

UTMB HANDBOOK OF OPERATING PROCEDURES

Section 6	Compliance	06/15/04 -Originated
Subject 6.5	Conflicts of Interest and Ethics	05/12/11 -Reviewed w/ changes
		02/01/14 -Reviewed w/ changes
Policy 6.5.1	Research Conflicts of Interest	02/01/14 -Effective
		Office of Institutional Compliance
		- Author

Research Conflicts of Interest

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.

Covered Family Member: for purposes of disclosure, a Covered Family Member includes (1) a spouse; (2) a dependent child or stepchild; (3) any other person financially dependent on the Covered Individual; and (4) any other person with whom the Covered Individual has joint financial interests such that an objective third party could reasonably conclude that the Covered Individual's decisions or other exercise of professional responsibilities at the institution could be influenced by the effect of that action on the person's financial interest. Any Individual may be identified as a Covered Family Member without regard to whether a legal or biological family relationship exists with the Covered Individual. If the Covered Individual is in doubt, the Covered Individual should resolve the doubt in favor of disclosure. In disclosing financial interests, the interest of any legal entity, including a foundation or a trust that is controlled or directed by the Individual or by the Individual and Covered Family Members is considered to be the interest of the Covered Individual or Covered Family Member as if the separate legal entity did not exist.

Covered Individual: an Individual who is required to complete a financial disclosure conflicts of interest form. UTMB requires the following to submit a financial conflicts of interest disclosure form: (1) all faculty engaged in organized research activities; (2) members of institutional research review-related committees; (3) staff members who negotiate or execute research agreements on behalf of UTMB; and (4) any Individual who, regardless of title or position, is responsible for the design, conduct or reporting of research, including a principal investigator, co-investigator, faculty agent, research tech, research nurse, staff, fellow or administrator who participates in research.

Fiduciary Position: a position the UTMB employee held in a for-profit or non-profit entity in the preceding twelve (12) months, including a position as a member of the board of directors, an officer, or other executive or management position, for which the Individual received any form of payment or reimbursement for expenses.

Research Conflict of Interest (RCOI): a significant outside interest of a UTMB employee or one of the employee's immediate family members that could directly or significantly affect the employee's performance of his or her

UTMB HANDBOOK OF OPERATING PROCEDURES

Section 6	Compliance	06/15/04 -Originated
Subject 6.5	Conflicts of Interest and Ethics	05/12/11 -Reviewed w/ changes
		02/01/14 -Reviewed w/ changes
Policy 6.5.1	Research Conflicts of Interest	02/01/14 -Effective
		Office of Institutional Compliance
		- Author

Definitions, continued

institutional responsibilities. The proper discharge of an employee's institutional responsibilities could be directly or significantly affected if the employment, service, activity, or interest: (1) might tend to influence the employee's conduct, decisions, or judgment in the design, conduct, or reporting of research results or in exercising an institutional responsibility related to research; (2) could reasonably be expected to impair the employee's judgment in performing his or her non-research related institutional responsibilities; or (3) might require or induce the employee to disclose confidential or proprietary information acquired through the performance of institutional responsibilities.

Honoraria: a payment provided to a UTMB employee from an academic entity, professional service organization, non-profit organization, federal or state agency, foundation, or other similar entity outside UTMB for service provided to the entity, speaking engagement or other public appearance that is beyond the employee's normal responsibilities to UTMB. Payments from private, for-profit, health-care related Industry shall not be considered honoraria.

Institutional Responsibilities: any professional responsibility performed by a Covered Individual on behalf of UTMB, including conducting research activities, teaching, professional practice, research consultation, institutional committee membership, and service on an institutional research committee or panel including, but not limited to, an Institutional Review Board (IRB), Data and Safety Monitoring Board (DSMB), or Pharmacy and Therapeutics Committee.

PHS Awarding Component: the organizational unit of the Public Health Service (PHS) that funds research.

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

Significant Financial Interest: A covered individual's disclosure statement must include the following information about the covered individual and covered family members, but only in regard to interests that reasonably appear to be related to the individual's institutional responsibilities:

1. **From a Publicly-Traded Entity:** the total amount and source of payments received in the preceding twelve (12) months from a publicly-traded entity and the value of any equity interest held in the entity on the date of disclosure, including: (a) salary or other payments for services such as consulting fees, honoraria, or paid authorship; and (b) equity interests held, including stock, stock options, or other ownership interest or entitlement to such an interest, valued by reference to public prices or other reasonable measures of fair market value.

UTMB HANDBOOK OF OPERATING PROCEDURES

Section 6	Compliance	06/15/04 -Originated
Subject 6.5	Conflicts of Interest and Ethics	05/12/11 -Reviewed w/ changes
		02/01/14 -Reviewed w/ changes
Policy 6.5.1	Research Conflicts of Interest	02/01/14 -Effective
		Office of Institutional Compliance
		- Author

Definitions, continued

2. **From a Non-Publicly Traded Entity:** the total amount and source of payments received in the preceding twelve (12) months from a non-publicly traded entity and a description of any equity interest held in the entity on the date of disclosure, including: (a) salary or other payments for services such as consulting fees, honoraria, or paid authorship; and (b) equity interests held in any amount, including stock, stock options, or other ownership interest or entitlement to such an interest.

3. **Travel:** any reimbursed or sponsored travel provided in the preceding twelve (12) months. The disclosure of travel must include the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, the value, and whether a Covered Family Member accompanied the Covered Individual on the trip. The Conflict of Interest Official may request further information about a Covered Individual's travel, including the monetary value of the travel, in order to determine whether the travel constitutes a RCOI.

(NOTE – There is a \$5,000 threshold in 1-3 above that is only relevant for determination of whether the interest is a Significant Financial Interest. For purposes of disclosure, there is a \$0 threshold. Therefore, covered individuals shall disclose any payments that reasonably appear to be related to the individual's institutional responsibilities, regardless of dollar amount.)

4. **Intellectual Property and Royalties:** a description of intellectual property rights held and any agreements to share in royalties related to those rights; and the amount and source of royalty income that the Covered Individual or Covered Family Member received or had the right to receive in the preceding twelve (12) months.

5. **Gifts:** the value and source of a single gift that the Covered Individual received in the preceding twelve (12) months that exceeds \$250 in value, or multiple gifts from a single entity that in the aggregate exceed \$250 in value, other than gifts from a Covered Family Member, or close personal friend with whom the Covered Individual has an independent relationship unrelated to his/her status or work at UTMB.

6. **Fiduciary Positions:** service as an officer, director, or fiduciary for a for-profit or nonprofit entity in the preceding twelve (12) months for which the Covered Individual received any sort of compensation, salary, or payment for expenses, and the name and principal address of the entity.

NOTE – Some of the interests described above require Covered Individuals to seek and acquire prior approval **before** engaging in the activity. Others allow covered individuals to update their disclosure statements within 30 days of

UTMB HANDBOOK OF OPERATING PROCEDURES

Section 6	Compliance	06/15/04 -Originated
Subject 6.5	Conflicts of Interest and Ethics	05/12/11 -Reviewed w/ changes
		02/01/14 -Reviewed w/ changes
Policy 6.5.1	Research Conflicts of Interest	02/01/14 -Effective
		Office of Institutional Compliance
		- Author

Definitions, continued

acquiring the interest. Please consult IHOP 6.5.3 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities* to determine if your activity requires prior approval.

The following interests are not considered to be “significant financial interests” and do not need to be disclosed by a Covered Individual on a disclosure statement:

1. Salary, royalties, or other remuneration paid by UTMB to the Covered Individual, if the Covered Individual is currently employed or otherwise appointed by UTMB;
2. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government, an institution of higher education as defined by 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education;
3. Income from service on an advisory committee or review panel for a Federal, state, or local government, an institution of higher education as defined by 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education;
4. Income from investment vehicles, such as mutual funds or retirement accounts, as long as the Covered Individual does not directly control the investment decisions made in those vehicles; or
5. Travel reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined by 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Scope

This policy applies to Covered Individuals, as defined above. This policy must be followed in addition to 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 – *Institutional Conflicts of Interest*; IHOP 6.5.5 – *Gifts, Honoraria, Fundraising and other Activities*, and other IHOP policies where applicable.

Policy

UTMB is committed to ensuring that financial interests of its researchers and the institution do not affect, or appear to affect, the design, conduct, or reporting of research or compromise the protection of human subjects. Therefore, members of the university community, including those conducting research, regardless of funding source, 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

UTMB HANDBOOK OF OPERATING PROCEDURES

Section 6	Compliance	06/15/04 -Originated
Subject 6.5	Conflicts of Interest and Ethics	05/12/11 -Reviewed w/ changes
		02/01/14 -Reviewed w/ changes
Policy 6.5.1	Research Conflicts of Interest	02/01/14 -Effective
		Office of Institutional Compliance
		- Author

Policy, continued

manage, reduce, or eliminate conflicts of interest.

This policy does not necessarily preclude the conduct of research where a conflict of interest, or potential conflict of interest, is present. Within the process, there may be situations where the research is allowed to proceed if it is of sufficient importance and appropriate safeguards are in place and in the case of human subjects research, there exists compelling circumstances that warrant allowing the protocol to proceed. 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 sixteen (16) sections:

1. [Conflict of Interest Official and Conflict of Interest Committee](#)
2. [Education and Training](#)
3. [Prior Approval of Requests for Outside Activity](#)
4. [Disclosure of Financial Interests](#)
5. [Disclosure Statement Review and Determination of Research Conflict of Interest](#)
6. [Activities and Interests that Do Not Require Disclosure and/or Prior Approval](#)
7. [Management of Financial Conflicts of Interest](#)
8. [Research Involving Human Subjects](#)
9. [Web Posting of Research Conflict of Interest Information and Policy](#)
10. [Certification and Reports to PHS](#)
11. [Reporting of Research Related Institutional Financial Interests](#)
12. [Collaborators, Contractors, and Sub-recipients](#)
13. [Enforcement and Compliance](#)
14. [Appeals](#)
15. [Maintenance of Records](#)
16. [Audits](#)

Section 1: Conflict of Interest Official (COIO) and Conflict of Interest Committee (COIC)

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.

UTMB HANDBOOK OF OPERATING PROCEDURES

Section 6	Compliance	06/15/04 -Originated
Subject 6.5	Conflicts of Interest and Ethics	05/12/11 -Reviewed w/ changes
		02/01/14 -Reviewed w/ changes
Policy 6.5.1	Research Conflicts of Interest	02/01/14 -Effective
		Office of Institutional Compliance
		- Author

Section 1: Conflict of Interest Official (COIO) and Conflict of Interest Committee (COIC), continued

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.

Section 2: Education and Training

Each Covered Individual must acknowledge annually that he/she is aware of and has read this policy and is aware of his/her responsibilities regarding disclosure of significant financial interests and of applicable federal and state regulations as well as UTMB and U.T. System policies.

A Covered Individual must complete training related to this policy and other applicable policies, regulations, and laws before engaging in research at the institution and at least once every four (4) years thereafter. A Covered Individual who is new to UTMB must satisfy this training requirement before engaging in research at the university or provide evidence of having completed the training at another institution of The University of Texas System within the previous four (4) years.

A Covered Individual must complete the training immediately if the institution finds that the Individual is not in compliance with this policy or the Individual's management plan, or if the institution revises this policy in a manner that affects the Individual's institutional responsibilities.

Failure to complete the required training may result in the withholding of access to funds related to federally-funded or other sponsored research activities until such time as the Covered Individual completes the training.

Section 3: Prior Approval of Requests for Outside Activities

IHOP 6.5.3 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities* requires certain Covered Individuals to seek and receive prior approval **before** engaging in certain outside activities. Please consult Section 2 of IHOP 6.5.3 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities* to determine if an activity you plan on engaging in requires prior approval.

UTMB HANDBOOK OF OPERATING PROCEDURES

Section 6	Compliance	06/15/04 -Originated
Subject 6.5	Conflicts of Interest and Ethics	05/12/11 -Reviewed w/ changes
		02/01/14 -Reviewed w/ changes
Policy 6.5.1	Research Conflicts of Interest	02/01/14 -Effective
		Office of Institutional Compliance
		- Author

Section 4: **Disclosure of** **Financial Interests**

Extent and Frequency of Disclosure:

In addition to requests for approval to engage in outside activities, a Covered Individual shall complete or update an RCOI disclosure statement that: (1) identifies all research in which the Covered Individual is engaged at the time of the disclosure; and (2) identifies each financial interest (see definition of Significant Financial Interest above for guidelines on what must be disclosed) of the Covered Individual and Covered Family members that reasonably appears to be related to the Individual's institutional responsibilities. In determining whether research or a financial interest should be disclosed, the Covered Individual should resolve the doubt in favor of disclosure. Failure to meet disclosure requirements may result in applications for federally-funded or other sponsored research not being forwarded to the federal agency or sponsor.

When to Disclose:

A Covered Individual shall submit or update an RCOI disclosure statement:

1. Not later than the 30th day of initial employment, or within thirty (30) days after a change in employment status covering the twelve (12) months preceding the date of disclosure;
2. **Annually**, during the disclosure period set by the institution;
3. Not later than the 30th day after acquiring a new financial interest that requires disclosure (NOTE: some outside activities (e.g., employment, board service, consulting, speaking engagements, etc.) must receive prior approval as required by IHOP 6.5.3 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities*); and
4. At the request of the UTMB President, the COIC, or the COIO or his/her designee.

A Covered Individual planning on participating in PHS-funded research project must submit an RCOI disclosure statement not later than at the time of the submission of the application to the PHS-related agency.

Section 5: **Disclosure** **Statement Review** **and** **Determination of** **Research Conflict** **of Interest**

Disclosure Statement Review:

The COIC, or its designee, shall review each financial interest disclosure statement and make three determinations: (1) whether any disclosure may be considered a significant financial interest; (2) whether any significant financial interest disclosed is related to a Covered Individual's institutional responsibilities; and (3) if so, whether an RCOI or COI exists.

A significant financial interest is related to research in which the Covered Individual is engaged if the COIC, or its designee, reasonably determines that the financial interest appears to be affected by the research or is in an entity whose financial interest appears to be affected by the research.

An RCOI exists when the COIC, or its designee, reasonably determines that a

UTMB HANDBOOK OF OPERATING PROCEDURES

Section 6	Compliance	06/15/04 -Originated
Subject 6.5	Conflicts of Interest and Ethics	05/12/11 -Reviewed w/ changes
		02/01/14 -Reviewed w/ changes
Policy 6.5.1	Research Conflicts of Interest	02/01/14 -Effective
		Office of Institutional Compliance
		- Author

Section 5: Disclosure Statement Review and Determination of Research Conflict of Interest, continued

significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.

No Expenditure of Funds Prior to Review and Determination:

Neither the institution nor a Covered Individual may expend research funds until all training requirements have been fulfilled relating to this and other applicable policies.

Cooperation with IRB and IACUC:

The COIO, the COIC, the Conflict of Interest Office and the appropriate Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) shall cooperate in the consideration of whether a Covered Individual has an RCOI with regard to human and/or animal subjects research and in the development and implementation of a management plan for that conflict of interest.

Section 6: Activities and Interests that Do Not Require Full Disclosure and/or Prior Approval

Please refer to Section 5 of IHOP 6.5.3 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities* to determine if your activity or interest is an exception to full disclosure and/or prior approval requirements.

Section 7: Management of Financial Conflicts of Interest

Management Required for Financial Conflicts of Interest:

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

While evaluation and management of the potential conflict is the goal, it is recognized that some conflicts may not be manageable. Nonetheless, when the investigator has a unique capability and must be involved with a critical research project to ensure its proper performance, it may be appropriate for the research to go forward with a well-defined and carefully-monitored management plan.

Neither the institution nor a Covered Individual may expend research funds unless the COIC, or its designee, has determined that no RCOI exists or that any RCOI is manageable in accordance with the terms of a management plan that has been adopted and implemented.

A management plan may impose any condition and prescribe any action necessary to manage a RCOI to ensure that the design, conduct, or reporting of the research is free from bias or the appearance of bias. Examples of conditions

UTMB HANDBOOK OF OPERATING PROCEDURES

Section 6	Compliance	06/15/04 -Originated
Subject 6.5	Conflicts of Interest and Ethics	05/12/11 -Reviewed w/ changes
		02/01/14 -Reviewed w/ changes
Policy 6.5.1	Research Conflicts of Interest	02/01/14 -Effective
		Office of Institutional Compliance
		- Author

Section 7: Management of Financial Conflicts of Interest, continued

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 the research plan;
5. change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
6. divestiture or reduction of the financial interest; or
7. severance of relationships that create an actual or potential RCOI.

A management plan must be in the form of a written agreement and must: (1) provide that the Covered Individual 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 conducting research 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.

If research is ongoing and a new Covered Individual discloses a significant financial interest related to that research or any other Covered Individual discloses a new significant financial interest related to that research, the COIC, or its designee, shall, not later than the sixtieth (60th) day after the filing of the disclosure statement: (1) review the disclosure statement to determine if a RCOI exists; and (2) if an RCOI exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the research.

In addition, if an RCOI was not timely identified or managed, or if a Covered Individual fails to comply with a management plan, the COIC, or its designee shall, not later than the 120th day after determining noncompliance: (1) complete and document a retrospective review and determination as to whether research conducted during the period of noncompliance was biased in the design, conduct, or reporting of the research; and (2) implement any measures necessary with regard to the Covered Individual's participation in the research between the date that the noncompliance is identified and the date the retrospective review is completed.

For PHS-Covered research projects, the retrospective review shall cover key

UTMB HANDBOOK OF OPERATING PROCEDURES

Section 6	Compliance	06/15/04 -Originated
Subject 6.5	Conflicts of Interest and Ethics	05/12/11 -Reviewed w/ changes
		02/01/14 -Reviewed w/ changes
Policy 6.5.1	Research Conflicts of Interest	02/01/14 -Effective
		Office of Institutional Compliance
		- Author

Section 7, continued

elements as specified by federal regulations and may result in updating the RCOI Report, notifying the PHS, and submitting a mitigation report as required by federal regulation.

Section 8: Research Involving Human Subjects

While the thresholds for disclosure are the same for all types of research, additional diligence in evaluation and management is required for research with potential risks to human subjects or with potential implications for medical care and the practice of medicine. The COIC applies the rebuttable presumption standard when reviewing financial conflicts of interest in human subjects research, i.e., Covered Individuals with significant financial interests may not conduct the research unless there are compelling circumstances.

Compelling circumstances include factors such as (1) unique investigator expertise; (2) unique access to particular patient populations; (3) nature of science; (4) level of risk for human subjects; and (5) degree to which financial interests and research are linked.

While this policy is consistent with simultaneous review of a given research proposal by both the COIC and IRB, the COIC review process will be completed and the report forwarded to the IRB Office before the protocol receives final review and approval by an Institutional Review Board (IRB). The IRB may request revision of the recommended management plan if it feels the conflict cannot be managed or the proposed plan is insufficient. These two committees will work in conjunction with each other and the COIC process should provide sufficient information to ensure that, as applicable, conflicts are managed and research participants are informed.

Section 9: Web Posting of Research Conflict of Interest Information and Policy

Posting of Information Regarding Specific Financial Conflicts of Interest:

With regard to each Covered Individual who (1) has an RCOI that is found to exist by the COIC; and (2) contributes to the scientific development or execution of the research project in a substantive, measurable way, including a Covered Individual who is the project director or principal investigator, UTMB shall make the following information available to the public through the Internet:

1. the Covered Individual's name;
2. the Covered Individual's title and role with respect to the research;
3. the name of the entity in which the significant financial interest is held;
4. the nature of the significant financial interest that constitutes a RCOI; and
5. the approximate value of the significant financial interest by range or, if the dollar value cannot be determined by reference to public prices or other reasonable measures of fair market value, a statement to that effect.

The approximate dollar value of the significant financial interest shall be

UTMB HANDBOOK OF OPERATING PROCEDURES

Section 6	Compliance	06/15/04 -Originated
Subject 6.5	Conflicts of Interest and Ethics	05/12/11 -Reviewed w/ changes
		02/01/14 -Reviewed w/ changes
Policy 6.5.1	Research Conflicts of Interest	02/01/14 -Effective
		Office of Institutional Compliance
		- Author

Section 9: **Web Posting of Research Conflict of Interest Information and Policy, continued**

provided within the following ranges if it can be determined by reference to public prices or other reasonable measures of fair market value:

1. \$0 - \$4,999;
2. \$5,000 - \$9,999;
3. \$10,000 - \$19,999;
4. amounts between \$20,000 - \$100,000 by increments of \$20,000; or
5. amounts above \$100,000 by increments of \$50,000.

UTMB will update the information required by this section annually. In addition, for any RCOI of a Covered Individual whose information must be posted under this section and for which the information was not previously posted, the institution will make the information required by this section available not later than the sixtieth (60th) day after the RCOI is identified.

The website on which the information is posted will note that the information is current as of the date listed and is subject to updates.

The information required by this section will remain available on the Internet for three (3) years after its most recent update.

For PHS-funded research, in regard to project directors, principal investigators, and other senior or key personnel, this information must be available through the Internet before expending PHS funds.

Posting of this Policy:

This policy and each update of this policy shall be publicly accessible through the Internet.

Section 10: **Certification and Reports to PHS**

Certification and Report Required:

Federal regulations require that each application for funding to the PHS include specific certifications and agreements in regard to this policy and financial conflicts of interest. Federal regulations also require that the institution make the reports required by this policy for PHS-funded research.

Research Conflict of Interest Report:

Before the expenditure of any funds under a PHS-funded research project, the appropriate institutional officials will make the RCOI Report to the PHS-awarding component in compliance with 42 CFR Part 50, Subpart F, and 45 CFR Part 94. In general, those regulations require an RCOI Report regarding those interests that the institution determines are Individual Financial Conflicts of Interest, including financial conflicts of interest of sub-recipients. The reporting will include specified information sufficient to enable the awarding component to understand the nature and extent of the financial conflict and to assess the appropriateness of the management plan related to the conflict of interest. The federal regulations require reporting within a specified period of

UTMB HANDBOOK OF OPERATING PROCEDURES

Section 6	Compliance	06/15/04 -Originated
Subject 6.5	Conflicts of Interest and Ethics	05/12/11 -Reviewed w/ changes
		02/01/14 -Reviewed w/ changes
Policy 6.5.1	Research Conflicts of Interest	02/01/14 -Effective
		Office of Institutional Compliance
		- Author

Section 10, **continued**

financial conflicts of interest identified subsequent to an earlier report and require annual updating of reports regarding previously disclosed financial conflicts of interest.

Section 11: **Reporting of** **Research Related** **Institutional** **Financial Interests**

Covered Individuals must also identify institutional financial interests related to their proposed research, if known, on the applicable disclosure form.

See IHOP 6.5.4 – Institutional Conflicts of Interest for additional information and guidance.

Section 12: **Collaborators,** **Contractors and** **Sub-recipients**

If research is to be carried out in cooperation with or through a subcontractor, contractor, or collaborator, including a person identified under federal regulations as a “sub-recipient,” UTMB must enter into a written agreement with the contracting party that provides legally enforceable terms that establish whether this policy or the financial conflicts of interest policy of the contracting party applies to the researchers of the contracting party.

If the policy of the contracting party applies to its researchers, the contracting party must certify that its policy is consistent with the requirements of any applicable federal regulations. If the contracting party cannot so certify, the agreement must state that the researchers are subject to this policy as Covered Individuals for disclosing significant financial interests that are directly related to the researcher’s work at UTMB.

If the policy of the contracting party applies to its researchers, the agreement must specify the time periods for the contracting party to report identified financial conflicts of interest to this institution. The time periods must be sufficient for this institution to make any reports required by federal regulation.

If the policy of this institution applies to the researchers of the contracting party, the agreement must specify the time periods for the researchers to submit a financial interest disclosure statement to this institution. The time periods must be sufficient for this institution to comply with its review, management, and reporting obligations under federal regulations.

Section 13: **Enforcement and** **Compliance**

Disclosure is a Condition of Employment or Relationship to Institution

1. UTMB Employees and Students: Timely, complete, and accurate disclosure of activities and financial interests consistent with this policy is a condition of employment at UTMB, and a Covered Individual who does not comply with this policy, including but not limited to, failure to 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 for employees or suspension or expulsion in the case of a student. Additional sanctions may include termination of the activity that is a conflict of interest, and/or divestiture of significant financial interests. In the case of a violation of

UTMB HANDBOOK OF OPERATING PROCEDURES

Section 6	Compliance	06/15/04 -Originated
Subject 6.5	Conflicts of Interest and Ethics	05/12/11 -Reviewed w/ changes
		02/01/14 -Reviewed w/ changes
Policy 6.5.1	Research Conflicts of Interest	02/01/14 -Effective
		Office of Institutional Compliance
		- Author

Section 13: Enforcement and Compliance, continued

criminal or civil law, violators may be subject to civil or criminal penalties.

2. **Non-UTMB Employees:** For a Covered Individual who is not an employee of UTMB, including contractors or consultants, compliance with this policy is a condition of participating with the institution in the capacity that qualifies the person as a Covered Individual. UTMB may require the Individual to execute a document certifying that the Individual knows that compliance with this policy is a condition of participation. Failure to comply with this policy including, but not limited to, failure to 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 relationship, termination of the activity that is a conflict of interest, 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.

Federal Enforcement

1. Federal regulations, 42 CFR Part 50, Subpart F, and 45 CFR Part 94, require the institution to notify the Public Health Service (PHS) of instances in which the failure of a Covered Individual to comply with this policy or a management plan appears to have biased the design, conduct, or reporting of PHS-funded research. The PHS awarding component may take enforcement action or require the institution to take action appropriate to maintaining objectivity in the research. The institution must make information available to the U.S. Department of Health and Human Services (HHS) or the PHS awarding component as required by federal regulation.
2. If the HHS determines clinical research funded by PHS to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a Covered Individual with a RCOI that was not managed or reported by the institution as required by federal regulation, the institution will require the Covered Individual involved to disclose the RCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

State Laws and Regulations and Institutional and UT System Policies

This policy supplements, and Covered Individuals 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, and the UTMB Institutional Handbook of Operating Procedures (IHOP) and UTMB's *Standard of Conduct Guide*.

UTMB HANDBOOK OF OPERATING PROCEDURES

Section 6	Compliance	06/15/04 -Originated
Subject 6.5	Conflicts of Interest and Ethics	05/12/11 -Reviewed w/ changes
		02/01/14 -Reviewed w/ changes
Policy 6.5.1	Research Conflicts of Interest	02/01/14 -Effective
		Office of Institutional Compliance
		- Author

Section 14: **Appeals**

An employee may appeal the finding by the COI Office that a requested activity is not permissible under this policy. An employee may also appeal the determination made by his/her supervisor that a permitted activity is denied. In either case, the employee must submit a written appeal (form found on the COI Office webpage) within 30 days of receipt of the notice of impermissibility or denial. The appeal will be directed to the Executive Vice President overseeing the enterprise or division in which the employee resides. The Executive Vice President may then choose to affirm the denial of the activity or reverse the determination and approve the requested activity. The Executive Vice President's determination is final. Alternatively, the Executive Vice President may transfer the appeal to an administrator, chair, or dean within the same enterprise or division for final determination. Finally, the Executive Vice President may choose to transfer the appeal to the COIC for final determination.

Section 15: **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 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.

Section 16: **Audits**

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

Contacts

Conflicts of Interest Office
Office of Institutional Compliance
(409) 266-9435
<http://www.utmb.edu/coi>

UTMB HANDBOOK OF OPERATING PROCEDURES

Section 6	Compliance	06/15/04 -Originated
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		02/01/14 -Reviewed w/ changes
Policy 6.5.1	Research Conflicts of Interest	02/01/14 -Effective
		Office of Institutional Compliance - Author

References

- [NIH Final Conflicts of Interest Rule \(8/25/11\)](#)
 - [20 U.S.C. Sec. 101 \(General Definition of an Institution of Higher Education\)](#)
 - [UT Regents' Rules and Regulations](#)
 - UT System Rule 180
 - UT System Rule 175
 - 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 – Institutional Conflicts of Interest
 - IHOP 6.5.5 – Gifts, Honoraria, Fundraising, and Other Activities
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