

# **UPDATES TO COMLS CONFLICT OF INTEREST DISCLOSURE**

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**May 30, 2024**



**THE UNIVERSITY OF  
TOLEDO**

# DISCLAIMER

- University policy terms control in the event any statements in this presentation or discussion are inconsistent with the policy.
- The information provided in this presentation is for educational purposes only. It is not legal advice and should not be construed as such.
- Consult with your legal counsel to obtain legal advice.
- University employees seeking legal advice related to university business or affairs should refer to the [Use of Legal Counsel Policy](#).

# “**BUT I AM NOT BIASED...**”

- COI ≠ individual character or intent
- COI = situation and appearance
- **COI definition** - might bias – or reasonably appear to bias
- COI may exist regardless of whether decisions are affected by a personal interest.



**Name of Policy:** College of Medicine & Life Sciences:  
**Individual Conflict of Interest in**  
**Education and Clinical Care**

**Policy Number:** 3364-81-01-004-01

**Approving Officer:** Executive Vice President for Clinical  
Affairs/Dean of College of Medicine and  
Life Sciences

**Responsible Agent:** Associate Dean for Faculty Affairs

**Scope:** College of Medicine and Life Sciences

**Effective date:** December 18, 2020

**Original effective date:** 07/01/2012

|                                     |                                   |                          |   |
|-------------------------------------|-----------------------------------|--------------------------|---|
| <input type="checkbox"/>            | New policy proposal               | <input type="checkbox"/> | Minor/technical revision of existing policy |
| <input checked="" type="checkbox"/> | Major revision of existing policy | <input type="checkbox"/> | Reaffirmation of existing policy            |

**Today we are discussing**

**Name of Policy:** [Financial Conflict of Interest](#)

**Policy Number:** 3364-70-01

**Approving Officer:** President

**Responsible Agent:** Vice President for Research

**Scope:** All University of Toledo Campuses



**Effective date:** July 22, 2020

**Original effective date:** March 25, 2008

|                                     |                                   |                          |   |
|-------------------------------------|-----------------------------------|--------------------------|---|
| <input type="checkbox"/>            | New policy proposal               | <input type="checkbox"/> | Minor/technical revision of existing policy |
| <input checked="" type="checkbox"/> | Major revision of existing policy | <input type="checkbox"/> | Reaffirmation of existing policy            |

**...which is distinct from...**

**Name of Policy:** Conflict of interest and nepotism

**Policy Number:** 3364-25-18

**Approving Officer:** President

**Responsible Agent:** Chief Human Resources Officer;  
Provost and Executive Vice President for Academic Affairs

**Scope:** All University of Toledo campuses



**Effective date:**  
October 20, 2023

**Original effective date:**  
June 22, 2011

**Keywords:**

|  |                                   |   |   |
|--|-----------------------------------|---|---|
|  | New policy                        | X | Minor/technical revision of existing policy |
|  | Major revision of existing policy |   | Reaffirmation of existing policy            |

...and is distinct from...

## Conflict of interest

Note that this list does not reflect the total number of policies that may relate to a topic but rather those that are most commonly applicable. To search the entire library for a particular policy subject or policy category, enter a key word in the Search Box on the left side, or browse by category.

- [Commercialization policy](#)
- [Conflict of interest for members of the board of trustees](#)
- [Conflict of interest and disclosure \(CME\)](#)
- [Facilities and administration policy](#)
- [Faculty consulting](#)
- [Financial conflict of interest policy for sponsored programs](#)
- [Individual conflict of interest in education and clinical care](#)
- [Interactions with the Pharmaceutical and Medical Device Industry and other Vendors at the University of Toledo Health Science Colleges and at The University Medical Center](#)
- [Conflict of interest and nepotism](#)
- [Principal investigator/project director responsibilities on sponsored projects](#)
- [Separation of Roles Among Academic Advisers to Ensure Confidentiality and Absence of Conflict of Interest in Medical Student Promotion and Evaluation Decisions](#)
- [Separation of Roles to Assure Confidentiality in the Provision of Health and Counseling Services to Medical Students and Absence of Conflict of Interest in Medical Student Evaluation, Promotion, and Dismissal](#)
- [The University of Toledo's Title IX \(sexual misconduct\) policy](#)
  - 3364-50-01.01 Title IX Procedures
- [Small business innovation research and small business technology transfer programs](#)

State Ethics Laws:

Chapter 102 of the Ohio Revised Code

Chapter 2921 of the Ohio Revised Code



# OHIO ETHICS LAW

- Compliance is solely the individual's responsibility
- Applies regardless of any determination made by the University
- The commission provides educational materials and resources
- The commission is available to provide advice and opinions regarding the application of the ethics law and related statutes.



# UToledo Faculty Rules and Regulations for Faculty not bound by Collective Bargaining Agreements

## H. Faculty Duties and Responsibilities

### 3. Professional activities conducted elsewhere

Lectureships, training, consulting arrangements, research and other professional activities that are conducted as extramural activities are encouraged to the extent that they do not interfere with the performance of primary duties and responsibilities at the University or impair the performance of the individual as a scholar, teacher, researcher, or administrator or create a conflict of interest. Such activities will require the prior approval of the department chair, dean of the appropriate college, and the Provost, and be in compliance with all University policies.

### 4. Clinical Practice



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## **(D) Responsibility to Disclose**

**(1) Conflicts of Interests for Faculty and Educational Administrators within the College of Medicine and Life Sciences may occur or appear to occur with outside entities during ongoing and legitimate research, professional, educational, and/or clinical activities. All COI are strongly discouraged but are sometimes unavoidable. Because even the appearance of a COI could have a negative impact on a Faculty member's or Educational Administrator's institutional responsibilities – and therefore reflect negatively on the University as a whole – it is the responsibility of the individual to disclose known and potential COI to the University to facilitate appropriate interventions and management or elimination of the COI.**

**Two major categories of conflicts of interest that may bias, or reasonably appear to bias, the education and clinical missions:**

**1. Financial Interests**

**2. Significant Relationships**

# 1. Financial Interests

- A. Equity interest in publicly traded or non-publicly traded company (*except mutual/pension funds*)
- B. Intellectual property rights (patents, copyrights, royalties), including those with potential value, that are the subject of educational or clinical activity
- C. Consulting fee, salary, honoraria, speaker fee, gift, payment, “in kind” compensation, cost of travel, lodging, etc. (*except scholarly communications, UTP practice plan, expected professional service with nominal honorarium*)

## 2. Significant Relationships

- A. Officer, director, board member of commercial sponsor of research, education, or clinical activity (paid or unpaid)
- B. Appointment to a scientific advisory board of a commercial sponsor of research, education, or clinical activity *(unless you have no financial interest in the sponsor or its products and agree not to have financial interest for 3 years)*

**College of Medicine and Life Sciences – University of Toledo**  
**Conflict of Interest in Education and Clinical Care Disclosure Form**

As outlined in University of Toledo (UToledo) College of Medicine and Life Sciences (COMLS) policy 3364-81-01-004-01 and in the Liaison Committee on Medical Education (LCME) Standard 1.2, all COMLS faculty and education administrators are required to submit conflict of interest (COI) disclosures to identify, manage, and provide appropriate oversight or elimination of situations that pose an actual or perceived COI in the operation of the medical education program, its associated clinical facilities, and any related enterprises.

\* Indicates a required field

|                                    |                      |
|------------------------------------|----------------------|
| <b>Name: First, Middle, Last</b> * | <input type="text"/> |
|------------------------------------|----------------------|

|                 |                      |
|-----------------|----------------------|
| <b>Email:</b> * | <input type="text"/> |
|-----------------|----------------------|

|                         |   |                      |                      |
|-------------------------|---|----------------------|----------------------|
| <b>Academic Rank:</b> * | <input type="text" value="Select One"/> | If Other enter here: | <input type="text"/> |
|-------------------------|---|----------------------|----------------------|

|  |   |
|--|---|
| <b>Administrative Title (if applicable):</b> | Examples include program director, course director, Assistant/Associate Dean, Chair, Director, etc. |
| <input type="text"/>                         |   |

|                               |                      |
|-------------------------------|----------------------|
| <b>Department/Division:</b> * | <input type="text"/> |
|-------------------------------|----------------------|

|                 |                      |
|-----------------|----------------------|
| <b>Chair:</b> * | <input type="text"/> |
|-----------------|----------------------|

|  |   |
|--|---|
| <b>Your role in medical education:</b> * | Examples include lecture in M1 or M2 courses, clerkship preceptor, elective preceptor, etc. |
|--|---|

|                      |  |
|----------------------|--|
| <input type="text"/> |  |
|----------------------|--|



|  |  |
|--|--|
| <b>Part 1 - Financial Interest Disclosure:</b> | Do you, your spouse, significant other, or dependent children have, or have had, within the past twelve (12) months <b>financial interests</b> in an <i>external</i> entity (company, non-profit, or public agency) with activities that are related to your institutional responsibilities? Examples of external financial interests include: salary, compensation, consulting fees, honoraria, speaker's fee, paid authorships, equity interests in a for-profit company or entity (stocks, stock options, or other ownership interests), intellectual property rights (such as royalties for patents or copyrights) not paid by UToledo, and/or reimbursed or sponsored travel (except from U.S. government agencies or higher educational institutions in the U.S.). |
|  | <input style="width: 150px; height: 25px; border: 1px solid red;" type="text" value="Select One"/>   |

|  |  |
|--|--|
| <b>Part 2 - Significant Relationship Disclosure:</b> | Have you, your spouse, significant other, or dependent children had a <b>significant relationship</b> with a commercial sponsor of research, educational, or clinical activities, whether paid or unpaid? Examples of significant relationships include serving as an officer, director, board member, or scientific advisory board member of a sponsor of research, educational, or clinical activities at UToledo. |
|  | <input style="width: 150px; height: 25px; border: 1px solid red;" type="text" value="Select One"/>   |

If you answered '**No**' to **both** Parts 1 and Part 2, then submission is complete.

If you answered '**Yes**' to **either** Part 1 or Part 2, then Part 3 **must** be completed.\*

**Please complete and return to your department administrator with your signed reappointment letter.  
If you have questions, reach out to Dr. Jason Huntley, Associate Dean for Faculty Affairs and  
Development at [Jason.Huntley@utoledo.edu](mailto:Jason.Huntley@utoledo.edu)**



| Name of external entity  | Conflict of Interest Owner  | Conflict of Interest Type   | Description of Financial Interest   | Value of Financial Interest   | Frequency of Financial Interest  | Description of Significant Relationship   | Potential impact on medical education  |
|--|---|---|---|---|--|---|--|
| If you answered 'Yes' to either financial interest (part 1) or significant relationship (part 2) with external entities, please individually list each external entity in separate rows. | Select below if the owner of the conflict of interest is 1. Self, 2. Spouse, partner, significant other, or 3. Dependent child for each external entity | Select below if the Conflict of interest is 1. Financial Interest or 2. Significant Relationship for each external entity | Note: You are NOT required to disclose income from: (1) Mutual funds for which you do not control the investment decisions within that fund; (2) Income from seminars, lectures, or teaching engagements sponsored by U.S. government agencies or U.S. higher education institutions; or (3) Royalty income from intellectual property generated from your invention licensed by UToledo. All other external income must be disclosed here. If Significant Relationship, please leave this field blank. | In round numbers (e.g., \$1000, \$5000, \$10,000, \$20,000), list current value, estimated value, or potential value of financial interest. If potential value, describe (e.g., royalty, future shares, future rights). If "in kind", estimate value. | <ul style="list-style-type: none"> <li>• If your financial interest was a one-time only occurrence, please list "one time only."</li> <li>• If your financial interest occurred multiple times per year, please indicate how many times per year, amount per occurrence, and total per year</li> </ul> | If you selected Significant Relationship to the left, please select the Significant Relationship below. If you selected Financial Interest to the left, please select "not applicable." | <ol style="list-style-type: none"> <li>(1) Please explain the potential crossover between this disclosure, either financial conflict or significant relationship, and your role in medical education;</li> <li>(2) Please explain how you will manage this conflict</li> </ol> |
| 1.   | Select One ▼  | Select One ▼  | Select One ▼<br>If you chose 10. Other, please enter description here.  |   |  | Select One: ▼<br>If you chose 6. Other, please enter description here.  |  |
| 2.   | Select One ▼  | Select One ▼  | Select One ▼<br>If you chose 10. Other, please enter description here.  |   |  | Select One: ▼<br>If you chose 6. Other, please enter description here.  |  |
| 3.   | Select One ▼  | Select One ▼  | Select One ▼<br>If you chose 10. Other, please enter description here.  |   |  | Select One: ▼<br>If you chose 6. Other, please enter description here.  |  |

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| 1.  | <div style="border: 1px solid black; padding: 2px;">Select One ▼</div>  | <div style="border: 1px solid black; padding: 2px;">Select One ▼</div>   | <div style="border: 1px solid black; padding: 2px;"> <div style="border: 1px solid black; padding: 2px;">Select One ▼</div> <ul style="list-style-type: none"> <li>1. Salary</li> <li>2. Compensation</li> <li>3. Consulting fee</li> <li>4. Honoraria</li> <li>5. Speaker's fee</li> <li>6. Paid authorship</li> <li>7. Equity interests in a for-profit company or entity (stock)</li> <li>8. Intellectual property rights (such as royalties for patents)</li> <li>9. Reimbursed or sponsored travel (except from U.S. gov)</li> <li>10. Other</li> </ul> </div> |  |  | <div style="border: 1px solid black; padding: 2px;">Select One: ▼</div> <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">If you chose 6. Other, please enter description here.</div> |   |
| 2.  | <div style="border: 1px solid black; padding: 2px;">Select One ▼</div>  | <div style="border: 1px solid black; padding: 2px;">Select One ▼</div>   | <div style="border: 1px solid black; padding: 2px;"> <div style="border: 1px solid black; padding: 2px;">Select One ▼</div> <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">If you chose 10. Other, please enter description here.</div> </div>  |  |  | <div style="border: 1px solid black; padding: 2px;">Select One: ▼</div> <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">If you chose 6. Other, please enter description here.</div> |   |
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| 1.   | Select One ▼  | Select One ▼  | Select One ▼<br>If you chose 10. Other, please enter description here.  |   |  | Select One: ▼<br>Select One:<br>1. Not applicable<br>2. Officer of an external<br>3. Director of an externa<br>4. Board member of an e<br>5. Scientific advisory bo<br>6. Other         |  |
| 2.   | Select One ▼  | Select One ▼  | Select One ▼<br>If you chose 10. Other, please enter description here.  |   |  | Select One: ▼<br>If you chose 6. Other, please enter description here.  |  |
| 3.   | Select One ▼  | Select One ▼  | Select One ▼<br>If you chose 10. Other, please enter description here.  |   |  | Select One: ▼<br>If you chose 6. Other, please enter description here.  |  |

# COI Disclosure Review

- Dean's Standing Committee on COI (peers)
- Option 1: No COI → No further action
- Option 2: Disclosed COI determined not to interfere with education and/or clinical care
- Option 3: Disclosed COI may interfere with education and/or clinical care – management plan requested and conflict posted on faculty webpage
- Option 4: Disclosed COI interferes with education and/or clinical care – management plan will not resolve conflict – faculty activities must stop

# COI FAQs:

- Mutual funds vs. individual stocks?
- Honoraria from invited lecture at a university or govt agency in U.S.? Outside U.S.?
- Income from UToledo sponsored patent
- Research grants or clinical trials
- Reimbursed travel
- External consulting
- Compensation for outside activities
- Frequency (once vs. four times a year)
- Potential crossover with medical education or clinical activity