POLICY STATEMENT

It is the policy of The University of Texas MD Anderson Cancer Center (MD Anderson) that Institutional Decision Makers, faculty, Trainees, and individuals responsible for the design, conduct, or reporting of all Research activities will follow established federal and state laws, regulations, and guiding principles that govern disclosure, reporting, and management of potential Conflicts of Interest. This policy complies with Public Health Service (PHS) regulations (42 CFR 50, Subpart F) and The University of Texas System (UT System) rules (UTS175) designed to protect the objectivity of Research, and complies with UT System rules (UTS180) designed to address other types of Conflict of Interest and Conflict of Commitment.

PURPOSE

This policy is intended to protect patient safety and welfare, safeguard the reputation and integrity of the institution, preserve the integrity of affiliated Research, ensure fulfillment of obligations to faculty and Trainees, clarify that the employment obligation of employees is to the institution, and require disclosure of all potential or actual Conflicts of Interest. This policy also serves the purpose of ensuring compliance with state ethics laws and UT Board of Regents Rules, while providing the framework for rules and procedures that will clearly delineate permissible outside activities, including relationships with for-profit entities that further the mission of MD Anderson or that serve another scholarly purpose.

SCOPE

This policy applies to all faculty members, Trainees, Supervisors, Institutional Decision Makers, and Investigators. This policy does not apply to Adjunct Faculty Members who do not serve as an Investigator. Other MD Anderson employees not covered by this policy must comply with the Conflict of Interest and Conflict of Commitment Policy (UTMDACC Institutional Policy # ADM0255).

TARGET AUDIENCE

The target audience for this policy includes, but is not limited to, faculty members, Trainees, Supervisors, Institutional Decision Makers, and Investigators.

DEFINITIONS

Adjunct Faculty Members: As defined by the Faculty Appointments Policy (UTMDACC Institutional Policy #ACA0023), part-time faculty appointments awarded to qualified persons from business, government, private practice, or another institution of higher education who teach or participate in teaching a course at MD Anderson or perform collaborative Research with faculty at MD Anderson, with or without Compensation (see Faculty Appointments Policy (UTMDACC Institutional Policy # ACA0023), Guidelines on Qualifications for Adjunct Appointments). Adjunct Faculty Members are exempt from the Conflict of Interest Policy for Faculty Members, Trainees, Faculty Supervisors,
Institutional Decision Makers, and Investigators of the University of Texas MD Anderson Cancer Center (UTMDACC Institutional Policy # ACA0001) unless they meet the definition of an Investigator herein.

**Awarding Component:** A federal organizational unit, including, but not limited to, a Public Health Service (PHS) that funds Research.

**Business Entity:** Any entity recognized by law through which business for profit is conducted, including a sole proprietorship, partnership, firm, corporation, holding company, joint stock company, receivership, or trust.

**Cash:** Remuneration in the form of consulting fees, honoraria, milestone payments, educational grants, preceptorships, salary or wages (other than salary and wages paid by MD Anderson), intellectual property rights or royalties not directly paid by MD Anderson, and Cash equivalents, which include anything of fixed and/or publicly traded value. This definition excludes up-front and annual maintenance fees and royalties received from MD Anderson and travel support or travel reimbursement. Note: Nonetheless, up-front and annual maintenance fees and royalties received from MD Anderson and travel support or travel reimbursement is required to be disclosed (see Section 3.2 of this policy).

**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 benefit including, but not limited to, salary, retainer, honoraria, intellectual property rights or royalties, or promised, deferred, or contingent interest. It also includes sponsored travel or travel reimbursement.

**Competitor:** Any institution or organization that competes for business with MD Anderson.

**Conflict of Commitment:** As defined by UTS180, a state in which the time or effort that a Covered Individual devotes to an outside activity directly or significantly interferes 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 Employment, board service, or other activity (see Sec. 8, Regents’ Rule 30104). Exceeding the amount of total time permitted by this policy for outside activities creates the appearance of a Conflict of Commitment.

**Conflict of Interest (COI):** A Significant Financial Interest or outside relationship that the Institutional Official (IO), in consultation with the Conflict of Interest Committee (COIC), determines could directly and significantly influence (or be perceived to directly and significantly influence) the employee’s performance of the employee’s Institutional Responsibilities, including patient care or the design, conduct, and/or reporting of Research. As defined by UTS180, the proper discharge of an employee’s Institutional Responsibilities could be directly or significantly affected if the Outside Employment, service, activity, or interest: (1) might tend to influence the way the employee performs his or her Institutional Responsibilities, or the employee knows or should know the interest is or has been offered with the intent to influence the employee’s conduct or decisions; (2) could reasonably be expected to impair the employee’s judgment in performing his or her Institutional Responsibilities; or (3) might require or induce the employee to disclose confidential or proprietary information acquired through the performance of Institutional Responsibilities.

**Covered Individual:** Investigators (as defined within this policy), Faculty Members (including Senior Medical Physicists), Trainees with an appointment of six continuous months or longer, Faculty Supervisors, and Institutional Decision Makers. Adjunct Faculty Members, Professor Emeritus appointments, Trainees with an appointment of less than six continuous months, high school students, college students, and part-time Clinical Specialists (as determined by Faculty and Academic Affairs) are specifically exempt from this policy unless they are an Investigator. Other MD Anderson employees not
covered by this policy must comply with the Conflict of Interest and Conflict of Commitment Policy (UTMDACC Institutional Policy # ADM0255).

Family Members: Defined as financially dependent person, including a spouse, dependent child, stepchild, domestic or civil partner, common law spouse, or equivalent same-sex partner. Also included are persons owning joint Financial Interests with individuals covered by this policy, including businesses, accounts, or property, that could reasonably influence the individual’s decisions or exercise of professional responsibilities at the institution. Individuals covered by this definition include both related and non-related, unmarried adults who reside in the same household as the individual and with whom the individual is financially interdependent as evidenced, for example, by the maintenance of a joint bank account, mortgage, or investments.

Financial Conflict of Interest – Research (FCOI-R): When the Institutional Official (IO) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the Research.

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

Immediate Family: Specific to Section 2.4 E of this policy, Immediate Family are individuals related by kinship, adoption (including certified foster children), or marriage who are living in the same household with individuals covered by this policy, and minor children of the individuals covered by this policy who are not living in the same household.

Institutional Decision Maker: Means the following MD Anderson employees:

- President, including President ad interim.
- Deputy President.
- Executive Vice Presidents.
- Provosts, Vice Provosts, including Deputy, Associate, and Assistant Provosts and Vice Provosts.
- Senior Vice Presidents, Vice Presidents, Associate Vice Presidents, and Assistant Vice Presidents.
- Deans, Vice Deans, Associate Deans, and Assistant Deans.
- Division Heads and Department Chairs.
- Directors of institutes within MD Anderson and Directors of MD Anderson’s organized business or Research support units (e.g., purchasing, sponsored projects, compliance, asset management, business affairs, etc.).
- Professionals in MD Anderson’s Office of Strategic Industry Ventures or the Office of Technology Commercialization with the authority to bind, negotiate on behalf of, or execute agreements for MD Anderson.
- Any other person designated by MD Anderson’s President as an Institutional Decision Maker for the purposes of this policy.

Institutional Official (IO): The official designated by MD Anderson to solicit and, with assistance from the COIC, review disclosures of Significant Financial Interests by Covered Individuals to determine whether a COI or FCOI-R exists and, if so, determine actions to be taken to Manage, reduce, or eliminate such conflict of interest. Any such determination by the IO may be appealed through the Exception Process in Section 13 of this policy.
Institutional Responsibilities: Any of the professional responsibilities of an individual subject to this policy on behalf of the institution, including Research, Research consultation, teaching, professional practice or patient care, institutional committee membership, or service on an institutional panel such as an Institutional Review Board (IRB) or Data and Safety Monitoring Board (DSMB).

Institutional Review Board (IRB): The board(s) formally designated by MD Anderson to assure the protection of the rights and welfare of human subjects, and to conduct initial and continuing review and approval of biomedical Research involving human subjects, including IRB-approved protocols.

Investigator: An individual who, regardless of title or position, is responsible for the design, conduct, or reporting of Research, including a Principal Investigator, a co-Investigator, collaborator, consultant, or project director. Individuals considered “responsible” in this definition include any person who is independently accountable for data, in any form, addressing the objectives of the funded or proposed Research, as identified by the Principal Investigator. This necessarily places responsibility on the accountable supervisory staff to identify who is an Investigator and potential Conflicts of Interest in their Research Team as it relates to funded or proposed investigation. Investigators are considered Covered Individuals under UTS175 policy.

Manage: Taking action to address a financial COI, which can include reducing or eliminating the financial COI, to ensure, to the extent possible, that the design, conduct, or reporting of Research will be free from bias.

Management Plan: Formal written plan to address a financial COI and/or Conflict of Commitment, which can include reducing or removing the financial COI, to ensure conduct with respect to the conflict will be free from bias, Managed appropriately, and disclosed according to the standards herein.

Nature and Extent: As defined by UTS180, shall include a description of the activity, the time commitment, and the anticipated length of time the commitment is expected to continue.

Outside Board: As defined by UTS180, the board, council, or other governing or advisory body of a business, civic, professional social, or religious organization, whether for profit or nonprofit.

Outside Employment: Any activity performed by an employee, other than fulfilling employment obligations at UT System or a UT System institution, for which remuneration is received, including distance teaching; any work for a third party, such as supervising, consulting, or advisory services; or other regular continuing employment for which Compensation, regular or occasional, is received. Work for another state agency is included in the definition of Outside Employment. See Ethics Policy (UTMDACC Institutional Policy # ADM0337).

Ownership Interest: 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. With respect to Covered Individuals, Ownership Interest also includes any license equity to the extent the Institutional Decision Maker is entitled to share in the proceeds upon liquidation of the license equity. See Intellectual Property Policy (UTMDACC Institutional Policy # ADM0345).

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

Research: A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge including human subjects protocols and all laboratory Research disciplines, as well as behavioral and social-sciences Research. The term encompasses basic and applied Research,
product development, and Research that is subject to regulation by the U.S. Food and Drug Administration. As used in this policy, the term includes any such activity for which Research funding is available from any source, including any PHS Awarding Component through a grant or cooperative agreement.

**Research Team:** Co-Investigators, Trainees, staff members, classified employees involved with Research, and internal collaborators.

**Scholarly Work:** Work created by an institution's faculty member or Trainee within his/her scope of employment and in his/her area of expertise or area in which he/she teaches. This definition especially applies to creative work that is peer reviewed and publicly disseminated. Specifically excluded from this definition is consulting work for for-profit companies, including subscription-based content providers. Paid authorship must be disclosed.

**Significant Financial Interest:** 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 the Covered Individual's spouse or dependent children, or other financially dependent persons (Family Members).

**Supervisor:** Any person who is the primary formal evaluator of another person, including Section Chief, Department Chair, Division Head, Provost and Executive Vice President, Chief Operating Officer, and President.

**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 MD Anderson may receive a portion of license consideration. This definition does not include non-profit or philanthropic groups unless the COIC and/or the IRB determine otherwise. See [Intellectual Property Policy](UTMDACC Institutional Policy # ADM0345).

**Trainee:** Graduate or other student, postdoctoral fellow, residents, or clinical fellow with an appointment of six continuous months or more. For purposes of compliance with this policy, the definition of Trainee will not include a high school student, regardless of their appointment length, unless they are an Investigator. Trainees excluded by this policy may still be subject to the Conflict of Interest and Conflict of Commitment Policy (UTMDACC Institutional Policy # ADM0255).

**University Time:** For faculty, this time is defined by the number of hours per week necessary for the performance of job duties, which include teaching, Research, service, and patient care. For some staff, this time is defined by a work day with set hours, and for other staff, this time is defined as a work day with set hours plus on-call service as needed.

### PROCEDURE

**1.0 Primary Responsibility**

1.1 If you are a full-time Covered Individual, then your primary employment responsibility is to MD Anderson and the accomplishment of the duties and responsibilities assigned to your position of appointment.

1.2 Faculty members, Trainees, and Institutional Decision Makers (Covered Individuals) must not:

   A. Accept outside commitments of time, effort, or employment - temporary or regular, that actually or potentially results in any COI with or interferes with the employee's independence of judgment or Institutional Responsibilities to MD Anderson;
B. Accept or solicit any gift, favor, or service that might reasonably tend to, or is being offered with the intent to, influence the employee in the performance of his/her Institutional Responsibilities;

C. Accept Outside Employment or engage in a business or professional activity that might reasonably require or induce the employee to disclose confidential information acquired in the performance of his/her Institutional Responsibilities;

D. Accept Outside Employment or Compensation that could reasonably impair the Covered Individual’s independence of judgment in the performance of his/her institutional duties;

E. Make personal investments that could reasonably create a substantial conflict between the employee’s private interest and the interests of the institution; or

F. Intentionally or knowingly solicit, accept, or agree to accept any benefit for having exercised the employee’s official powers or performed the employee’s official duties in favor of another.

1.3 No Covered Individual may serve as a member of a Board of Directors, executive, or as an officer (paid or unpaid) of any for-profit legal entity, Competitor of MD Anderson, or any other legal entity related to one’s Institutional Responsibilities or general area of professional expertise as referenced in Section 3.2 of this policy if the IO in consultation with the COIC determines such a role presents a COI or FCOI-R. Serving as a member of a Scientific Advisory Board or board of a professional or philanthropic society is permitted, provided that it is disclosed and does not conflict with Section 1.2 of this policy. Disclosure requirements for board activities and other outside activities are stated in Section 3.0 of this policy.

1.4 No Covered Individual will accept pay from private persons or corporations for any work that is part of his/her Institutional Responsibilities.

1.5 A Covered Individual who is employed 50% or more by MD Anderson or receives 50% or more of his/her salary from MD Anderson may not receive income for services during a 12 month period from a single entity and their subsidiaries in the form of Cash amounting to more than $40,000 or 25% of his/her total base salary, whichever is greater. This restriction on outside Compensation also applies, regardless of employment status, in instances where the Covered Individual is conducting any Research at MD Anderson that is determined to be a COI by the IO in consultation with the COIC.

1.6 State resources, such as the property of MD Anderson, will not be utilized for purposes of consultation or employment with an entity other than MD Anderson unless permission has been obtained in advance from the President and provision has been made for Compensation to the institution. For limitations of use of certain MD Anderson resources, see Use of Information Technology Policy (UTMDACC Institutional Policy # ADM0263).

1.7 The name, The University of Texas MD Anderson Cancer Center, is considered a resource of the institution and therefore will not be utilized for Outside Employment or other non-MD Anderson activity/purpose unless permission has been obtained in advance from the President or his designee and provision has been made for Compensation to MD Anderson. Any use must comply with Trademarks Policy (UTMDACC Institutional Policy # ADM0346).
2.0 Conflicts of Interest and Research

2.1 Objectivity in Research:

A. It is the policy of MD Anderson 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) to ensure there is a reasonable expectation that the design, conduct, or reporting of Research will be free from bias resulting from Investigator COI.

B. Subgrantees, contractors, and collaborating Investigators are also required to be in compliance with 42 CFR Part 50, Subpart F, as further described in MD Anderson’s Standard Operating Procedure for Subgrantees, Contractors, and Collaborating Investigators.

C. The IO(s) must review all financial disclosures required under Section 3.2 of this policy (including those that meet the definition of Significant Financial Interest as defined in 42 CFR Part 50, Subpart F) to determine whether an FCOI-R exists, and, if so, to determine what actions, if any, should be taken by the institution to Manage such COI. Such requirements may not apply to the Small Business Innovation Research (SBIR) Program Phase I applications, as determined by the COIC.

D. If the IO(s) in consultation with the COIC (and the IRB, if involving human subjects Research) determines that an Investigator has an FCOI-R, the IO(s), in cooperation with the Investigator and other appropriate individuals as designated by the IO(s), shall develop a COI Management and Monitoring Plan governing that FCOI-R, in accordance with applicable standard operating procedures. This Plan shall specify the steps that have been taken to Manage the FCOI-R.

E. Neither the institution nor an Investigator may expend Research funds unless the IO(s) have determined that no FCOI-R exists or that any FCOI-R is manageable in accordance with the terms of COI Management and Monitoring Plan that has been adopted and implemented.

F. The institution will follow all requirements for management and reporting of a FCOI-R (including any instance where an FCOI-R was not properly identified or Managed prior to expenditure of federal funds) as outlined in 42 CFR Part 50, Subpart F.

G. For PHS-covered Research projects, FCOI-R identified subsequent to an earlier report are required to be reported to the PHS Awarding Component within 60 days and also require annual updating of reports regarding previously disclosed FCOI-R in compliance with 42 CFR Part 50, Subpart F.

H. Additionally, if an FCOI-R was not timely identified or Managed, or if an Investigator fails to comply with a COI Management and Monitoring Plan, the institution shall, within 120 days of identification of a FCOI-R, complete a retrospective review of the individual’s activities conducted during the period of noncompliance to determine whether such noncompliance biased the design, conduct, or reporting of related Research. This retrospective review shall be conducted and documented in accordance with the requirements of 42 CFR Part 50, Subpart F and in accordance with the institution’s standard operating procedure. For PHS-covered Research projects, the retrospective review shall cover key elements as specified by federal regulations and may result in updating a COI disclosure, notifying the PHS, and submitting a mitigation report, as required by federal regulations.

I. If the Department of Health and Human Services determines that 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 an individual covered by this policy who has an FCOI-R that was not Managed or reported by the institution as required by federal regulations, the institution will require the individual to disclose the FCOI-R in each public presentation of the results of the Research and to request an addendum to previously published presentations.

J. Certain information concerning each identified FCOI-R, as determined by the COIC in cooperation with the IO(s), shall be made available on a publicly accessible Web site in a manner consistent with 42 CFR Part 50, Subpart F and UTS175, and consistent with MD Anderson’s Standard Operating Procedure for Publication of Conflicts of Interest. Additionally, this policy and each update of this policy must also be publicly accessible through the Internet.

K. All Investigators shall be provided a copy of this policy, and shall complete training in regard to this policy and other applicable policies, regulations, and laws before engaging in Research at the institution and at least every four years thereafter. An Investigator who is new to the institution 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 years. An Investigator must complete re-training immediately if the institution finds that the individual is not in compliance with this policy or the individual’s COI Management and Monitoring Plan, or if the institution revises this policy in a manner that affects the individual’s duties. The Office of Research Administration is responsible for ensuring that appropriate faculty, staff, Trainees, and other persons participate in training with regard to this policy and applicable laws.

2.2 All Research:

A. No Research will be conducted at MD Anderson for which payment is dependent upon a specific outcome.

B. In all instances of sponsored Research, including those that do not involve patient care, disclosure of all financial connections to the Supporting Entity must be made in any publication or oral presentation concerning the Research. Disclosure of such relationships to the Supporting Entity may also be required when applying for grants, contracts, or sponsored Research, if required by the Supporting Entity.

C. A COI Management and Monitoring Plan (see Procedure for Obtaining Approval of Plan to Manage Conflicts of Interest) may be required to Manage an FCOI-R in situations that are not noted above or in Section 2.3 or 2.4 of this policy, as determined appropriate by the COIC or the IRB.

D. Trainees may only participate in Research sponsored by an entity in which the Trainee’s Supervisor holds an Ownership Interest or with which the Supervisor has signed a confidentiality agreement with limits on publication, on a voluntary basis after full discussion of the relationship, the potential confidentiality issues and the risk of publication delays associated with the work. Written confirmation of such discussions, signed and dated by the Trainee and Supervisor, must be provided to the COIC for Trainees who choose to participate in such sponsored Research. Trainees are encouraged to contact the IO if they have questions or concerns regarding their participation in such sponsored Research projects.

E. Any FCOI-R related to Research that is conducted under a faculty member’s supervision must be disclosed in writing to members of the Research Team.
2.3 Non-Clinical Trial Research:

A. If a Principal Investigator (or Co-Principal Investigator) for any non-Clinical Trial Research protocol or sponsored Research agreement or his/her spouse and/or dependent children holds any Ownership Interest in the Supporting Entity, review and approval by the COIC is required prior to beginning the Research in order to implement appropriate management or restrictions in order to ensure and maintain the objectivity and integrity of the Research.

B. A Principal Investigator (or Co-Principal Investigator) and/or his/her spouse and/or dependent children may not receive Cash of $25,000 or more within a 12-month period from a Supporting Entity that funds the Principal Investigator's non-Clinical Trial Research, unless a COI Management and Monitoring Plan has been implemented to Manage such conflict(s) of interest (see Procedure for Obtaining Approval of Plan to Manage Conflicts of Interest). A Plan is also required when:

- A faculty member and/or his/her spouse and/or dependent children has an Ownership Interest in an entity and the faculty member collaborates with that entity on Research activities; and/or
- A faculty member and/or his/her spouse and/or dependent children holds a decision-making role in the Supporting Entity and the faculty member collaborates with that Supporting Entity on Research activities.

2.4 Clinical Trial Research:

A. No payment shall be received by an individual for enrolling patients on Clinical Trial Research. Payment to MD Anderson on a per-patient basis should be limited to costs incurred, reflect the fair market value of services performed, and be commensurate with the efforts of the individuals performing the Research.

B. A Covered Individual may not serve as the Principal Investigator (or Co-Principal Investigator) for Clinical Trial Research or sponsored Research agreement if he/she or his/her spouse and/or dependent children has:

- Any Ownership Interest in any entity in which the IO in consultation with the COIC determines a COI or FCOI-R exists that cannot be Managed which is the Supporting Entity, or;
- Received Cash of $25,000 or greater within the previous 12-month period from the Supporting Entity.

Additional restrictions apply to any covered clinical study as defined by the FDA in CFR Title 21 Part 54.

C. The following must be disclosed in the informed consent document:

- All financial relationships of an Investigator;
- All Ownership Interests in the Supporting Entity of a faculty member involved as a Collaborator in the Clinical Trial Research (non-Principal Investigator) or his/her Family Members;
- Cash of $10,000 or more received by a faculty member involved as a Collaborator in the Clinical Trial Research or his/her Family Members from the Supporting Entity in the 12-month period prior to the approval of each continuing review until termination of the protocol;
- Any royalty income received by any of the foregoing from the Supporting Entity or their Family Members;
- Any significant financial relationship held by MD Anderson itself in a Supporting Entity; and
- The IRB may impose additional requirements in consideration of the interests of the Research subjects.

D. Because of the unconditional priority of patient care, there may be exceptional situations wherein a Covered Individual who has a Financial Interest in the Supporting Entity that is prohibited by Section 2.4 A-C of this policy, must serve as Principal Investigator on Clinical Trial Research. In such cases, the President may give written permission to a faculty member with a potential FCOI-R, authorizing that faculty member to act as the Principal Investigator of that Clinical Trial Research. This information will be disclosed to all patients, prior to their being asked to enroll on that IRB Approved Protocol, in the informed consent document, and to the COIC.

In all cases of Presidential waivers involving Clinical Trial Research, the waiver is subject to the approval of the IRB. The IRB may determine that an unmanageable conflict exists and the waived activity affecting the Clinical Trial Research cannot proceed.

E. The Institutional Compliance Office maintains a database listing companies in which faculty members, Investigators, Trainees, Institutional Decision Makers, and their Family Members hold Financial Interests. Patients on any Clinical Trial Research, or their Immediate Family, will have access to pertinent information from this database upon request, and patients shall be notified of this right of access in the informed consent document.

F. The IO(s) and the appropriate IRB shall cooperate in the consideration of whether an Investigator (including his/her Family Member) has an FCOI-R in regard to Clinical Trial Research and in the development and implementation of a COI Management and Monitoring Plan for that FCOI-R. The IRB may impose additional requirements or restrictions, and shall convey its final decision to the faculty member, the COIC, the IO, and the Vice President of the Office of Clinical Research.

G. The IRB relies upon the accuracy of disclosures made by Investigators in the COI Database, and it is the Investigator’s responsibility to ensure that disclosures are made in the informed consent document in accordance with Section 2.4 C of this policy. Investigators should ensure that the IRB is aware of any Financial Interest related to each IRB Clinical Trial Research protocol within a timely manner (but within a maximum of 30 days) so that a determination can be made regarding inclusion on the informed consent document in accordance with Section 2.4 C of this policy. Any circumstances that alter existing disclosure reports must be brought to the attention of the COIC and IRB within 30 days of discovery. The 30-day grace period does not apply to consulting agreements or other relationships where a formal written contract is expected, which are to be reported and approved prior to signing or executing that contract as indicated under Section 3.2 of this policy.

3.0 Disclosure Requirements

3.1 Full disclosure to the COIC of all Outside Employment and other financial relationships is required by all individuals subject to this policy (Covered Individuals) as stated below. There is no lower limit for disclosure unless specifically stated otherwise. Certain disclosures must be approved in advance, as stated below (pre-approval requirements do not apply to part-time faculty with less than a 9-month or 12-month appointment unless the activity reasonably
relates to Institutional Responsibilities, as defined in Section 3.2 of this policy). Investigators on funded Research (regardless of the source of funding) must also certify in the institutional electronic Research proposal data systems whether they have a Financial Interest related to that Research project.

3.2 Disclosures Required to Comply with Objectivity in Research (UTS175):

The following Financial Interests and outside relationships related to one’s Institutional Responsibilities or general area of expertise are required to be disclosed by all Covered Individuals in order to meet UTS175 and PHS requirements (42 CFR Part 50, Subpart F).

Financial Interests that are reasonably related to a Covered Individual’s Institutional Responsibilities includes any services for or remuneration from an entity involved in healthcare, patient care, or that develops, manufactures, distributes, or arranges for the development, manufacture, or distribution of any pharmaceutical product, medical device, biotechnology device or material, chemical substance or compound, or software used in patient care or Research, or that coordinates continuing medical education, conducts business transactions with MD Anderson in excess of $5,000, or has a license agreement with MD Anderson, or is a Competitor of MD Anderson. The financial relationships of covered Family Members that reasonably appears to be related to these types of relationships must also be disclosed but are not subject to the prior approval requirement. In determining whether a Financial Interest should be disclosed, doubt should be resolved in favor of disclosure.

A. Disclosures that Require Pre-Approval:

Prior approval is required before these types of relationships can begin (unless specifically exempt from disclosure under Section 3.2 C of this policy):

- All Outside Employment or compensated activity related to one’s Institutional Responsibilities (as described above), including consulting, speaking, scientific advisory services, or receipt of honoraria or other remuneration (as described above). Approval must also be received prior to signing a contract with a for-profit entity for such services, whether paid or unpaid. With respect to Continuing Medical Education (CME) activities, the names of both the funding entity and organizing entity should be disclosed;

- Paid or unpaid board member positions, company officer, or other fiduciary positions held in a for-profit business or other for-profit legal entity related to one’s Institutional Responsibilities (as described above). These relationships also require presidential approval (waiver), as stated in Section 1.3 of this policy.

B. Other Disclosures Required:

The following other types of Financial Interests related to a Covered Individual’s Institutional Responsibilities (including those held by a covered Family Member) must be disclosed within 30 days of acquiring the Financial Interest:

- Ownership Interests in an entity related to the Covered Individual’s Institutional Responsibilities or held by a Covered Family Member, including stock, stock options, business ownership, or other Financial Interests held in any legal entity such as a foundation or trust. Interests held in a legal entity such as a foundation or a trust controlled or directed by the Covered Individual and/or a covered Family Member must also be disclosed as if the separate legal entity did not exist;

- Family Members’ Outside Employment or other compensated activity (if related to Covered Individual’s Institutional Responsibilities, as described above);
- Paid authorship and paid Scholarly Work activities on behalf of a non-profit professional society or academic journal (including paid authorship, editing, educational speaking, or compensated scientific advisory activities) that reach or exceed $5,000 within a 12-month period (for all payments from that entity combined, including royalties or any travel reimbursement or support);

- Board member positions, company officer, or other fiduciary positions held in a non-profit business or for-profit legal entity related to the Covered Individual’s Institutional Responsibilities (as described above). Unpaid philanthropic and professional society board positions are permitted as stated in Section 1.3 of this policy without the need for a presidential waiver, but must be disclosed;

- Gifts (e.g., entertainment tickets, meals, gift certificates, etc.);

- Reimbursed or sponsored travel from an outside entity (unless specifically exempt from disclosure under Section 3.2 C of this policy. The minimum required details include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The institution may request further details, including disclosure of the monetary value, to assist in its review and determination of the existence of an FCOI-R;

- Royalty income or entitlement to payments received from an entity or from the institution (e.g., bonus or milestone payments, but excluding royalties and payments for Scholarly Work covered above);

- Any license agreement or other rights held by a third party or other legal entity in any intellectual property invented or created by the individual covered by this policy;

- Any direct or indirect Compensation or payment from an entity with respect to intellectual property of which the individual covered by this policy is an inventor or creator;

- Other financial relationships where a Covered Individual receives or holds consideration (such as Cash or an Ownership Interest) directly or has the right to direct transfer or ownership of the consideration to a designee(s) of his/her choice (including institutional accounts);

- Any other relationships or disclosures as required by the COIC Chair (or Vice-Chair), the Provost, or the President of the institution within 30 days of acquiring the relationship, or as specified by the COIC Chair (or Vice-Chair), the Provost, or the President of the institution.

C. Disclosure Exceptions (Exempt from Disclosure):

The following activities and financial relationships are considered exempt from the disclosure requirements under this policy as permitted under PHS Regulations (42 CFR Part 50, Subpart F) and UTS175, provided that remuneration or travel support is not provided directly by a pharmaceutical company, device manufacturer, or other biomedical entity. For purposes of compliance with UTS180, such disclosures are considered consistent with MD Anderson’s mission, and are considered “pre-approved” without the requirement for disclosure:

- Salary or remuneration paid by MD Anderson if currently employed or appointed by MD Anderson (with the exception of royalties, which must be disclosed as covered above);
• Payment for service on advisory committees, review panels, seminars (speaking),
  lectures, or teaching engagements or travel reimbursement or support provided by
  the US federal, state, or local government;

• Payment for service on advisory committees, review panels, seminars (speaking),
  lectures, or teaching engagements or travel reimbursement support provided by
  US higher academic institutions, US Research institutes affiliated with a US
  academic institution, or US medical centers;

• Income from investment vehicles, such as mutual funds, retirement accounts, or
  blind trusts, as long as the individual subject to this policy does not directly control
  the Investment decisions made in these vehicles. With respect to blind trusts, the
  identity of the companies in the portfolio in the blind trust must also be unknown
  and meet the requirements of the Ethics in Government Act of 1978.

• Unpaid Scholarly Work activities (e.g., activities that would normally be considered
  part of one’s academic duties such as writing scholarly or educational journal
  articles, books or book chapters, or serving as an editor of a scientific journal) are
  not required to be disclosed unless payment is received.

3.3 Guiding Principles for Disclosures:

A. Required disclosures must be made in accordance with procedures and formats as
required by the COIC. Disclosures that are not submitted on time, but otherwise meet all
of the COIC’s minimum requirements may, at the discretion of the COIC and consistent
with applicable Standard Operating Procedures, be acknowledged ("retrospectively
approved" for purposes of complying with UTS180), provided the involved individual
does not have a history of repeated or egregious noncompliance with this policy.

B. Any disclosures that are determined by the IO(s) to be a COI or Conflict of Commitment
will require a Conflict Management Plan. The Plan must be signed by the individual
subject to this policy and by his or her chair, and submitted through the Office of
Research Administration to be reviewed and approved by the COIC, the Provost, and
(where appropriate) by UT System.

C. The COIC reserves the right to administratively or retrospectively approve, rescind any
previously approved decisions, and/or re-review any disclosures at its own discretion (for
example, in light of new information that may impact Research or create an FCOI-R).
Disclosures that are rejected (disapproved) by the COIC or the COIC Chair can be re-
reviewed by the full committee.

D. In making disclosures under this Section, the individual shall disclose dollar amounts in
rounded, whole dollars, provide the name and principal address for the source, and
distinguish among information pertaining to the Faculty member, Trainee, Investigator,
Institutional Decision Maker, and covered Family Members whose Financial Interests
and activities are being disclosed.

E. The institution shall maintain records of financial disclosures with respect to each
conflicting interest related to PHS grants or cooperative agreements for Research other
than SBIR Program Phase I applications, as well as records regarding any actions taken
on those disclosures for a minimum of three years from the date of submission of the
final expenditures report for such PHS grant or cooperative agreement, or where
applicable, from other dates specified in 45 CFR 74.53(b) for different situations.

F. The President of MD Anderson must submit disclosures as required by UTS180 and
UTS123. If the President of MD Anderson is also an Investigator as defined by this
policy, disclosures should also be submitted according to the policy requirements of this policy.

3.4 Annual Certification:

Prior to the first day of March of every year, each Covered Individual shall provide the COIC with an Annual Certification Report attesting to the accuracy of those relationships and Research disclosed within the previous 12-month period or from the previous certification (whichever is longer) which are subject to disclosure as described in Section 3.0 of this policy. The report shall be in the form provided by the COIC. This report must also be provided by new hires subject to this policy within 60 days of beginning MD Anderson employment, but before serving as an Investigator on any Research or being listed as an Investigator on a grant application/progress report/non-competing renewal or other Research project submission (regardless of the source of Research funding).

A. In the event that a Covered Individual does not hold any Ownership Interest, or have any of the other relationships with any of the categories of Business Entities listed in Sections 3.2 of this policy, he or she shall provide an affirmative statement of the non-existence of such interests or relationships to the COIC prior to the first day of March of every year, as well as within 60 days of beginning employment at MD Anderson.

B. Any corrections or substantial changes to disclosed relationships, or relationships that were not previously timely disclosed as required under Section 3.2 of this policy must be submitted and completed during Annual Certification.

C. Information provided by the disclosure form will be maintained in a confidential manner, subject to certain exceptions and to the extent allowed by law, in the Office of Research Administration.

D. Trainees with an appointment greater than or equal to six continuous months must complete the annual certification.

E. Adjunct Faculty Members who do not fall under the definition of an Investigator in this policy are not required to complete an Annual Certification unless specifically requested by the President or Provost (or his/her designee), or the COIC.

F. High school and college undergraduate students who do not meet the definition of an Investigator are excluded from completing an Annual Certification.

G. Part-time Clinical Specialists (as determined by Faculty and Academic Affairs) who do not engage in Research or serve as an Investigator are not required to complete an Annual Certification unless specifically requested by the President or Provost (or his/her designee), or the COIC.

H. Adjunct Faculty Members, Trainees, and Clinical Specialists who are not Investigators and are considered “exempt” under this policy may still be subject to disclosure and Annual Certification requirements.

I. Investigators must have a current Annual Certification prior to submitting an application for PHS-funded Research. An individual who is new to the institution and who is planning to participate in an on-going PHS-funded Research project shall submit the statement within 60 days of beginning MD Anderson employment, and prior to being listed on a grant submission or other Research project submission.

Anyone to whom these procedures apply who (a) fails to provide the Annual Certification on or before the first day of March of every year, upon being notified of such failure and refusing to remedy such failure; or (b) knowingly or repeatedly violates these procedures, is subject to
disciplinary action as described in Section 12.0 of this policy. Failure to provide the required Annual Certification and disclosures subject to this policy and to abide by the procedures herein places the institution at considerable risk, and therefore may constitute good cause shown for disciplinary action up to and including termination.

4.0 Rules for Outside Relationships

4.1 Any consulting agreement or other written contract for services or to provide for receipt of anything of value entered into between a faculty member, Trainee, Investigator, faculty Supervisor, or Institutional Decision Maker and an outside Business Entity required to be disclosed under Section 3.0 of this policy shall be presented to COIC for compliance review and approval prior to execution of the agreement, and is required for approval of the disclosure. A copy of any other agreement, contract, offer letter, or documentation pertaining to a disclosed outside relationship must also be provided to the COIC upon request. Information which must be kept confidential by law (i.e., classified government work) is not required to be provided, but disclosure is still required including sufficient details regarding the entity name, Nature and Extent of the services, and Compensation. In addition, a contract or sufficient documentation must still be provided for approval of the disclosure.

4.2 Individuals should consult the Guidelines for Consulting Agreements prior to entering into any consulting relationship and are personally responsible for compliance therewith.

4.3 All consulting agreements or other contracts for outside relationships must not violate institutional policy or the Texas Penal Code §36.07, Acceptance of Honorarium and must be in conformance with The Rules and Regulations of The Board of Regents of The University of Texas System.

4.4 It is incumbent upon the individuals subject to this Policy to provide presentations free of third party commitments, restrictions, and other influences that may bias or create the appearance of bias in the presented material, which may compromise scientific integrity and public trust. To this end, and consistent with Section 4.3 of this policy, individuals subject to this Policy:

A. Must retain full control and authorship over presentation content and must not allow presentations to be subject to prior approval by any third party other than approval of the use of proprietary information.

B. May not deliver a presentation if a third party has the right to dictate the content of such presentation.

C. Must disclose to the audience any third party Compensation received that could be perceived to bias the presentation.

D. May not present slides or materials authored by a third party as their own.

E. May not deliver presentations that do not comply with this Policy, regardless of whether Compensation is received.

4.5 All individuals subject to this Policy must comply with MD Anderson’s Scientific Publication Policy (UTMDACC Institutional Policy # ACA0018).

4.6 All consulting agreements or other written contracts for an outside relationship must state the maximum number of days that are required for the individual to fulfill the agreement. The maximum number of days required by all agreements entered into by an individual may not exceed 30 days per fiscal year.
5.0 Conflict of Interest Committee (COIC) Procedure

5.1 COIC rules, responsibilities, procedures, and membership guidelines are set forth in the Conflict of Interest Committee By-Laws.

5.2 The By-Laws and/or Policies of the IRBs, Clinical Research Committees, Psychosocial, Behavioral, and Health Services Research Committee, Institutional Animal Care and Use Committee, and Institutional Biosafety Committee will require members to disclose conflicts to the Committee and Chair. Members must abstain from voting on issues for which the member has a COI. A copy of the relevant By-Laws or Policies may be obtained from each Committee.

6.0 Extramural Leave

See Faculty Extramural Leave Policy (UTMDACC Institutional Policy # ACA0051).

7.0 Medical Consultation/Expert Witness

Any Compensation received by a faculty member, who is a physician and contractual member of the PRS, received pursuant to a consulting agreement involving:

7.1 Serving as an expert witness for trial preparation, affidavit, or testimony;

7.2 Consultation concerning the medical management of an identifiable patient or patients made the subject of such consulting agreement; or

7.3 Review of, or participation in, the care, supervision of care, or analysis of any data, regarding management and diagnosis of an identifiable patient or patients made the subject of such consulting agreement, will be delivered to PRS and will be referred to the Chief Legal Officer for a recommendation on dispensation. The Chief Legal Officer will make a recommendation to the PRS Executive Committee. The PRS Executive Committee will then determine whether such Compensation falls within one or more of the exceptions as defined by the By-Laws of the PRS. Such determination will be made within 30 days of referral to the Chief Legal Officer. Nothing in this rule supersedes the definition of professional income, or exceptions thereto, as provided in the By-Laws of the PRS.

8.0 Negotiations

8.1 No one may negotiate on behalf of MD Anderson who has a COI in that negotiation.

8.2 No Covered Individual will participate in any manner in any negotiations on behalf of MD Anderson with an outside entity that involves either a financial transaction or a licensing agreement involving MD Anderson, if such person or his/her Family Member has either:

A. An Ownership Interest in the outside entity;

B. A consulting agreement with the outside entity that provides for receipt by the faculty member or decision maker of anything of value of $10,000.00 or greater within the previous 12-month period; or

C. Received anything of cumulative value of $10,000.00 or greater from the outside entity in the previous 12-month period; or

D. Serves on any scientific or advisory board of the outside entity.

This does not include negotiations involving sponsored Research agreements.
8.3 An employee may not transact any business in an official capacity with any Business Entity of which the employee is an officer, agent, or member, or in which the employee owns a substantial interest.

8.4 Additionally, before MD Anderson may purchase any supplies, materials, services, equipment, or property from an employee or the employee’s Business Entity, the President or designee must approve the purchase, and the purchase may be made only if the cost is less than the cost available from any other known source.

8.5 The President may grant individual exceptions to this principle for particular transactions. These exceptions will be in writing, and provided to the COIC, the involved person, and the involved outside entity by the President.

8.6 In situations where participation in negotiations is not allowed, the COIC and/or the person will request that the Chief Legal Officer transmit notification of the prohibition against participation to the outside entity.

9.0 Supervisory Relationships

9.1 Conflicts of interest in the supervision of faculty, Trainees, and staff by direct Supervisors are prohibited, as described below.

9.2 Individuals in supervisory positions must consider the adverse consequences that any external financial relationships might have on their ability to adequately perform their required responsibilities as Supervisors of Faculty or students.

9.3 No direct Supervisor will be responsible for oversight or approval of another person’s compliance with the commitment of time requirements as specified in the Faculty Extramural Leave Policy (UTMDACC Institutional Policy # ACA0051), with regard to an outside entity if such Supervisor has

A. An Ownership Interest an outside entity in which the IO in consultation with the COIC determines a COI or FCOI exists that cannot be Managed or;

B. Receives Cash of $25,000 or greater in any 12-month period from the outside entity with which the supervised person has made a commitment for Compensation or time.

9.4 No Supervisor and/or his/her spouse and/or dependent children may have an Ownership Interest in any outside entity in which the IO in consultation with the COIC determines a COI or FCOI exists that cannot be Managed. Additionally, no Supervisor and/or his/her spouse and/or dependent children can receive Cash valued at $25,000 or greater from an outside entity (1) that funds Research directed by a faculty member who reports directly to that Supervisor; or (2) is providing a non-FDA-approved product for use in Clinical Trial Research directed by a Principal Investigator who is a faculty member who reports directly to that Supervisor.

9.5 Note: other restrictions concerning Supervisory relationships of Trainees apply in instances of sponsored Research as per Section 2.2 E of this policy.

9.6 In the event that a Supervisor is prohibited from oversight or approval for the reasons stated above, oversight and approval will be assigned to an alternate Supervisor by the President or the President's designee or a duly constituted committee of supervisory peers. In such instances where a Supervisor’s oversight and approval of a Principal Investigator on an IRB protocol has been reassigned (per Section 9.4 of this policy), the Supervisor may not serve as an Investigator on the IRB protocol.
10.0 The Institution

For information regarding institutional conflicts of interest, please see the Institutional Conflict of Interest Policy for the University of Texas MD Anderson Cancer Center and Institutional Decision Makers (UTMDACC Institutional Policy # ADM1273).

11.0 Licensing and Equity

11.1 Any faculty member, Trainee, or Institutional Decision Maker who is the creator of intellectual property owned by the Board of Regents of The University of Texas System and licensed to a Business Entity in which such individual has an Ownership Interest is required to submit a disclosure and implement a COI Management and Monitoring Plan (see Procedure for Obtaining Approval of Plan to Manage Conflicts of Interest). An individual who holds equity in the third party at the time of license execution should have a Plan in place prior to execution of the license. An individual who does not hold equity at the time of license execution, but is entitled to share in the proceeds from the liquidation of License Equity, shall submit a Plan within thirty (30) days of execution of the license in accordance with Intellectual Property Policy (UTMDACC Institutional Policy # ADM0345).

12.0 Compliance

12.1 In order to protect the standing of the institution and continued eligibility for federal and state funding, protect patient safety and welfare, and preserve the integrity of affiliated Research, disciplinary action may be warranted for noncompliant individuals subject to this policy. Noncompliance with this policy and/or written recommendations of the COIC shall be reported to the Provost and Executive Vice President. The Provost or designee shall communicate in writing to the COIC and the person involved a directive for the elimination or management of such noncompliance. In matters where the noncompliant party is the Provost and Executive Vice President, the matter will be reported to the President and the President or designee will provide the communication to the Provost and Executive Vice President to eliminate or Manage the noncompliant activity. The involved person shall provide a written report acknowledging compliance with the directive to the COIC. Relationships that were allowed or permitted under prior policies as well as relationships that existed prior to employment at MD Anderson that are not in compliance with the current policy will be reviewed by the COIC.

12.2 If an individual subject to this policy does not comply with a directive of the Provost, disciplinary action, including but not limited to one or of the following may be imposed upon the noncompliant individual, at the discretion of the Provost: a) Research activities may be put on hold; b) clinical activities may be put on hold; c) eligibility for internal funding; d) financial penalties may be assessed on the faculty member’s PRS account. Failure to comply with a directive of the Provost and Executive Vice President or President concerning a COI or commitment may also, at the determination of the President, constitute good cause shown as grounds for termination in accordance with the procedures stated in The University of Texas Regents’ Rules and the University of Texas MD Anderson Handbook of Operating Procedures.

12.3 In addition to the general provisions noted above, additional penalties may be imposed upon individuals who are noncompliant with completing the Annual Certification.

A. The Office of Research Administrative will send out a 30-day email notification reminding the faculty, Trainees, or others subject to this policy that the Annual Certification is required to be completed prior to March 1 of each year.

B. Annual Certifications are to be completed within 30 days of the initial notice. Thereafter, a “Notice of Delinquency” will be sent to the noncompliant faculty member, Trainee, or other individual subject to this policy, and his/her Supervisor.
C. If the Annual Certification is not completed within two weeks of the “Notice of Delinquency,” in addition to the potential penalties already noted above, $1,000.00 may be deducted from the faculty member's PRS Development Fund. An additional penalty of $200.00/day will be assessed until the completed Annual Certification is received in the Office of Research Administration.

D. If the faculty member does not complete the Annual Certification in a timely manner in the subsequent year, $1,500.00 may be deducted from the faculty member’s PRS Development fund and an additional penalty of $200.00/day as described above.

E. If the faculty member’s PRS Development Fund account has been depleted, the maximum eligibility for the Supplemental Annuity Program (SAP) of that fiscal year will be reduced by an amount equivalent to the financial penalties as described above.

13.0 Exceptions to Policy

13.1 Exceptions to any part of this policy or exceptions to any determinations made under this policy, accompanied by a rationale, may be requested from the President through the Office of Research Administration.

13.2 The IRB has final authority where an exception would adversely impact clinical Research or human subject safety and welfare.

13.3 Exceptions applying to the President to any part of this policy are subject to approval by The University of Texas System (UT System), as specified in Regents’ Rules. The granting of a waiver/exception to the President by The Board of Regents of UT System should be disclosed to the COIC for information purposes only.
ATTACHMENTS / LINKS

By-Laws of the Physicians Referral Service.

Conflict of Interest Committee By-Laws.

Conflict of Interest Disclosure to Research Team Form.

Guidelines for Outside Agreements (Attachment # ATT1103).

Guidelines on Qualifications for Adjunct Appointments (Attachment # ATT1780).

PHS grants.

Procedure for Managing Conflicts of Interest.

Public Health Service (PHS).

University of Texas MD Anderson Handbook of Operating Procedures.

UTS175.

UTS180.

RELATED POLICIES

Conflict of Interest and Conflict of Commitment Policy (UTMDACC Institutional Policy # ADM0255).

Institutional Conflict of Interest Policy for the University of Texas MD Anderson Cancer Center and its Institutional Decision Makers (UTMDACC Institutional Policy # ADM1273).

Ethics Policy (UTMDACC Institutional Policy # ADM0337).

Faculty Appointments Policy (UTMDACC Institutional Policy # ACA0023).

Faculty Extramural Leave Policy (UTMDACC Institutional Policy # ACA0051).

Intellectual Property Policy (UTMDACC Institutional Policy # ADM0345).

Scientific Publication Policy (UTMDACC Institutional Policy # ACA0018).

Trademarks Policy (UTMDACC Institutional Policy # ADM0346).

Use of Information Technology Policy (UTMDACC Institutional Policy # ADM0263).

JOINT COMMISSION STANDARDS / NATIONAL PATIENT SAFETY GOALS

None.

OTHER RELATED ACCREDITATION / REGULATORY STANDARDS

Department of Health and Human Services 45 CFR 74.53 (b).

Food and Drug Administration (FDA) 21 CFR Part 54.

Public Health Service (PHS) 42 CFR Part 50.

Statutory Standards of Conduct for State Employees, Section 572.051, Texas Government Code.

Texas Penal Code §36.07, Acceptance of Honorarium.


The University of Texas System, Policy 180 – Conflicts of Interest, Conflicts of Commitment, and Outside Activities.

The University of Texas System Regents’ Rules and Regulations.

The University of Texas System Regents’ Rules and Regulations, Rule 30104 – Conflict of Interest, Conflict of Commitment, and Outside Activities.

REFERENCES

None.
POLICY APPROVAL

Approved With Revisions Date: 01/04/2018
Approved Without Revisions Date:
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Version: 72.0

RESPONSIBLE DEPARTMENT(S)

Office of Research Administration & Operations