Policy Goals

- Protect Research Participants
- Protect the Integrity of the Research
- Protect the Institution, Faculty, Employees and Students
 - Funding Status
 - Litigation
 - Reputation/Public Image
- Best Policy Practices

Potential for Conflict of Interest in R&D

Sponsored Research and COI

In the sponsored research setting, a potential conflict exists when:

there is a possibility that an individual's outside financial interests, or employment, could affect the design, conduct, or reporting of the research.

Conflict of Interest in R&D: Reporting

Reporting COI Exemptions to the State's Ethics Commission

- The University shall report all approved COI Exemptions to the State Ethics Commission on a quarterly basis with copies of all COI Disclosure Forms submitted in connection with research and development relationships that have been approved.
- The University, through the COI Committee Chair, will develop and maintain a file, available for public review that will contain all approved relationships with applicable COI Disclosure Forms.
- Approved COI Exemptions are subject to Annual Update Reports to the COIC.

State: Financial Interests & Conflict of Interest in R&D

An official or employee may not "be employed by" or "have a financial interest in" an entity that does business with the official's/employee's agency or that is regulated by the official's/employee's agency.

There is no threshold for employment. "Be Employed by" includes, but is not limited to, faculty consulting/contractual service agreements.

Maryland Law defines "Financial Interest" as:

- Ownership of more than 3% of a business entity by board member or employee **or spouse of board member or employee**
- Ownership of securities that represent more than 3% of a business entity by board member or employee **or spouse of board member or employee**
- Ownership of an interest (e.g., shares) with a market value of more than \$1,000.

Federal: Financial Interests & Conflict of Interest in R&D

- Under federal law, a “financial interest” is an interest of more than \$5,000 per year in outside income.
 - A financial interest consists of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appear to be related to the Investigator’s institutional responsibilities:
 - Salary;
 - Any payment for services (e.g., consulting fees, honoraria, paid authorship); and
 - Equity interest holdings, including any stock, stock option, or other ownership interest.
- *Significant financial interest* does not include financial interests (salary, royalties, or other remuneration) paid by the Institution to the Investigator. This also does not include equity considerations held by the institution to be shared with the investigator under IP Policy provisions.

Q&A on Conflict of Interest in R&D

Summary Q&A

- How do you know if there is a potential for COI in R&D?
 - Discuss with your dept. chair/unit head, COI Committee member or OTT
- How do you report a potential COI in R&D?
 - COI Disclosure Form is Submitted to Department Chair/Unit Head; Dean/VP
 - Form is Submitted to COIC Committee Chair for Review
 - Either no COI Exists, or a COI Form with Management Plan is Submitted to COIC
 - COIC Reviews; Determines Recommendation Exemption (to MSU President)
- How can you mitigate/manage COI in R&D?
 - Discuss early with a COI committee member for guidance or referral
 - Many COI in R&D are manageable under an approved COI Management Plan
 - Discuss with the Office of Technology Transfer if the COI is related to Morgan Intellectual Property or Technology Transfer

Q&A on Conflict of Interest in R&D

- Go to the Morgan COI Website for more specific information and resources

<https://www.morgan.edu/office-of-research-administration/research-compliance/conflict-of-interest>

- COI Policy and Procedures
- COI Disclosure Form
- Process Description and Flow Chart
- Guidance Materials for Faculty and Staff
- Information, Education and Training Materials
- COI Committee Member List
- Update on COI Committee Work
- Minutes of COI Committee Meetings and Meeting Schedule