

**Institutional Handbook of Operating Procedures  
Policy 06.05.01**

Section: Compliance	Responsible Vice President: VP and Chief Compliance Officer
Subject: Conflicts of Interest and Ethics	Responsible Entity: Office of Institutional Compliance

**I. Title**

*Research Conflicts of Interest*

**II. Purpose**

This policy establishes standards and requirements to protect the institution’s reputation, integrity, and objectivity with respect to research funded under Public Health Service (PHS) grants, cooperative agreements, industry sponsored research, and all other research regardless of sponsoring entity. This policy also serves to require periodic training and disclosure of certain financial interests and outside activities to ensure compliance with federal regulations, state laws, The University of Texas System policies (UTS policies), The University of Texas Board of Regents’ Rules (Regents’ Rules), and institutional policies, so that research performed at the institution will be free of bias resulting from financial conflicts of interest.

**III. Scope**

This policy applies to Covered Individuals and Covered Family Members, as defined below. This policy must be followed in addition to IHOP - 06.05.03 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities*; IHOP - 06.05.04 – *Institutional Conflicts of Interest*; IHOP - 06.05.05 – *Gifts, Vendor and Industry Interactions, and Other Activities*, IHOP – 06.05.06 – *Code of Ethics and Standards of Conduct for State Employees*, and other IHOP policies where applicable.

**IV. Policy**

It is UTMB policy that Covered Individuals must follow established federal and state laws, regulations, other applicable UTMB institutional policies, and guiding principles that govern the disclosure, reporting, and management of potential conflicts of interest. This policy complies with Public Health Service (PHS) regulations (42 CFR 50, Subpart F), UT System rules (UTS 175 and UTS 180), and other federal regulations designed to protect the integrity and objectivity of research.

**V. Guiding Principles**

V.1 Ethical Standards of Conduct

Covered Individuals are State Employees of Texas and public servants (see Texas Government Code § 572.051; IHOP 06.05.06 – *Code of Ethics and Standards of Conduct for State Employees*), and therefore must not:

- A. Accept Outside Activities, Benefits, or Compensation, each as defined below, that results in an unmanageable Conflict of Interest or interfere with, or could appear to interfere with, the Covered Individual's Institutional Responsibilities;
- B. Accept or solicit any Benefit that may reasonably tend to, or is offered with the intent to, influence the Covered Individual in the performance of their Institutional Responsibilities;
- C. Intentionally or knowingly solicit, accept, or agree to accept any Benefit for having exercised the Covered Individual's official authority or for having performed the Covered Individual's Institutional Responsibilities in favor of another person or entity;
- D. Disclose confidential information acquired through their position at UTMB or accept Outside Activities or Benefits that might reasonably require or prompt the Covered Individual to disclose confidential information acquired in the performance of their Institutional Responsibilities;
- E. Accept Outside Activities, Benefits, or Compensation that could reasonably be expected to impair, or appear to impair, the Covered Individual's independence of judgment in the performance of their Institutional Responsibilities;
- F. Use the Covered Individual's position at or association with UTMB to further a non-UTMB interest. This includes, but is not limited to, using or referencing one's position at or association with UTMB to solicit any Benefit, business, or donations for an Outside Activity or personal interest; market products or services for a business or an Outside Activity; or use their UTMB position to further the personal interest, business interest, or financial interest of a family member or personal friend; and
- G. Make personal investments that could create an unmanageable Conflict of Interest between the Covered Individual's private interests and the institution's interests.

## V.2 Conflicts of Interest in Research

- A. It is UTMB policy that all research, including PHS-funded research, must be conducted in compliance with federal requirements, including those set forth in 42 CFR Part 50, Subpart F (PHS Regulations), as well as UTS policies, Regents' Rules, and institutional policies to ensure there is a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from conflicts of interest.
- B. All Covered Individuals must complete conflicts of interest training as described in Section VI below and complete financial disclosure requirements as described in Section VII below.
- C. The Institutional Official for COI (IO-COI), or his/her designee, will review Financial Interest Disclosure Statements required under Section VII of this policy to determine whether the disclosed Financial Interest is a Significant Financial Interest, prior to the institution's expenditure of research funds.
- D. If the IO-COI, or his/her designee, in cooperation with the Conflict of Interest Committee (COIC), or the Covered Individual, as necessary, determines that a Covered Individual's Significant Financial Interest is reasonably related to PHS-funded or other sponsored research and could directly and significantly affect the design, conduct, or reporting of the sponsored research, then a Financial Conflict of Interest-Research (FCOI-R) exists.

- E. If the IO-COI, or his/her designee, determines that a Covered Individual has a FCOI-R, the IO-COI or his/her designee, in cooperation with the COIC, the Covered Individual, and other appropriate individuals as needed, must develop a COI Management Plan governing the FCOI-R, if applicable. This Plan must specify the steps that must be taken to manage, reduce, or eliminate the FCOI-R.
- F. The institution will follow all requirements for management and reporting of a FCOI-R (including any instance where a FCOI-R was not properly identified or managed prior to expenditure of federal funds) as outlined in 42 CFR Part 50, Subpart F.
- G. Subrecipients, subgrantees, contractors, and collaborating Investigators must comply with 42 CFR Part 50, Subpart F, as further described below in Section 11.
- H. Certain information concerning each identified FCOI-R, as determined by the IO-COI, or his/her designee, or COIC, must be made available within five business days of a written request in a manner consistent with 42 CFR Part 50, Subpart F and UTS 175. Additionally, this policy and each update of this policy must be publicly accessible through the Internet.

### V.3 Outside Activities

- A. In addition to the requirements set forth in this policy, all Covered Individuals must comply with IHOP 06.05.03 - *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities*, for the prior approval of an Outside Activity.
- B. A Covered Individual must not transact any business in an official UTMB capacity with any entity of which the Covered Individual or a Covered Family Member is an officer, agent, or member, or in which the Covered Individual or Covered Family Member holds an Ownership Interest. For purposes of this Section, Ownership Interests are not restricted to only those that are reasonably related to a Covered Individual's Institutional Responsibilities, but rather include any ownership in any entity by a Covered Individual or Covered Family Member.
- C. Covered Individuals must not accept Compensation from private persons or entities for any work that is part of their Institutional Responsibilities.
- D. State resources must not be utilized for a Covered Individual's Outside Activity. The time, materials, and equipment used by Covered Individuals are considered state resources for purposes of this policy.
- E. The following names and associated trademarks of: The University of Texas Medical Branch, UTMB, and UTMB Health, are institutional resources and therefore may not be utilized for Outside Activities or other non-institutional activities or purposes.

## VI. Training Requirements

### VI.1 Periodic Training Required

- A. All Covered Individuals, including those who are new to the institution, are required to complete research conflicts of interest training regarding this policy and other applicable policies, regulations, and laws before engaging in research, regardless of funding sponsor, at the institution and at least every four (4) years thereafter.

- B. A Covered Individual must complete re-training immediately if the IO-COI, or his/her designee, or COIC, finds that the Covered Individual is not in compliance with this policy or with the Covered Individual's COI Management Plan, or if the institution revises this policy in a manner that affects the individual's duties.
- C. 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.

## **VII. Disclosure of Financial Interests**

### **VII.1 Disclosure Requirements**

- A. 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 the disclosure of Financial Interests and of applicable federal and state regulations as well as UTMB and UT System policies.
- B. There is no lower limit for disclosure of Financial Interests unless specifically stated otherwise.
- C. An Outside Activity request or a Disclosure Statement must be submitted regardless of whether the activity is performed during the Covered Individual's normal business working hours, Paid Time Off (PTO), evenings, weekends, holidays, or some other form of leave.
- D. Any agreement or contract between a Covered Individual and a third party required to be disclosed or as part of an Outside Activity under this Section must be presented to the IO-COI, or his/her designee, for compliance review and approval prior to execution of the agreement with the third party.
- E. A Covered Individual must complete an Outside Activity Request or Disclosure Statement at the direction of the IO-COI, or his/her designee, or the COIC, regardless of whether the Outside Activity or Financial Interest would otherwise require disclosure under this policy.
- F. In determining whether a Financial Interest should be disclosed, the Covered Individual should resolve the doubt in favor of disclosure.

### **VII.2 What to Disclose**

- A. A Covered Individual must seek prior approval for any Outside Activity, including, but not limited to, part-time employment, consulting, outside board service, speaking engagements, or any other activity involving a direct payment to the Covered Individual. Covered Individuals must also comply with IHOP 06.05.03 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities*.
- B. A Covered Individual must seek prior approval for any compensated or uncompensated services, employment, appointment, or other relationship with a foreign governmental entity, agency, or institution. This includes, but is not limited to, adjunct, honorary, or visiting faculty appointments at institutions of higher education outside the United States.

- C. A Covered Individual's or Covered Family Member's Ownership Interest in any entity that could be reasonably related to the Covered Individual's Institutional Responsibilities must be disclosed.
- D. Any Financial Interests of Covered Family Members that are reasonably related to a Covered Individual's Institutional Responsibilities must be disclosed.
- E. Sponsored or reimbursed travel provided by a professional society, pharmaceutical company, device manufacturer, or other biomedical entity must be disclosed.
- F. Income from intellectual property rights and interests (e.g., patents, trademarks, copyrights) must be disclosed.

### VII.3 When to Request Prior Approval or Make a Disclosure

- A. Covered Individuals must request prior approval for an Outside Activity, including board service, at least 30 days prior to the start date of the proposed activity. The Covered Individual must provide the IO-COI, or his/her designee, or the Conflicts of Interest Office, with a copy of the Covered Individual's proposed agreement or contract with the outside entity for compliance review before the activity may be started.
- B. All Financial Interests, other than Outside Activities requiring prior approval, must be disclosed within thirty (30) days of acquisition or the beginning of the relationship.
- C. All sponsored or reimbursed travel (except as stated in Section 7.5 below), regardless of whether an honoraria or other payment is received, must be disclosed within thirty (30) days of the end of the trip.
- D. A Covered Individual must submit a disclosure or complete or finalize an annual disclosure statement at the request of the IO-COI, or his/her designee, the Conflicts of Interest Office, or the COIC.

### VII.4 Annual Disclosure Period

- A. Every Covered Individual must complete Financial Interest disclosure requirements or finalize a Disclosure Statement during the institution's annual disclosure period.
- B. Each Covered Individual must attest to the accuracy of his/her relationships and research disclosed within the preceding 12-month period or from the previous certification (whichever is longer) on his/her Disclosure Statement.
- C. Any Covered Individual who has nothing that requires disclosure must provide an affirmative statement of the non-existence of such Financial Interests or Outside Activities as part of the annual disclosure period or at the request of the IO-COI, or his/her designee, the Conflicts of Interest Office, or the COIC.
- D. Any updates, corrections, or substantial changes to disclosed relationships, or relationships that were not previously and timely disclosed under this policy, must be submitted and completed during the annual disclosure period.

- E. A Covered Individual must submit a Disclosure Statement no later than at the time of application for PHS-funded or other sponsored research.

#### VII.5 Exempt from Disclosure

The following are not required to be disclosed by a Covered Individual:

- A. Salary, royalties, or other remuneration paid by UTMB to the Covered Individual, if the Covered Individual is currently employed or otherwise appointed by UTMB.
- B. Income from seminars, lectures, or teaching engagements sponsored by a United States Federal, state, or local government, a U.S. institution of higher education as defined by 20 U.S.C. § 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute affiliated with an institution of higher education.
- C. Income from service on an advisory committee or review panel for a United States Federal, state, or local government, a U.S. institution of higher education as defined by 20 U.S.C. § 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute affiliated with an institution of higher education.
- D. 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.
- E. Travel reimbursed or sponsored by a United States Federal, state, or local government agency, a U.S. institution of higher education as defined by 20 U.S.C. § 1001(a), a U.S. academic teaching hospital, a medical center, or a U.S. research institute that is affiliated with an institution of higher education.

#### VII.6 Disclosure Review

- A. The IO-COI, or his/her designee, shall review each Financial Interest Disclosure Statement and make three determinations, namely (1) whether a disclosed Financial Interest is a Significant Financial Interest, (2) whether a Significant Financial Interest is reasonably related to PHS-funded or other sponsored research and could directly and significantly affect the design, conduct, or reporting of the sponsored research, and (3) if so, whether a FCOI-R exists.
- B. If a FCOI-R exists, the IO-COI, or his/her designee, in collaboration with the COIC, the Covered Individual, and others as necessary, will implement a Management Plan to manage or reduce the conflict or the appearance of a conflict.

### **VIII. Compensation Limits for Faculty and Administrative and Professional (A&P) Employees**

#### VIII.1 Per Day

- A. Full-time faculty and A&P employees may not accept more than \$10,000 in Compensation for Outside Activity services lasting one day, provided that at no time the fees accepted exceed the fair market value of the services provided.

#### VIII.2 Per Year

- A. Full-time faculty and A&P employees must not accept Compensation for an Outside Activity from a single outside entity in an amount that exceeds 25 percent of the individual's UTMB base pay and must not accept aggregate Compensation from all outside entities exceeding 50 percent of the individual's base pay.
- B. For purposes of calculating the 12-month period, Compensation for services is attributed at the time of services, regardless of when the Compensation is actually received by the Covered Individual. If no specific date of service is provided, the effective date of the agreement will be used.
- C. Compensation in the form of reimbursed or sponsored travel as part of research activities and Compensation from accredited CME activities performed on behalf of approved entities will not count towards the 25 percent or 50 percent limits.

## **IX. Management and Monitoring of Financial Conflicts of Interest-Research**

- IX.1 The IO-COI, or his/her designee, in collaboration with the COIC, the Covered Individual, and others as necessary, is responsible for the development and implementation of FCOI-R Management Plans.
- IX.2 A Management Plan must be in the form of a written agreement and may impose any condition and prescribe any action necessary to manage a FCOI-R to 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, but are not limited to:
  - A. Public disclosure of the FCOI-R in presentations and publications;
  - B. Disclosure, including retroactive notification, of the FCOI-R to human subjects, sponsors of research, and/or the research team;
  - C. 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 FCOI-R;
  - D. Modification of the research plan;
  - E. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
  - F. Divestiture or reduction of the financial interest;
  - G. Severance of relationships that create an actual or potential FCOI-R.
- IX.3 The Management Plan must be signed by the Covered Individual and either the IO-COI, or his/her designee, or Chair of the COIC. Depending on the nature and extent of the Conflict of Interest, it must also be reviewed and approved by the COIC and signed by the Covered Individual's Department Chair, or Executive Vice President (EVP). The Covered Individual and Chair or EVP, are responsible for implementation of and compliance with the Management Plan.
- IX.4 The IRB of record for a Clinical Trial may include additional safeguards in COI Management Plans related to a Clinical Trial involving a FCOI-R if it determines that the Management Plan does not provide sufficient protection for the human subjects enrolled.
- IX.5 If, in the course of ongoing research, a Covered Individual discloses a Significant Financial Interest (SFI) related to the research, or any other Covered Individual discloses a new SFI related to that research, or if the institution learns of a previously undisclosed SFI related to the research,

the IO, or his/her designee, or the COIC, shall, not later than the sixtieth (60th) day after the filing of the Disclosure Statement: (1) review the Disclosure Statement of the Significant Financial Interest; (2) determine whether it is related to PHS-funded research; (3) determine whether a FCOI-R exists; and, if so (4) implement an interim Management Plan or implement other interim measures to ensure the objectivity of the research. UTMB will follow all requirements for management and reporting of a FCOI-R as outlined in 42 CFR Part 50, Subpart F.

- IX.6 If a FCOI-R was not timely identified or managed, or if a Covered Individual fails to comply with a Management Plan, the IO-COI, or his/her designee, or the COIC 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.
- IX.7 For PHS-Covered research projects, the retrospective review shall cover key elements as specified by federal regulations and may result in updating the FCOI-R Report, notifying the PHS promptly, and submitting a mitigation report as required by federal regulation.
- IX.8 UTMB will provide for regular monitoring of Financial Interest Disclosure Statements to determine Covered Individual and institutional compliance with this policy.
- IX.9 If the U.S Department of Health and Human Services determines that a PHS-funded clinical research study with the purpose of evaluating the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a FCOI-R that was not managed by UTMB as required by federal regulation, the Investigator shall disclose the FCOI-R in each public presentation of the research results and request an addendum to previously published presentations.

## **X. Research Involving Human Subjects**

### **X.1 Rebuttable Presumption**

- A. A Covered Individual may not serve as the Principal Investigator (PI) on a Clinical Trial, except as stated in Subparts (B) and (C) below, if they or a Covered Family Member has:
- i. Any Ownership Interest in the Supporting Entity that results in a COI or FCOI-R that cannot be managed or;
  - ii. Received Compensation of \$25,000 or greater within the previous 12-month period from the Supporting Entity;
  - iii. For purposes of calculating the 12-month period, Compensation for services is attributed at the time of service, regardless of when the Compensation is received from the Supporting Entity. If no specific date of service is provided for in the Disclosure Statement, the effective date of the agreement will be used or the date determined by the IO-COI, or his/her designee.
  - iv. Compensation in the form of reimbursed or sponsored travel and Compensation from accredited CME activities performed on behalf of approved entities do not count towards the \$25,000 cap.



- B. A Covered Individual may serve as PI of a Clinical Trial despite the restrictions listed in Subpart (A) above if there are compelling circumstances to do so.
- C. Compelling circumstances are those facts that convince the IO-COI, or his/her designee, the COIC, or the IRB, that a Covered Individual who has a Conflict of Interest or FCOI-R should be permitted to conduct the human subjects research, considering the following factors:
  - 1. the nature of the research;
  - 2. the nature and magnitude of the Financial Interest;
  - 3. how closely the Financial Interest is related to the research;
  - 4. the extent to which the interest may be affected by the research;
  - 5. the degree of risk to the human subjects involved that is inherent in the research protocol;
  - 6. the extent to which the investigator is uniquely qualified to perform the research study;
  - 7. the extent to which the interest is amenable to effective oversight and management.
- D. If the IO-COI, or his/her designee, or the COIC, determines that a Covered Individual may serve as PI of a Clinical Trial under compelling circumstances, the IRB will be notified so that it can make any decisions necessary to ensure the safety of human subjects.

## **XI. Collaborators, Contractors, and Subrecipients**

- A. Research conducted in cooperation with or through a subcontractor, contractor, or collaborator, including a person identified under federal regulations as a “sub-recipient,” shall be conducted by written agreement between UTMB and 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. In any event, this policy and its procedures apply to UTMB employees.
- 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. The agreement must also specify the time periods for the contracting party to report identified financial conflicts of interest to UTMB. The time periods must be sufficient for UTMB to make any reports required by federal regulation. If this policy, UTMB’s policy, 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 UTMB. The time periods must be sufficient for UTMB to comply with the review, management, and reporting obligations under federal regulations.
- C. Notwithstanding the above, all UTMB Covered Individuals are required to comply with this policy.

## **XII. Avoiding Bias in Presentations and Publications**

- XII.1 Covered Individuals must ensure that their presentations and publications are free of third-party commitments, restrictions, and other influences that may bias or create the appearance of bias in the presented/published material or that may compromise scientific integrity and public trust.
- XII.2 Covered Individuals:

- A. Must retain full control and authorship over presentation content and must not allow presentations to be subject to prior approval by any outside entity other than approval of the use of proprietary information;
- B. Must not deliver a presentation if an outside entity has the right to dictate the content of such presentation;
- C. Must disclose to the audience any Compensation received from an outside entity that could be perceived to bias the presentation. These disclosures should be of sufficient length and detail that a reasonable person could read and comprehend the nature and extent of the relationship;
- D. Must not present slides or materials authored by an outside entity as their own; and
- E. Must not deliver presentations that do not comply with this Policy, regardless of whether Compensation is received.

12.3 Covered Individuals must disclose all Outside Activities and Financial Interests as required by the rules of the conference or respective journal or publication in which they are publishing.

### **XIII. Compliance**

XIII.1 Compliance with this policy by Covered Individuals is of the utmost importance and serves to protect the safety and welfare of patients and human subjects, ensures adherence to UTMB's standards of clinical care, and promotes and preserves the integrity of research and research reporting.

XIII.2 Compliance with this policy is a condition of a Covered Individual's employment, appointment, or enrollment as a student. Noncompliance with this policy will be evaluated by the IO-COI, or his/her designee, in collaboration with the COIC, and other institutional senior leadership as necessary.

XIII.3 Noncompliance may result in discipline, up to and including termination of employment for employees and 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 a Significant Financial Interest. In the case of a violation of civil or criminal law, violators may be subject to civil or criminal penalties.

XIII.4 This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where those requirements are more restrictive than this policy, those requirements will take precedence.

### **XIV. Appeal Process**

XIV.1 A Covered Individual may appeal a determination made by the Conflicts of Interest Office, the IO-COI, or his/her designee, or the COIC, that a requested Outside Activity, Benefit, or other Financial Interest is not permissible under this policy.

XIV.2 A Covered Individual may appeal the determination made by his/her supervisor that a permitted Outside Activity, Benefit, or Financial Interest is denied.

- XIV.3 To appeal, the Covered Individual must submit a written appeal to the Conflicts of Interest Office within thirty (30) days of receipt of the notice of impermissibility or denial.
- XIV.4 The appeal will be directed to the Executive Vice President (EVP) overseeing the enterprise or division in which the Covered Individual resides.
- XIV.5 The EVP may then choose to do one of the following:
- A. Affirm the denial of the activity. The EVP's decision is final.
  - B. Reverse the decision and approve the requested Outside Activity. The EVP's decision is final.
  - C. Transfer the appeal to an administrator, chair, or dean within the same enterprise or division as the requesting employee for final determination.
  - D. Transfer the appeal to the IO-COI, or his/her designee, or the COIC for final determination.

## **XV. Maintenance of Records**

- 15.1 UTMB will provide for a centralized repository for Financial Interest Disclosure Statements, Management Plans, and related records.
- 15.2 Records regarding the disclosure of Financial Interests, and the management of conflicts 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; (3) the date of final resolution of any investigation, audit, or legal action involving the records; or (4) the date the information was most recently updated.
- 15.3 Records regarding Financial Interest Disclosure Forms and other relevant documentation shall be considered confidential and the information disclosed in the forms will be available only to individuals duly charged with the responsibility for review, except as required under Section 5.2(H). Additionally, information may be released in accordance with and as required by Texas law or lawful court order.
- 15.4 UTMB shall follow institutional policies regarding the maintenance of records as well as the requirements in 45 CFR 75.361, where applicable.

## **XVIII. Definitions**

**Benefit:** Anything of value including Compensation or any other form of advantage as may be determined by the Institutional Official for Conflicts of Interest (IO-COI), or his/her designee, that is reasonably regarded as valuable or providing a monetary gain or advantage, including financial or monetary gains to other persons or entities in which the beneficiary has a direct and substantial interest. Examples of Benefits include, but are not limited to, cash; gifts; awards; transportation and lodging; food and beverages; tickets to entertainment and sporting events; and honoraria. *See also*, Financial Interest as defined below.

**Clinical Trial:** A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

**Compensation:** Any form of existing or potential fiscal advantage, regardless of whether the value is readily ascertainable including, but not limited to, salary from an entity other than UTMB and any other form of payment for services, such as consulting fees; retainers; honoraria; intellectual property rights or royalties; Ownership Interests; or promised, deferred, or contingent interests; or any other form of Compensation as determined by the Institutional Official for Conflicts of Interest (IO-COI) or his/her designee. Compensation also includes sponsored travel or travel reimbursement.

**Conflict of Commitment (COC):** A state in which the time or effort that a Covered Individual devotes to an Outside Activity directly or significantly interferes, or could appear to interfere, with the Covered Individual's fulfillment of their Institutional Responsibilities, or when the Covered Individual uses state property without authority in connection with the Covered Individual's Outside Activity including, but not limited to, board service, consulting, ownership or investment interest in a business entity, or other activity (*see* Sec. 8, Regents' Rule 30104).

**Conflict of Interest (COI):** Any Benefit, Financial Interest, or Outside Activity of a Covered Individual or Covered Family Member that could directly or significantly influence the Covered Individual's performance of their Institutional Responsibilities. The proper discharge of a Covered Individual's Institutional Responsibilities could be directly or significantly influenced if the Benefit, Financial Interest, or Outside Activity: (1) might tend to influence the way the Covered Individual performs their Institutional Responsibilities, or the Covered Individual knows or should know the interest is or has been offered with the intent to influence the Covered Individual's conduct or decisions; (2) could reasonably be expected to impair the Covered Individual's judgment in performing their Institutional Responsibilities; or (3) might require or induce the Covered Individual to disclose confidential or proprietary information acquired through the performance of Institutional Responsibilities.

**Covered Family Member:** A spouse (official, traditional, or common law), or any related or non-related unmarried adult who resides in the same household as the Covered Individual and with whom the Covered Individual is financially interdependent as evidenced, for example, by the maintenance of a joint bank account, mortgage, or investments. Covered Family Member also means any individual with whom the Covered Individual has a relationship that could reasonably be perceived to unduly influence the performance or fulfillment of the Covered Individual's Institutional Responsibilities.

**Covered Individual:** A Covered Individual includes, but is not limited to, any UTMB employee, Investigator, Institutional Leader, faculty member, adjunct faculty member, student, Trainee, or any other individual involved in any research activity (bench, animal science, or human subjects), or who is otherwise responsible for the design, conduct, or reporting of Research. A Covered Individual includes any employee who is a member of the Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC), the Institutional Biosafety Committee (IBC), and any Animal Resource Center (ARC) employee.

**Disclosure Statement:** A statement of Financial Interests disclosed by a Covered Individual, as well as those of a Covered Family Member, or an affirmation that the Covered Individual has no Financial Interests to disclose, as required by this policy.

**Financial Conflict of Interest-Research (FCOI-R):** A Significant Financial Interest as determined by the IO-COI, or his/her designee, that could directly and significantly affect the design, conduct, or reporting of Research.

**Financial Interest:** Anything of monetary value, including Compensation, whether or not the value is readily ascertainable. *See also*, Benefit as defined above.

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

**Institutional Official for COI (IO-COI):** The conflicts of interest official designated by the President of UTMB to determine permissibility of conflicts of interest and ethics issues related to this policy and other applicable institutional policies.

**Institutional Responsibilities:** Any academic or professional responsibility of an individual subject to this policy on behalf of the institution including, but not limited to, research; research consultation; teaching; professional practice; outreach; institutional committee membership; and service on an institutional research committee or panel including, but not limited to, an Institutional Review Board (IRB); Institutional Animal Care and Use Committee (IACUC); Institutional Biosafety Committee (IBC); or Data and Safety Monitoring Board (DSMB).

**Investigator:** An individual who, regardless of title or position, is responsible for the design, conduct, or reporting of Research, including a Principal Investigator; co-Investigator; collaborator; consultant; project director; or any other individuals designated as such by the Principal Investigator. Investigators are considered Covered Individuals under this policy.

**Management Plan:** A formal, written plan to address an FCOI-R, which can include reducing or removing the conflict of interest to ensure that the design, conduct, or reporting of research will be free of bias.

**Outside Activity:** Any personal activity performed by Institutional Personnel for which Compensation is received, other than fulfilling academic or employment obligations to UTMB. This includes, but is not limited to, distance teaching; any work for a third party, such as supervising, consulting, or advisory services; or other employment for which Compensation, regular or occasional, is received. This also applies to uncompensated outside board service and any other compensated or uncompensated activity that might pose a conflict of interest or conflict of commitment.

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

**Principal Investigator:** The individual who is the responsible leader of an investigative team and responsible for the design, conduct, or reporting of a Research project or program.

**Significant Financial Interest (SFI):** A Financial Interest that reasonably appears to be related to the Covered Individual's Institutional Responsibilities, as defined by 42 CFR Part 50, Subpart F. This definition includes the Financial Interests of Covered Family Members, but only as to interests that reasonably appear to be related to the Covered Individual's Institutional Responsibilities.

1. For publicly traded Entities, if the value of any Remuneration received from the Entity in the twelve months preceding the disclosure combined with the value of any Equity Interest of the Investigator in the Entity as of the date of disclosure, when aggregated, exceeds \$5,000.
2. For non-publicly traded Entities (including, but not limited to, private "start-up" companies, closely held corporations, partnerships, or sole proprietorships), if either:

- a. the value of any Remuneration received from the Entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or
- b. the Investigator and/or Covered Family Member holds any Equity Interest (i.e., there is no *de minimis* amount for Equity Interests in a non-publicly traded Entity) in the Entity;
3. Income from any intellectual property rights and interests (e.g., patents, trademarks, copyrights) in the previous twelve (12) months; or
4. All reimbursed or Sponsored Travel from an Entity in the twelve (12) months preceding disclosure; however, travel that is reimbursed or sponsored by a federal, state, or local government agency in the United States, an American institution of higher education as defined at 20 U.S.C. 1001(a), an American academic teaching hospital, an American medical center, or a research institute that is affiliated with an American Institution of higher education **does not** need to be disclosed as an SFI.

**Supporting Entity:** An entity that (a) provides funding for a research study either directly or through a subcontract or grant; (b) provides a study drug, device, or other material for use in an IRB-approved protocol; or (c) has licensed technology and/or patents that cover the study drug, device, or other material, or its uses in an IRB-approved protocol for which the Principal Investigator and/or UTMB may receive a portion of license consideration. This definition does not include non-profit or philanthropic groups unless the IO-COI, or his/her designee, or the COIC, and/or the IRB determine otherwise.

**Trainees:** Medical, graduate, or other students, postdoctoral fellows, residents, or clinical fellows with a UTMB appointment of six (6) continuous months or more. For purposes of this definition, Trainee does not include high school students, college students, and part-time clinical specialists, unless they otherwise meet the definition of Covered Individual.

**XIX. Relevant System Policies and Procedures**

[UT Regents' Rules and Regulations](#)

[UT System Rule 180](#)

[UT System Rule 175](#)

**XX. Related UTMB Policies and Procedures**

[IHOP - 06.05.03 – Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities](#)

[IHOP - 06.05.04 – Institutional Conflicts of Interest](#)

[IHOP - 06.05.05 – Gifts, Vendor and Industry Interactions, and Other Activities](#)

[IHOP - 06.05.06 – Code of Ethics and Standards of Conduct for State Employees](#)

**XXI. Additional References**

[NIH Final Conflicts of Interest Rule \(8/25/11\)](#)

**XXII. Dates Approved or Amended**

<i>Originated:</i> 06/15/2004	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>
05/12/2011	02/03/2015
02/01/2014	03/06/2017
06/06/2022	

**XXIII. Contact Information**

Conflicts of Interest Office

Office of Institutional Compliance

[coi.in@utmb.edu](mailto:coi.in@utmb.edu)