


<b>Name of Policy:</b> <u>College of Medicine &amp; Life Sciences: Individual Conflict of Interest in Education and Clinical Care</u>		 <b>Effective date:</b> 7/1/24 <b>Original effective date:</b> 7/1/12	
<b>Policy Number:</b> 3364-81-01-004-01			
<b>Approving Officer:</b> Dean of College of Medicine and Life Sciences			
<b>Responsible Agent:</b> Associate Dean for Faculty Affairs			
<b>Scope:</b> College of Medicine and Life Sciences			
<input type="checkbox"/>	New policy proposal	<input checked="" type="checkbox"/>	Minor/technical revision of existing policy
<input type="checkbox"/>	Major revision of existing policy	<input type="checkbox"/>	Reaffirmation of existing policy

(A) Policy Statement

To maintain academic and clinical integrity, as well as the public trust, the University of Toledo (UToledo) College of Medicine and Life Sciences (COMLS) must maintain a comprehensive Conflict of Interest (COI) oversight program to address both actual and perceived COIs. Faculty and Educational Administrators must disclose outside financial interests, outside compensation and outside activities relating to their professional and administrative activities in education and clinical care. The COMLS will review COI disclosures, request COI management plans for situations where an actual or perceived COI exists, and work with Faculty, Educational Administrators, and their Department to provide appropriate oversight and COI management, consistent with this and other applicable institutional policies, and any federal regulations applicable to the individual’s activities. Faculty and Educational Administrators must avoid COI that are not manageable, consistent with applicable policies, laws and regulations.

(B) Purpose of policy

It is the purpose of this policy to set forth the requirements for the COMLS Faculty and Educational Administrators related to COI disclosures and the process to identify, manage and provide appropriate oversight or elimination of situations that pose an actual or perceived COI. The purpose of these requirements is to avoid the impact of actual or perceived COI in the operation of the medical education program, its associated clinical facilities and any related enterprises.

(C) Scope

This policy only applies to COMLS faculty and staff in their role in education and clinical training. For an individual’s role in the design, conduct, or reporting of sponsored projects or human subject research, whether funded or unfunded by an external sponsor, the University policy entitled ‘Financial Conflict of Interest’, 3364-70-01, applies.

## (D) Responsibility to Disclose

- (1) Conflicts of Interests for Faculty and Educational Administrators within COMLS may occur or appear to occur with outside entities during ongoing and legitimate research, professional, educational, and/or clinical activities. COMLS strongly discourages all COI but they 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.

## (E) Definitions

- (1) “Clinical Activities” include all patient and non-patient interactions that occur because of the professional clinical expertise of the faculty member.
- (2) “Conflict of Interest” (COI), as used in this policy, refers to any situation in which the Financial Interests or Significant Relationships of the Faculty, Educational Administrators, or their family members might bias – or reasonably appear to bias – the educational and clinical missions of UToledo.
- (3) “Educational Administrators,” as used in this policy, means individuals who participate in decision making affecting the medical education program.
- (4) “Family” includes: a) grandparents; b) parents; c) spouse or partner; d) children, whether dependent or not; e) grandchildren; f) siblings; or g) any person related by blood or marriage and residing in the same household.
- (5) “Financial Interest,” as used in this policy, refers to payments to, and/or equity interests of, the individual or the individual's Family, and appears to be related to the individual's Institutional Responsibilities for one or more of the following interests:
  - (a) An equity interest or entitlement to equity (including options or warrants) in a *publicly traded* or *non-publicly traded* entity, except when that interest or equity is in the form of a mutual fund or pension fund.
  - (b) Intellectual property rights (e.g., patents, copyrights), royalties or milestone payments from such rights, and agreements to share in royalties related to such rights, including those with potential monetary value, whether direct or indirect, from the sales of a commercial or investigational product that is the subject of the educational activity or clinical activity; or
  - (c) Consulting fees, salary, honoraria, speakers' fees, gifts or other payments, or “in kind” compensation from any source, costs of travel, lodging, etc. paid by a for-profit entity for attendance at seminars, meetings, etc., unless this travel is required for participation in a clinical research study (e.g., an investigator's meeting prior to initiation of the University of Toledo as a clinical trial site), with the exception of the following:
    - (i) Publication - Scholarly communications in the form of books, movies, television productions, *etc.*, though frequently earning financial profit for a faculty member and for another party, are not consultation. Such communications may be

subject to university policies governing intellectual property. This exception does not include payments for “ghost writing” for commercial or non-commercial entities, which is never allowable.

- (ii) Clinical Practice - Faculty participation in a practice plan approved by the UToledo Board of Trustees.
  - (iii) Professional Service – External professional activities that reflect normal and expected public service activities of faculty and that do not entail compensation beyond reimbursement for expenses and/or a nominal honorarium.
- (6) “Faculty” and “Educational Administrators,” as used in this policy, refers to full or part-time COMLS Faculty who are engaged in activities while in the employment of the UToledo and who are responsible for the design, conduct or delivery of research, education or clinical care; or who, on behalf of the COMLS, have professional oversight for or make purchases related to these activities. The definition of faculty excludes faculty with a non-compensated community-based or ProMedica-based appointments.
- (7) “Significant Relationship,” as used in this policy, means one or more of the following:
- (a) An appointment to serve, in either a personal or representative capacity, as an officer, director, or board member of a commercial sponsor of UToledo research, educational or clinical activity whether the person receives remuneration for such service; or
  - (b) An appointment to serve on the scientific advisory board of a commercial sponsor of UToledo research, education, or clinical activity, unless the official has no current Financial Interest in the sponsor or its commercial or investigational products and agrees not to hold such an interest for a period of no less than three years following completion of any related research, education, or clinical activity.
- (F) Procedure
- (1) Administration and supervision of the Individual Conflict of Interest in Education and Clinical Care: The University will seek to manage conflicts of interest to avoid negative consequences for the University’s mission.
- For sponsored projects or human subject research, whether funded or unfunded, financial conflicts of interest will be evaluated and managed as outlined in university policy 3364-70-01, Financial Conflict of Interest, as that policy applies to all University faculty, staff, and students (including post-doctoral fellow and scholars) regardless of title or position. Refer to section (c) of that policy.
- (a) The COMLS utilizes the following measures to recognize, manage, and resolve COI in educational and clinical care:
    - (i) Forms/processes to report individual conflicts of interest are managed by
      - (a) Each Faculty member and Educational Administrator will submit a COI in Education and Clinical Care Report to the Office of Faculty Affairs on a form

the COMLS Office of Faculty Affairs and Development. Such reports will be:

- (i) submitted not less than annually, on or before June 30, and;
  - (ii) updated within 30 days of acquiring a new Financial Interest or Significant Relationship.
- (b) An individual who has no Financial Interests or Significant Relationship in education or clinical care must submit a report certifying their lack of reportable COI.
- (c) This reporting requirement is in addition to any other reporting or disclosure required by law or university policy including but not limited to University Policy 3364-70-01: Financial Conflicts of Interest (Research and Sponsored Programs), as well as the prohibitions of the Ohio Ethics Law.

The COMLS Office of Faculty Affairs and Development will review all disclosures required by this policy and make an initial assessment regarding whether a COI exists. If a COI exists, the Office of Faculty Affairs and Development will determine whether the conflict can be mitigated by disclosure alone or whether the disclosure will be referred to the Conflict of Interest Committee for review, consistent with this policy.

(ii) Conflict of Interest Committee.

- (a) The COMLS will establish a COMLS Individual Conflict of Interest in Education and Clinical Care Committee (referred to as COMLS COI Committee). The COMLS dean appoints the COMLS COI Committee, which reports to the Associate Dean for Faculty Affairs and Development. The Chair of the COMLS COI Committee must be independent of any college administrator. In the event the Associate Dean for Faculty Affairs and Development is involved in the conflict, the COMLS COI Committee will report to the COMLS Dean. If the COMLS Dean is involved in the conflict, the COMLS COI Committee will report to the President.
- (b) The COMLS COI Committee will be responsible for review of the issues surrounding any educational or clinical care conflict or potential conflict, to determine whether a conflict does, in fact, exist. If the COI Committee determines that a conflict does exist, it will notify the individual of the committee's decision, and then work with the individual to review and approve an appropriate conflict management plan, in consultation with the individual and the individual's supervisor(s) and the COMLS Office of Faculty Affairs and Development. The purpose of the conflict management plan is to impose conditions to ensure effective management of the educational or clinical care COI and provide credible oversight of educational or clinical care COI prior to and during the activity associated with the conflict of interest. Final approval of the management plan will occur through the COMLS COI committee.
- (c) The individual, the individual's supervisor(s) and the COMLS Dean will receive the final conflict management plan. As part of the conflict management plan, all COI must be posted on the individual's COMLS webpage (i.e., COMLS faculty webpage).
- (d) Individuals who are subject to a COMLS COI management plan may submit a written appeal of the COMLS COI committee's decision and/or management

plan to the COMLS Dean.

- (e) An individual may appeal a COI committee decision in writing to the COMLS Dean within 30 days of the date of the COMLS COI notification of decision. The COMLS Dean will respond within 14 days of receipt of a written appeal, either affirming or reversing the decision and will notify the individual, the COMLS COI committee, and the faculty member's supervisor(s) of their decision.
  
  - (f) The COMLS COI Committee will be authorized to take the following actions to manage the COI, including, but not limited to:
    - (i) Obtain and review all documentation needed for evaluation of the potential COI;
    - (ii) Determine whether a genuine COI exists;
    - (iii) Request, review, and approve a conflict management plan;
    - (iv) Require individuals who are subject to a management plan to provide verification that COI are listed on the individual's COMLS webpage in accordance with any management plan issued pursuant to this policy;
    - (v) Recommend to the COMLS Dean (or Provost if the COMLS Dean has an unmitigated COI) that faculty activities be suspended if the conflict management plan cannot mitigate that conflict(s), pursuant to the UToledo *'Faculty Rules and Regulations for Faculty not bound by Collective Bargaining Agreements'* and other applicable policies;
    - (vi) Report confirmed COI and conflict management plans to the UToledo Institutional Compliance Office.
  
  - (g) The Institutional Official (IO) charged with communicating with sponsors and external agencies, as required by federal regulations, is the Vice President for Research, per UToledo policy 3364-70-01, Financial Conflict of Interest. The Vice President for Research will determine if the conflict management plan requires communication with sponsors and external agencies.
- (b) Individuals must cooperate with the review and implementation of the conflict management plan. Individuals are required to comply with the final conflict management plan as set forth by the COMLS COI Committee and approved by the COMLS Dean, unless otherwise determined by the appeal process outlined in (F)(1)(ii)(d) and (F)(1)(ii)(e). Failure to cooperate or comply with the requirements of this policy may result in disciplinary action, up to and including termination of employment, subject to the rights set forth in the Faculty Rules and Regulations.

(2) Compliance Reporting of COI

- (a) The University of Toledo maintains a Compliance and Ethics hotline to allow all employees to report possible violations of law or policy anonymously. Additional information is available at The University of Toledo institutional compliance website <https://www.utoledo.edu/offices/internalaudit/institutional-compliance/> <http://www.utoledo.edu/offices/internalaudit/institutional-compliance/Anonymous%20Reporting.html>. All members of the University of Toledo are expected to report in good faith any concerns about possible violations of any policy, law, rule, regulation, contract or grant governing any University activity.
- (b) In addition to the UToledo Compliance and Ethics hotline, the Associate Dean for Faculty Affairs and Development, the COMLS Dean, or the Chief Compliance Officer of the Institutional Compliance Office can accept reports of possible COI/FCOI, and/or violations of law or policy.

(G) Additional Policies and Ohio Ethics Law Notice. In all instances, regardless of determinations made pursuant to this policy, employees must abide by protections to the public embodied in the Ohio Ethics Law and related statutes found in Chapters 102 and 2921 of the Ohio Revised Code, and as interpreted by the Ohio Ethics Commission and Ohio Courts. The Ohio Ethics Law prohibits certain activities in which an employee’s personal or immediate family members’ financial or business matters might intersect with university interests. Provisions of Ohio Ethics Law as applied to University of Toledo employees in their roles as public employees is outlined in UToledo Policy Number: 3364-25-50. Furthermore, as elaborated under Policy Number: 3364-25-18: Conflict of Interest and Nepotism, all employees of the state of Ohio must avoid situations in which they might gain personally because of the decisions they make or influence as public servants. The conduct and activities of all employees is also subject to the Bylaws of the Board of Trustees of the University (rule 3364-1-06 of the Administrative Code). Other COI policies can be found on the University of Toledo policy website (View by Content Area/Conflict of Interest or <https://www.utoledo.edu/policies/content.html/#conflict>).

<p>Approved by:</p> <p><u>/s/</u>                  Christopher J. Cooper, M.D.                  Dean, College of Medicine and Life Sciences</p> <p><u>7/1/24</u>                  Date</p> <p><i>Review/Revision Completed by:</i>                  Dean, College of Medicine and Life Sciences                  Office of Legal Affairs</p>	<p><b>Policies Superseded by This Policy:</b></p> <p>None</p> <p><b>Initial effective date:</b> 7/1/12</p> <p><b>Review/Revision Date:</b></p> <ul style="list-style-type: none"> <li>• 12/18/20</li> <li>• 7/1/24</li> </ul> <p><b>Next review date:</b> 7/1/27 (three years from most recent revision/review date)</p>
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