Section 11		Research	06/15/04 -Originated
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Policy	**11.1.2**	**Disclosure of Financial Interests and Management and Reporting of Financial Conflicts of Interest in Research**	01/01/12 – Effective Research Services - Author

Disclosure of Financial Interests, and Management and Reporting of Financial Conflicts of Interest in Research

Definitions

Covered Family Member:

a. A "Covered Family Member" includes: (1) any spouse, (2) 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 relationship.

b. Any individual may be identified as Covered Family 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.

c. 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;
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.

Individual Conflict of Interest: Activities or personal financial interests that may directly and significantly affect, or have the appearance of directly and significantly affecting, an individual's professional judgment in the design, conduct, or reporting of Research results or in exercising an institutional duty or responsibility related to Research.

Institutional Responsibilities: Any of the professional responsibilities of a Covered Individual on behalf of UTMB, including Research, Research consultation, teaching, professional practice, institutional committee membership, or service on an institutional panel including, but not limited to, an Institutional Review Board (IRB), Data and Safety Monitoring Board

Definitions, continued

(DSMB), or Pharmacy and Therapeutics Committee.

Remuneration : Any receipt of, or promise of future receipt of, payments, salary, compensation, honoraria, paid authorship, consulting fees, equity interest (e.g. stock, stock option, or other ownership interest), or in-kind benefits for services provided for any purpose not directly related to the reasonable costs of conducting Research, as specified in any agreement.

Research: Any systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term includes both basic and applied Research and product development.

***Significant Financial Interest*:**

A. The following interests are considered to be significant financial interests, subject to the exclusions provided by Subsection (b) of this section, a Covered Individual's disclosure statement must include the following information in regard to the Covered Individual and Covered Family Members, only if it reasonably appears to be related to the Covered Individual's Institutional Responsibilities:

1. Payments received from, or equity interest in, any publicly-traded entity: the total amount and source of remuneration 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 that, when aggregated, exceeds $5,000 including:
   a. as to payments received: (i) salary; and (ii) any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and
   2. as to equity interests held, any 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;

2. Payments received from a non-publicly traded entity or equity interest in a non-publicly traded entity:
   a. the total amount and source of payments received in the preceding twelve (12) months from an entity that is not publicly traded that, when aggregated, exceeds $5,000, including (i) salary; and (ii) any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and
   b. a description of any equity interest held in an entity that is not publicly traded, including any stock, stock options, or other ownership interests or entitlements to such an interest;
3. Intellectual Property and Royalties.
   a. A description of intellectual property rights held and any agreements to share in royalties related to those rights; and

Definitions, continued

b. 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;

4. **Travel.** Any amount for reimbursed or sponsored travel in the preceding twelve (12) months, including the purpose of the travel, the identity of the sponsor/organizer, the destination, and the duration. Covered Individuals are **not** required to disclose travel that is 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.

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; and

6. **Fiduciary Positions:** A fiduciary position the Covered Individual held in a for-profit or nonprofit 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 Covered Individual received any form of remuneration or reimbursement for expenses, and the name and principal address of the entity.

B. 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;

Definitions, continued

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.

C. In making disclosures under this section, a Covered Individual shall:

1. Disclose the dollar amounts in rounded, whole dollars;
2. When describing a source, provide the name and principal address for the source; and
3. Distinguish among information pertaining to the Covered Individual and Covered Family Members whose financial interests and activities are also disclosed by the Covered Individual.

D. The Conflict of Interest Official, or his/her designee, 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 financial conflict of interest.

Collaborators, Contractors, and Sub-recipients:

A. 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 research being performed.

B. 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.

C. 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.

Definitions, continued

D. 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 regulation

Education and Training:

A. Each Covered Individual must acknowledge annually that the individual is aware of and has read this policy and is aware of the Covered Individual's responsibilities regarding disclosure of Significant Financial Interests and of applicable federal and state regulations and institutional and UT System policies.

B. A Covered Individual must complete training in regard to this policy and 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 complete the training before engaging in research at the institution or provide evidence of having completed the training at another institution of The University of Texas System within the last 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 duties. 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 required disclosure.

C. The Conflicts of Interest Office within Research Services, in conjunction with the Office of Institutional Compliance, is responsible for ensuring that appropriate faculty, staff, trainees, and other persons participate in training in regard to this policy and applicable laws.

Policy

This policy governs the disclosure of individual financial interests and the management and reporting of an individual financial conflict of interest in research performed at UTMB. This policy provides requirements for the disclosure of financial interests that comply with disclosure requirements of federal regulations of the U.S. Department of Health and Human Services (HHS) and the HHS Public Health Service, but this policy is not limited in application to PHS-funded research. Rather, this policy applies broadly to research performed at UTMB, without regard to whether the research has

Policy, continued

external funding and regardless of funding source. This policy applies **in addition to** other UTMB policies, such as UTMB's Standard of Conduct Guide, and other IHOP policies governing disclosure of activities and financial interests. If you are a Covered Individual and have any doubt as to whether this policy applies to a potentially significant financial interest, please contact UTMB's Conflicts of Interest Office within Research Services or the Office of Institutional Compliance.

The policy is divided into the following ten (10) sections:

1. Disclosure of Significant Financial Interests Related to Institutional Responsibilities
2. Conflict of Interest Official; Conflict of Interest Committee (COIC)
3. Disclosure Statement Review; Determination of Financial Conflict of Interest
4. Management of Financial Conflicts of Interest
5. Web Posting of Financial Conflict of Interest Information
6. Certification and Reports to PHS
7. Enforcement and Compliance
8. Appeals
9. Maintenance of Records
10. Audits

Section 1:

Disclosure of Significant Financial Interests Related to Institutional Responsibilities

Extent and Frequency of Disclosure

A. As often as required by sub-section (b) of this section, a Covered Individual shall complete or update a financial conflict of interest disclosure statement that: (1) identifies all research in which the Covered Individual is engaged at the time of the disclosure; and (2) discloses each Significant Financial Interest of the 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.

B. **When to Disclose:** A Covered Individual shall submit or update a financial conflict of interest disclosure:

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, not later than March 1; and
3. Not later than the 30th day after acquiring a new financial interest that requires disclosure;
4. At the request of the UTMB President, UTMB Conflicts of Interest Committee, or the Conflict of Interest Official or his/her designee.
5. A Covered Individual planning to participate in PHS-funded

research project must submit a financial interest disclosure statement not later than at the time of the application to the PHS-related agency.

C. If a Covered Individual discloses payments, intellectual property interests, or royalties, the Covered Individual must provide a copy of any related agreement, contract, offer letter, or other documentation on request of (1) The President of UTMB; (2) The Conflict of Interest Official; or (3) Any other person or entity with administrative responsibility in regard to reviewing financial interest disclosure statements or approving a related management plan.

Contents of Disclosure: Significant Financial Interests

A. The following interests are considered to be significant financial interests and, subject to the exclusions provided by sub-section (b) of this section, a Covered Individual's disclosure statement must include the following information in regard to 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. Payments received from, or equity interest in, any **publicly-traded** entity: the total amount and source of remuneration 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 that, when aggregated, exceeds $5,000 including:
   a. as to payments received: (i) salary; and (ii) any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and
   b. as to equity interests held, any 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;

2. Payments received from a **non-publicly traded** entity or equity interest in a non-publicly traded entity:
   a. the total amount and source of payments received in the preceding twelve (12) months from an entity that is not publicly traded that, when aggregated, exceeds $5,000, including (i) salary; and (ii) any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and
   b. a description of any equity interest held in an entity that is not publicly traded, including any stock, stock options, or other ownership interests or entitlements to such an interest;

3. **Intellectual Property and Royalties.**
   a. A description of intellectual property rights held and any agreements to share in royalties related to those rights; and

Disclosure of Significant Financial Interests Related to Institutional Responsibilities, continued

b. 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;

4. **Travel.** Any amount for reimbursed or sponsored travel in the preceding twelve (12) months, including the purpose of the travel, the identity of the sponsor/organizer, the destination, and the duration. Covered Individuals are **not** required to disclose travel that is 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.

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; and

6. **Fiduciary Positions.** A fiduciary position the Covered Individual held in a for-profit or nonprofit 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 Covered Individual received any form of remuneration or reimbursement for expenses, and the name and principal address of the entity.

B. 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;

Disclosure of Significant Financial Interests Related to Institutional Responsibilities, continued

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.

C. In making disclosures under this section, a Covered Individual shall:

1. Disclose the dollar amounts in rounded, whole dollars;
2. When describing a source, provide the name and principal address for the source; and
3. Distinguish among information pertaining to the Covered Individual and Covered Family Members whose financial interests and activities are also disclosed by the Covered Individual.

D. The Conflict of Interest Official, or his/her designee, 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 financial conflict of interest.

Section 2:

Conflict of Interest Official; 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, who shall report to the UTMB President regarding all Research conflicts of interest activities. The Conflict of Interest Official shall perform the duties required by this policy and other duties as assigned by the President. Service as the Conflict of Interest Official 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 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 Conflict of Interest Official, the UTMB President shall appoint a Conflict of Interest Committee (COIC) to advise the Conflict of Interest Official in meeting 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, Office of Research Subject Protections,

Conflict of Interest Official; Conflict of Interest Committee (COIC), continued

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.

Section 3:

Disclosure Statement Review; Determination of Financial Conflict of Interest

Disclosure Statement Review

A. The Conflict of Interest Official, or his/her designee, shall review each financial interest disclosure statement and make two determinations: (1) whether any significant financial interest disclosed is related to research in which the Covered Individual is engaged; and (2) if so, whether a financial conflict of interest exists.

B. A Significant Financial Interest is related to research in which the Covered Individual is engaged if the Conflict of Interest Official, or his/her 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.

C. A financial conflict of interest exists when the Conflict of Interest Official, or his/her designee, reasonably determines that a 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 The Conflict of Interest Official and the appropriate IRB shall cooperate in the consideration of whether a Covered Individual has a financial conflict of interest in regard to human subjects research and in the development and implementation of a management plan for that conflict of interest.

Section 4:

Management of Financial Conflicts of Interest

Management Required for Financial Conflicts of Interest.

A. If the Conflict of Interest Official determines that a Covered Individual has a financial conflict of interest, the official, in cooperation with the Covered Individual and other appropriate individuals designated by the Conflict of Interest Official, shall develop a management plan governing that conflict of interest.

Management of Financial Conflicts of Interest, continued

B. 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 Conflict of Interest Official shall, not later than the sixtieth (60th) day after the filing of the disclosure statement:

1. review the disclosure statement to determine if a financial conflict of interest exists; and
2. if a financial conflict of interest exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the research.

C. If the Conflict of Interest Official learns of a significant financial interest that was not timely disclosed or was not timely reviewed, the Conflict of Interest Official shall, not later than the sixtieth (60th) day after learning of the interest:

1. determine whether the significant financial interest is a financial conflict of interest; and
2. if a financial conflict of interest exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the research going forward.

D. In addition, if a financial conflict of interest was not timely identified or managed, or if a Covered Individual fails to comply with a management plan, the Conflict of Interest Official 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.

E. For PHS-covered research projects, the retrospective review shall cover key elements as specified by federal regulations and may result in updating the Financial Conflict of Interest Report described by Section 7.02, notifying the PHS, and submitting a mitigation report as required by federal regulation.

Management Plan Design and Agreement.

A. A management plan may impose any condition and prescribe any action necessary to manage a financial conflict of interest, including an action reducing or eliminating the financial conflict of interest, to

Management of Financial Conflicts of Interest, continued

ensure that the design, conduct, or reporting of the research is free from bias or the appearance of bias. Examples of conditions or actions that may be prescribed include:

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. divesture or reduction of the financial interest; or
7. severance of relationships that create an actual or potential financial conflict of interest.

B. 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 identify each specific person responsible for monitoring compliance with the management plan.

Monitoring and Compliance

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.

Section 5:

Web Posting of Financial Conflict of Interest Information

Posting of this Policy

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

Posting of Information Regarding Specific Financial Conflicts of Interest

A. For each financial conflict of interest that is found to exist by the Conflict of Interest Official, UTMB will make the following information available to the public through the Internet in regard to each Covered Individual who contributes to the scientific development or execution of the research project in a substantive, measureable way, including a Covered Individual who is the project director or principal investigator, including:
   1. the covered individual's name;

Web Posting of Financial Conflict of Interest Information, continued

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 financial conflict of interest; 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.

B. The approximate dollar value of the significant financial interest shall be provided within the following ranges if it can 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.

C. UTMB will update the information required by this section annually. In addition, for any financial conflict of interest 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 financial conflict of interest is identified.

D. 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.

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

F. 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.

Section 6:

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.

Financial Conflict of Interest Report

Before the expenditure of any funds under a PHS-funded research project, the

Certification and Reports to PHS, continued

appropriate institutional officials will make the Financial Conflict of Interest 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 a Financial Conflict of Interest Report regarding those interests that the institution determines are 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 financial conflicts of interest identified subsequent to an earlier report and require annual updating of reports regarding previously disclosed financial conflicts of interest.

Section 7:

Enforcement and Compliance

Disclosure is a Condition of Employment or Relationship to Institution.

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

B. 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

A. Federal regulations, 42 CFR Part 50, Subpart F, and 45 CFR Part 94, require the institution to notify the 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

Enforcement and Compliance, continued

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 HHS or the PHS awarding component as required by federal regulation.

B. 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 financial conflict of interest 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 financial conflict of interest 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*.

Section 8:

Appeals

Appeals Procedure
Covered Individuals who wish to appeal a decision of the Conflict of Interest Official, or his/her designee, or a decision made by the Conflict of Interest Committee, may present an appeal to his/her appropriate Dean or Vice President. If the Dean or Vice President approves the appeal, then the appeal is moved forward to the UTMB President for final review. The UTMB President shall decide whether to uphold the decision made by the Conflict of Interest Official and/or Conflict of Interest Committee or allow the activity in question of the Covered Individual.

Section 9:

Maintenance of Records

Records

A. 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 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.

B. UTMB will provide for a centralized repository for financial interest

Maintenance of Records, continued

disclosure statements, management plans, and related records.

C. The Conflict of Interest Official, 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.

D. 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 10:

Audits

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

References

NIH Final Conflicts of Interest Rule (8/25/11)
20 U.S.C. Sec. 101 (General Definition of an Institution of Higher Education) - http://us-code.vlex.com/vid/definition-institution-higher-education-19196079
UT System Regents' Rules and Regulations - http://www.utsystem.edu/BOR/rules/
UTMB Conflict of Interest webpage - http://research.utmb.edu/comp-coi/default.shtm
UTMB Standards of Conduct Guide - http://www.utmb.edu/compliance/standardsofconduct.htm