

Institutional Handbook of Operating Procedures Policy 06.05.04	
Section: Compliance	Responsible Vice President: Chief Compliance Officer
Subject: Conflicts of Interest and Ethics	Responsible Entity: Office of Institutional Compliance

I. Title

Institutional Conflicts of Interest

II. Purpose

This policy establishes requirements and procedures to identify, manage, or eliminate situations in which the institutional interests and activities of UTMB, or the individual financial interests and activities of Institutional Leaders, affect or appear to affect the research, education, clinical care, business transactions, or other activities of the institution. To that end, UTMB and Institutional Leaders will follow federal and state laws, regulations, and guiding principles that govern the disclosure, reporting, and management of potential and actual Institutional Conflicts of Interest (ICOI).

III. Scope

This policy applies to Institutional Conflicts of Interest (ICOI) of, and Institutional Leaders (ILs) within, UTMB, as defined below. Institutional Leaders must follow this policy as well as IHOP - 06.05.01 – *Research Conflicts of Interest*, IHOP - 06.05.03 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities*; IHOP - 06.05.05 – *Gifts, Vendor and Industry Interactions, and Other Activities*, IHOP – 06.05.06 – *Code of Ethics and Standards of Conduct for State Employees*, and other IHOP policies where applicable.

IV. Policy

UTMB encourages its faculty, staff, students, and trainees to establish relationships with a variety of entities for the purpose of developing new technologies and treatments that advance scientific knowledge and contribute to the public welfare. Such activities and relationships, however, must be balanced with the need to disclose and mitigate potential ICOIs and to avoid the creation of institutional or personal conflicts with regard to UTMB’s financial or business interests.

This policy is divided into the following sections:

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V. Guiding Principles

- A. Relationships between UTMB and public or private entities are encouraged to the extent that such relationships are appropriate and further UTMB's mission.
- B. An Institutional Conflict of Interest (ICOI) may arise when UTMB's Significant Financial Institutional Interests (SFIIs) or the Financial Interests and/or Outside Activities of Institutional Leaders are coupled with a current or reasonably foreseeable UTMB activity such as research, teaching, or clinical care.
- C. An ICOI may arise in situations such as:
 - 1. If UTMB were to license intellectual property to an outside entity and/or holds substantial royalty or equity interests in the entity which may be affected by ongoing UTMB research or other UTMB activities;
 - 2. If substantial gifts to UTMB appear to be connected to decisions related to the institution's primary missions in ways that may not be appropriate;
 - 3. If UTMB holds substantial investments or equity interest in an outside entity that has a financial or business relationship with UTMB;
 - 4. If a Financial Interest or an Outside Activity of an Institutional Leader affects, or appears to detrimentally affect, clinical, business, educational, research, or other decisions of UTMB;
 - 5. If UTMB were to enter into a transaction that compromises, or appears to compromise, the institution's research, teaching, service to students, patient care, outreach mission activities, or its institutional reputation.
- D. To protect UTMB's reputation, integrity, and objectivity with respect to research and clinical care, the SFIIs of UTMB and the Financial Interests and Outside Activities of ILs must be identified, disclosed, and reviewed to prevent potential ICOIs.

VI. Institutional Official-COI and Conflict of Interest Committee

VI.1 Institutional Official-COI

- A. The Institutional Official for Conflicts of Interest (IO-COI), or his/her designee, is responsible for the review of a Financial Interest Disclosure Statement or Outside Activity request submitted by an IL and to make a preliminary determination of whether a disclosure or activity constitutes an ICOI.
- B. The IO-COI, or his/her designee, is also responsible for the review of all UTMB institutional Financial Interests and relationships, including licensing revenues, other Ownership Interests, and gifts and to make a preliminary determination of whether such interest constitutes an ICOI.

VI.2 The Conflict of Interest Committee

- A. The Conflict of Interest Committee (COIC) consists of faculty members and administrators from academic, clinical, and basic science departments, representatives from various institutional areas such as the Office of Technology Transfer, Office of Institutional Compliance, Legal Affairs, the Human Research Protection Program, Purchasing, and Sponsored Programs, as well as a representative from the local community.
- B. The Conflict of Interest Committee (COIC) is empowered to identify, disclose, and provide advice on the management or elimination of all facets of research, individual, and institutional conflicts of interest.

VII. Institutional Leader Financial Interests and Outside Activities

VII.1 An Institutional Leader (IL) is subject to, and required to make certain disclosures and requests for prior approval for an Outside Activity, as outlined in the following:

- A. IHOP - 06.05.01 – *Research Conflicts of Interest*;
 - i. An IL engaged in any research activity is required to complete an annual Disclosure Statement of all Financial Interests and periodic conflicts of interest training as set forth in IHOP 06.05.01.
 - ii. An IL engaged in research is required to seek and receive prior approval for an Outside Activity as set forth in IHOP 06.05.03.
 - B. IHOP - 06.05.03 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities*;
 - i. An IL not engaged in research activity is required to disclose certain Financial Interests and seek and receive prior approval for an Outside Activity as set forth in IHOP 06.05.03.
 - C. IHOP - 06.05.06 – *Code of Ethics and Standards of Conduct for State Employees*.
- 7.2 An Institutional Conflict of Interest (ICOI) may arise when a Financial Interest or Outside Activity of an IL, acting within his/her authority on behalf of the institution, may affect or appear to affect the research, education, clinical care, business decisions, or other activities of UTMB.

VIII. Institutional Financial Interests

VIII.1 An Institutional Conflict of Interest (ICOI) may arise when a Significant Financial Institutional Interest (SFII) of UTMB affects, or appears to affect, the research, education, clinical care, business decisions, or other activities of the institution.

VIII.2 An SFII includes, but is not limited to, the following:

- A. Interests under Technology Transfer Licensing Agreements: Payments, including royalty payments, milestone payments, and other licensing fees, resulting from technology transfer licensing that, if the arrangements are equal to or greater than \$150,000 in the twelve-month period immediately preceding the definitive agreement covering the research in question.

- B. Non-Publicly Traded Equity: Institutional held equity interests equal to or greater than \$250,000 in a non-publicly traded company resulting from the transfer of UTMB technology or an institutional direct equity investment where such company is: (i) the sponsor of research at UTMB or (ii) the manufacturer, marketer, or option/license holder of UTMB technology to be studied or tested at or under the auspices of UTMB.
- C. Publicly-Traded Equity: Institutionally held Ownership Interests exceeding \$250,000 in value in a publicly-traded company resulting from the transfer of UTMB technology, where such company is: (i) the sponsor of the research at the institution, or (ii) the manufacturer, marketer, or option/license holder of UTMB technology to be studied or tested at or under the auspices of UTMB.
- D. Gifts: Gifts (including gifts in kind) which are important to the mission of UTMB that exceed \$200,000 from a potential commercial sponsor of research or a company that owns or controls products being studied or tested, or a philanthropic unit or an individual affiliated with such a company. This does not include gifts secured by UTMB's Development Office.

IX. Identification and Management of ICOIs

IX.1 Institutional Leader (IL) Financial Interests and Outside Activities

- A. Consistent with IHOP 06.05.01 and 06.05.03, the IO-COI, or his/her designee, shall review the Financial Interest Disclosure Statements and Outside Activity Requests from ILs to determine whether a potential ICOI exists.
- B. The COIC will make a final determination of whether the IL's Financial Interest or Outside Activity substantially affects the research, education, clinical care, business decisions, or other activities of UTMB.
- C. Upon finding that a Financial Interest or Outside Activity of an IL is an ICOI, the COIC will take action to manage, reduce, or eliminate the conflict. This can include the implementation of an ICOI Management Plan.
- D. In the event that a Financial Interest or Outside Activity of the President, including President ad interim, rises to the level of an ICOI as determined by the COIC, the COIC will report its recommendations directly to UT System Administration.

IX.2 Institutional Financial Interests

- A. The IO-COI, or his/her designee, shall review reports listing licensing/equity interests and gifts provided by UTMB's Office of Technology Transfer and Development Office, respectively, to determine whether a Significant Financial Institutional Interest (SFII) exists.
- B. The COIC will make a final determination of whether an SFII results in an ICOI of the institution and thus substantially affects ongoing research performed at UTMB.
- C. Upon finding that an SFII constitutes an ICOI, the COIC will take action to manage, reduce, or eliminate the conflict. This includes the implementation of an ICOI Management Plan.

IX.3 Management Plans

- A. If the COIC determines that a Financial Interest or Outside Activity of an IL or an SFII of the institution constitutes an ICOI, it may implement a Management Plan.
- B. A Management Plan must be in the form of a written agreement and may impose any condition and prescribe any action necessary to manage the ICOI.

X. Non-Compliance

- X.1** Noncompliance with this policy or resulting ICOI management plans on the part of faculty or staff as determined by the appropriate dean, director, supervisor, the COIC, or the IO-COI or his/her designee, may be subject to institutional sanctions up to and including termination of employment in accordance with applicable disciplinary procedures.

XI. Definitions

Disclosure Statement: A statement of Financial Interests disclosed by an Institutional Leader or an affirmation that the Institutional Leader has no Financial Interests to disclose.

Financial Interest: Anything of monetary value whether or not the value is readily ascertainable.

Institutional Conflict of Interest (ICOI): A situation in which the research, education, clinical care, business transactions, or other activities of UTMB may be compromised because of an external financial or business relationship held by the institution or the Financial Interest or Outside Activity of an Institutional Leader.

Institutional Leader (IL): Includes the President, including President ad interim, the President's Chief of Staff, and Executive Vice Presidents.

Institutional Official for COI (IO-COI): The conflicts of interest official designated by UTMB to solicit and, with assistance from the COIC as needed, review Financial Interest Disclosure Statements and Outside Activity requests submitted by Institutional Leaders, as well as reports and information provided by UTMB offices for purposes of determining whether a possible ICOI exists.

Management Plan: A formal, written plan to address an ICOI, which can include reducing or removing the conflict of interest to ensure that the design, conduct, or reporting of research will be free of bias or that the Financial Interest or Outside Activity of an IL does not substantially and detrimentally affect the research, education, clinical care, business transactions, or other activities of the institution.

Outside Activity: Any activity performed by an IL other than fulfilling academic or employment obligations to UTMB for which compensation is received, including distance teaching; any work for a third party, such as supervising, consulting, or advisory services; or other employment for which compensation, regular or occasional, is received.

Ownership Interest: Includes, but is not limited to, any stock, stock options, warrants, or other equity interest in any corporation, partnership, or other legal entity, excluding (i) shares in mutual funds, and (ii) stock, stock options, or warrants, where the disposition or acquisition is not directly controlled by the owner and where the owner has no right to intervene in the handling of such assets, *e.g.*, stock, stock

options, or warrants held in blind trusts (to the extent that the identity of the assets in the blind trust is unknown). Ownership interest includes any license equity.

Significant Financial Institutional Interest (SFII): A Financial Interest of the institution that could substantially and detrimentally affect the design, conduct, or reporting of research performed at the institution.

XII. Relevant System Policies and Procedures

- [UT System Regents' Rules and Regulations](#)
- [UTMB Standards of Conduct Guide](#)
- [UT System Rule 189](#)
- [UT System Rule 180](#)
- [UT System Rule 175](#)

XIII. Related UTMB Policies and Procedures

- [IHOP - 06.05.01 – Research Conflicts of Interest](#)
- [IHOP - 06.05.03 – Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities](#)
- [IHOP - 06.05.05 – Gifts, Vendor and Industry Interactions, and Other Activities](#)
- [IHOP – 06.05.06 – Code of Ethics and Standards of Conduct for State Employees](#)

XIV. Dates Approved or Amended

<i>Originated:</i> 08/06/2012	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>
02/19/2014	02/20/2014
02/12/2015	03/06/2017
05/11/2023	

XV. Contact Information

Conflicts of Interest Office
 Office of Institutional Compliance
coi.in@utmb.edu
<http://www.utmb.edu/coi>