Institutional Handbook of Operating Procedures Policy 6.5.4	
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. Scope

This policy applies to all Institutional Officials, as defined above, as well as UTMB as an entity. This policy must be followed in addition to IHOP 6.5.1 – *Research Conflicts of Interest*; IHOP 6.5.2 – *Ethical Interactions with Industry*, IHOP 6.5.3 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities*, IHOP 6.5.4 – *Gifts, Honoraria, Fundraising, and Other Activities* and other IHOP policies where applicable.

III. Policy

UTMB is committed to ensuring that its decisions regarding purchasing activities, investments, research, teaching, outreach, and other activities are not compromised or perceived as biased by financial and business considerations of the institution and its Institutional Officials. Therefore, members of the university community including Institutional Officials must disclose potential conflicts of interest and, when appropriate, work with the institution's Conflict of Interest Official and Conflict of Interest Committee to develop and implement plans to manage, reduce, or eliminate conflicts of interest. If a specific federal law or regulation provides different requirements than this policy, the more stringent requirement applies.

This policy is divided into the following sections:

Conflict of Interest Official and Conflict of Interest Committee 1
Financial Holdings or Investments of UTMB 2
Prior Approval of Requests for Outside Activity 3
Disclosure of Financial Holdings or Investment and Outside Activities of Institutional Officials 3
Management of Institutional Conflicts of Interest 4
Enforcement and Compliance 4
Appeals 5
Maintenance of Records 5
Monitoring 5

IV. Conflict of Interest Official and Conflict of Interest Committee

Conflict of Interest Official:

The President of UTMB is responsible for overseeing implementation of this policy and may provide additional procedures and supplementary forms, as appropriate, consistent with this policy and applicable federal and state regulations and policies.

The UTMB President shall appoint a Conflict of Interest Official (COIO), who shall report to the UTMB President regarding all conflicts of interest activities. The COIO shall perform the duties required by this policy and other duties as assigned by the President. Service as the COIO is in addition to any other capacities in which the person serves the institution. Additionally, the UTMB President shall establish processes for the review of prior approval forms and conflict of interest disclosure statements, for managing, reducing, or eliminating conflicts of interest, and for resolving disputes related to managing, reducing, or eliminating conflicts of interest.

Conflict of Interest Committee:

Upon recommendation of the COIO, the UTMB President shall appoint a Conflict of Interest Committee (COIC) to meet the duties prescribed in this policy. The COIC shall consist of: faculty members and administrators from academic, clinical, and basic science departments; representative from various university areas such as Research Services, UTMB's Human Research Protection Program, Purchasing, Office of Institutional Compliance, and Legal Affairs, as well as representatives from the local Galveston County community.

The COIC shall meet as necessary to review disclosures and other related issues brought to the attention of the Committee. The COIC shall make recommendations as needed including the design of management plans in order to manage, reduce, or eliminate identified conflicts of interest and conflicts of commitment.

V. Financial Holdings or Investments of UTMB

Investments:

Except for equity acquired as part of a licensing agreement and gifts of equity to UTMB, only the University of Texas Investment Management Company (UTIMCO) is authorized to acquire equity in companies on behalf of UTMB. The policy of UTIMCO is to maintain a separation of the sources of information and decision-making related to the investment of UTMB's assets and the operations of the University, including the conduct of research. This firewall is important to separate the research and other academic functions from the investment function of the University. UTIMCO oversees investments in the Permanent University Fund, the Permanent Health Fund, the Long Term Fund, the Short Intermediate Term Fund, and other assets.

Licensing Activities:

When UTMB licenses technology or other intellectual property, it may receive equity in a company as a result of that license and/or a royalty or other fee as compensation for the use of that intellectual property. UTMB may also receive equity or other financial interests as part of a co-investment in the company by the University. An Institutional Conflict of Interest (ICOI) may be created if an investigator at UTMB undertakes to do human subjects research on a drug, device, biologic or other item on which the Board of Regents of the University of Texas System owns a patent or has filed a patent application, has licensed intellectual property, or receives royalties or other licensing fees. To address such potential conflicts of interest and to ensure the integrity of research, the COIC may institute an appropriate management plan, including independent review from another UTMB researcher designated by the Committee.

UTMB's Office of Technology Transfer (OTT), which serves as a bridge between UTMB-sponsored research and commercialization partners, shall provide the COIO or his/her designee with quarterly reports that disclose the entities in which UTMB (i.e., through UTIMCO) holds equity positions, or from which it has the right to receive royalty payments. The COIO or his/her designee will then compare the disclosures to ongoing or proposed human subjects research involving those entities to determine whether a significant ICOI exists. If a significant ICOI exists, the matter will be brought before the COIC for further action, if necessary.

Gifts to UTMB:

UTMB may receive gifts from corporate entities that act as vendors for the institution or sponsor research involving human subjects conducted at the university.

A gift is any item of value given to UTMB by a donor who expects nothing significant of value in return, other than recognition and disposition of the gift in accordance with the donor's wishes. In general, the following characteristics describe a gift:

1. Gifts may be accompanied by an agreement that restricts the use of the funds to a particular purpose; beyond that, no contractual requirements are imposed (beyond the requirements of responsible stewardship) and there are no "deliverables" to the donor, e.g., no rights to tangible or intellectual property.

2. A gift is typically irrevocable. While the gift may be intended for use within a certain timeframe, there is usually no specified "period of performance" or "start" and "stop" dates as associated with sponsored projects.

3. There is no formal fiscal accountability to the donor beyond periodic progress reports and summary reports of expenditures. These reports may be thought of as requirements of good stewardship, and as such, may be required by the terms of a gift. They are not characterized as contractual obligations or "deliverables."

Gift solicitations should be coordinated with UTMB's Office of Development and conducted according to that Office's policies and procedures. The Office of Development shall provide the COIO or his/her designee with quarterly reports that disclose the entities which provided UTMB with monetary gifts over $50,000.

The COIO or his/her designee will then compare the disclosures to ongoing or proposed human subjects research involving those entities to determine whether a significant ICOI exists. If a significant ICOI exists, the matter will be brought before the COIC for further action, if necessary.

VI. Prior Approval of Requests for Outside Activity

IHOP 6.5.3 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities* requires Institutional Officials to seek and receive prior approval **before** engaging in certain outside activities. Please consult IHOP 6.5.3 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities* for details regarding prior approval of Institutional Officials outside activities.

VII. Disclosure of Financial Holdings or Investment and Outside Activities of Institutional Officials

Because of their supervisory and institutional decision-making functions, Institutional Officials encounter conflict of interest situations beyond those faced by most faculty and other administrators. They often do not conduct research, teaching, or faculty service projects in their administrative capacities but may be in a position to influence how these activities are conducted and reported at the institution. Institutional Officials' business and significant financial relationships with outside entities must be disclosed to prevent any real or perceived institutional conflicts of interest.

Research-related Functions:

Pursuant to IHOP 6.5.1 – *Research Conflicts of Interest*, Institutional Officials, including those in a temporary or interim position, who have research oversight authority or have immediate oversight of human subjects research must disclose financial holdings and equity interests in outside entities that may sponsor research conducted at UTMB. These individuals include, but are not limited to, members of UTMB's Executive Committee, School Deans, Department Chairs, and Vice Chairs/Administrators.

Financial interests of the President are disclosed through a process conducted by the Texas Ethics Commission. Please consult IHOP 6.5.1 – *Research Conflicts of Interest for disclosure rules if you are an Institutional Official who has oversight over research or can affect the design, conduct, or reporting of research in any way.*

Non-Research-related Functions:

If you are an Institutional Official whose responsibilities are not related to research in any way described above, you must follow the disclosure rules outlined in IHOP 6.5.3 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities*.

Gifts:

There are two standards under Texas law governing gifts – (1) a general standard of conduct applicable to all employees and (2) a criminal standard applicable only to Institutional Officials (i.e., those persons who make recommendations or decisions about contracts, financial transactions, and employee appointments).

See IHOP 6.5.5 - *Gifts, Honoraria, Fundraising, and Other Activities* for guidance on gift acceptance allowances and procedures for Institutional Officials and other employees.

VIII. Management of Institutional Conflicts of Interest

The COIC is responsible for overseeing the development and implementation of ICOI management plans.

A management plan may impose any condition and prescribe any action necessary to manage an ICOI to ensure that the financial activity or outside activity is free from bias or the appearance of bias.

Examples of conditions or actions that may be prescribed include, but are not limited to:

1. public disclosure of the conflict of interest in presentations and publications;
2. for human subjects research, direct disclosure of the conflict of interest to research participants;
3. appointment of an independent monitor with authority to take measures to protect the design, conduct, and reporting of research against bias, or the appearance of bias, resulting from the conflict of interest;
4. modification of a research plan; or
5. severance of relationships that create an actual or potential ICOI.

A management plan must be in the form of a written agreement and must: (1) provide that the Institutional Official acknowledges receipt of the plan and understands the requirements of this policy and the required actions and other terms of the plan, including the time frames for required actions; and (2) clearly identifies each specific person responsible for monitoring compliance with the management plan.

Each person under a management plan shall comply fully and promptly with the plan, and each person identified in the management plan as having responsibility for monitoring compliance with the plan shall carefully and fully monitor that compliance.

IX. Enforcement and Compliance

Disclosure is a Condition of Employment or Relationship to Institution:

Timely, complete, and accurate disclosure of activities and financial interests consistent with this policy is a condition of employment at UTMB. An Institutional Official who does not comply with this policy, including but not limited to failure to timely file or knowingly filing an incomplete, erroneous or

misleading disclosure statement and/or failure to comply with other policy requirements, is subject to discipline, up to and including termination of employment. Additional sanctions may include termination of the activity that is a conflict and/or divestiture of significant financial interests. In the case of a violation of criminal or civil law, violators may be subject to civil or criminal penalties.

State Laws and Regulations and Institutional and UT System Policies:
This policy supplements, and Institutional Officials are required to adhere to, federal and state laws and regulations as well as other UTMB policies, including but not limited to the Rules and Regulations of the University of Texas System Board of Regents, University of Texas System Business Procedure Memoranda, the UTMB Institutional Handbook of Operating Procedures (IHOP), and UTMB's *Standard of Conduct Guide*.

X. Appeals

Please consult IHOP 6.5.3 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities* for details regarding the appeals process for denied requests for prior approval.

XI. Maintenance of Records

UTMB will provide for a centralized repository for financial interest disclosure statements, management plans, and related records.

Records regarding the disclosure of financial interests, and the management of a conflict of interest including financial interest disclosure statements, a reviewing official's determinations, and other records of institutional actions, shall be retained for the longer of at least three (3) years after: (1) the date of creation; (2) the date of termination or completion of a research award or contract, or the submission of the final expenditures report, for research identified in a disclosure statement; or (3) the date of final resolution of any investigation, audit, or similar action involving the records.

The COIO, or another person designated by the President of UTMB, shall provide the chancellor of The University of Texas System, upon request, with copies of all guidelines, procedures, and forms used by the institution relating to financial conflicts of interest and shall ensure that the Chancellor receives copies of any revised guidelines, procedures, and forms simultaneously with the implementation of the revision.

The disclosure forms shall be considered confidential and the information disclosed in the forms will be available only to individuals duly charged with the responsibility for review. However, the information may be released in accordance with and as required by Texas law or lawful court order.

XII. Monitoring

The institution will provide for regular monitoring of financial interest disclosure statements to determine individual and institutional compliance with this policy.

XIII. Definitions

Conflict of Commitment (COC): a state in which the time or effort that a UTMB employee devotes to an outside activity directly or significantly interferes with the employee's fulfillment of his or her institutional responsibilities or when the employee uses State property without authority in connection with the employee's outside employment, board service, or other activity. Exceeding the amount of total time permitted by U.T. System or UTMB policy for outside activities creates the appearance of a conflict of commitment.

Human Subject: is defined as any living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private

information. Research involving a human subject requires panel review and approval by a UTMB Institutional Review Board (IRB).

Institutional Conflict of Interest (ICOI): a situation in which the purchasing activities, research, teaching, outreach, or other activities of UTMB may be compromised because of an external financial or business relationship held by the institution or by an institutional leader or his or her family members that may bring financial gain to UTMB, any of its divisions, departments, or Institutional Officials.

Institutional Officials: those individuals, including those in a temporary or interim position, who have direct authority over faculty appointments, salaries, promotions, and/or allocation of institutional resources, such as assignment of graduate students or other trainees, funding or space, or faculty who are conducting human subjects research. Such individuals include, but are not limited to, members of UTMB's Executive Committee, School Deans, Department Chairs, and Vice Chairs/Administrators. Financial interests of the President are disclosed through a process conducted by the Texas Ethics Commission.

Outside Entity: any organization (including for-profit or not-for-profit and whether incorporated or otherwise) that is not owned or controlled by UTMB, or any individual that is not employed or otherwise affiliated with UTMB.

Research: a systematic investigation designed to develop or contribute to generalizable knowledge, including biomedical, behavioral, and social-sciences research or other scholarly activity.

Significant Institutional Conflict of Interest: an institutional conflict of interest is deemed to be "significant" when the financial interest or outside activities of UTMB, or of its Institutional Officials, may compromise, or appear to bias, purchasing activities, investments, research, teaching, outreach and other institutional duties or activities.

XIV. Relevant System Policies and Procedures

- UT System Regents' Rules and Regulations - http://www.utsystem.edu/BOR/rules/
- UTMB Standards of Conduct Guide - http://www.utmb.edu/compliance/standardsofconduct.htm
- UT Regents' Rules and Regulations
- UT System Rule 180UT System Rule 175

XV. Related UTMB Policies and Procedures

- IHOP 6.5.1 – Research Conflicts of Interest
- IHOP 6.5.2 – Ethical Interactions with Industry
- IHOP 6.5.3 – Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities
- IHOP 6.5.5 – Gifts, Honoraria, Fundraising, and Other Activities

XVI. Dates Approved or Amended

Originated: 08/06/12	
Reviewed with Changes	*Reviewed without Changes*
02/19/14	02/20/14
02/12/15	

XVII. Contact Information

Conflicts of Interest Office
Office of Institutional Compliance
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http://www.utmb.edu/coi