


<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> December 18, 2020 <b>Original effective date:</b> 07/01/2012	
<b>Policy Number:</b> 3364-81-01-004-01			
<b>Approving Officer:</b> Executive Vice President for Clinical Affairs/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 type="checkbox"/>	Minor/technical revision of existing policy
<input checked="" 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 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 disclosures and provide appropriate oversight and management plans for situations that create an actual or perceived COI, provided the COI can be managed consistent with this and other applicable institutional policies, the Ohio Ethics Laws regarding COI, and any federal regulations applicable to the individual’s activities. Faculty and Educational Administrators must avoid COI that cannot be managed 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 is restricted to COMLS faculty and staff in their role in education and clinical training. For an individual’s role as a researcher in sponsored programs or human subject research, University policy, Financial conflict of Interest, 3364-70-01, applies.

## (D) Responsibility to Disclose

- (1) Conflicts of Interests for Faculty and Educational Administrators within the College of Medicine 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.

## (E) Definitions

- (1) “Clinical Activities” include all patient and non-patient interactions that occur as a consequence of the professional clinical expertise of the faculty member.
- (2) “Conflict of Interest” (COI) as used in this policy, refer 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 The University of Toledo.
- (3) “Educational Administrators” as used in this policy means individuals who participate in decision making affecting the medical education program.
- (4) “Family” includes, but is not limited to: a) grandparents; b) parents; c spouse; d) e) children, whether dependent or not; f) grandchildren; g) brothers and sisters; or h) any person related by blood or marriage and residing in the same household.
- (5) “Financial Interest” as used in this policy exists for 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 viewed as 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 University of Toledo 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”: for the purposes of this policy, Faculty in the College of Medicine and Life Science are defined as full or part-time faculty engaged in activities while in the employment of the University of Toledo and who are responsible for the design, conduct or delivery of research, education or clinical care; or who on behalf of the College of Medicine have professional oversight for or make purchases related to these activities. Faculty with a non-compensated community based appointments are excluded from the definition of faculty.
- (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 UT research, educational or clinical activity whether or not remuneration is received for such service; or
  - (b) An appointment to serve on the scientific advisory board of a commercial sponsor of UT 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 in order 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 as this policy is restricted specifically to COMLS faculty and staff only in their role in education and clinical training. As stated in section (c), this policy is restricted to COMLS faculty and staff in their role in education and clinical training and for an individual’s role as a researcher in sponsored programs or human subject research, additional University policies including the Financial Conflict of Interest, 3364-70-01, apply.

- (a) The COMLS utilizes the following measures to recognize, manage, and resolve COI in educational and clinical care:
  - (i) Reports of individual conflict of interest
    - (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

prescribed by the Office of Faculty Affairs. Such report 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 Office of Faculty Affairs will review all disclosures required by this policy and make an initial assessment regarding whether or not a COI exists. If a COI exists, the Office of Faculty Affairs will determine whether the conflict can be mitigated by disclosure alone, otherwise the Office of Faculty Affairs will refer the disclosure 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 COI Committee is appointed by the Dean of the COMLS and reports to the Associate Dean for Faculty Affairs. The Chair of the COMLS COI Committee must be independent of any college administrator. In the event the Associate Dean for Faculty Affairs is involved in the conflict, the COMLS COI Committee reports to the Dean of the COMLS. If the Dean is involved in the conflict, the COMLS COI Committee reports 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, and if so, it will notify the individual of the decision, and then develop an appropriate management plan in consultation with the individual and the individual's supervisors and the COMLS Office of Faculty Affairs. The purpose of the 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 final management plan will be provided to the individual, the individual's supervisors and the Dean of the COMLS.
- (d) Individuals who are subject to a COMLS COI management plan will be permitted to submit a written appeal of the COMLS COI committee's decision and/or management plan to the Dean of the COMLS. 3364 – 70 – 01

- (i) An individual may appeal a COI committee decision in writing to the Dean of the COMLS within 30 days of the date of the COMLS COI notification of decision. The Dean of the COMLS 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 departmental chair of his/her decision.
  - (e) 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/FCOI;
    - (ii) develop and implement a Conflict Management Plan;
    - (iii) suspend faculty activities with ongoing COI/FCOI which cannot be mitigated by the Conflict Management Plan.
  - (f) The Institutional Official (IO) charged with communicating with sponsors and external agencies as required by federal regulations is the Vice President for Research as per ORSP policy 3364-70-01 in the event that the educational or clinical COI management plan requires communication with sponsors and external agencies.
- (b) Faculty members will cooperate with the review of the conflict and formation of the Conflict Management Plan. Faculty are required to comply with the final Conflict Management Plan as set forth by the COMLS COI and approved by the Dean of the COMLS unless reversed by the appeal process outlined in .(F)(1)(ii)(d)(i) 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 UT Compliance and Ethics hotline, reports of possible COI/FCOI, and/or violations of law or policy can be directed to the Associate Dean for Faculty Affairs, the Dean of the COMLS, or the Chief Compliance Officer of the Institutional Compliance Office.
  
- (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. 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 as a result 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 Cooper, M.D.                  Executive VP for Clinical Affairs and Dean,                  College of Medicine</p> <p><u>12/18/2020</u>                  Date</p> <p><i>Review/Revision Completed by:</i>                  Executive VP for Clinical Affairs and Dean,                  College of Medicine                  Office of Legal Affairs</p>	<p><b>Policies Superseded by This Policy:</b></p> <p><b>Initial effective date:</b> 07/01/2012</p> <p><b>Review/Revision Date:</b> 12/18/2020</p> <p><b>Next review date: December 18, 2023</b></p>
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