

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	November 2015
Policy 10.1.6	Conflicts of Interest in Research and Disclosure	Responsibility:	Vice President for Research

CONFLICTS OF INTEREST IN RESEARCH AND DISCLOSURE

Overview

This policy governs the disclosure of individual significant financial interests and the management and reporting of an individual financial conflict of interest in research performed at UT Health Science Center at San Antonio, an institution of The University of Texas System.

This policy provides requirements for the disclosure of financial interests that comply with the disclosure requirements of federal regulations of the U.S. Department of Health and Human Services (HHS) and the HHS Public Health Service, but this policy is not limited in application to PHS-funded research. Rather, this policy applies broadly to research performed at the institution, without regard to whether the research has external funding and, if externally funded, regardless of the funding source. For this purpose, “research” means any systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge. The term includes both basic and applied research and product development.

This policy applies in addition to general institutional policies, such as policies on standards of conduct, as well as other policies governing disclosure of activities and financial interests in non-research related activities.

If a specific federal law or regulation provides different requirements than this policy, the more stringent requirement applies

Fundamental Principles

The Health Science Center is committed to safeguarding the public trust and to complying with all policy and statutory requirements. The following principles, therefore, are among those that underlie the Health Science Center’s policy on conflicts of interest and commitment:

1. External activities should not compromise a Covered Individual’s ability to perform all the activities expected of him or her as a Health Science Center employee.
 2. A Covered Individual should not receive remuneration for the
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conduct of his or her research at the Health Science Center except through Health Science Center channels (such as salary).

3. A Covered Individual should not conduct research at the Health Science Center under circumstances in which a reasonable person would infer that the Health Science Center activity could have been distorted by the desire for or expectation of direct or indirect external economic advantage.
4. Health Science Center Researchers, as defined by this policy, must not be precluded from publishing their work by agreements with external sponsors.
5. Graduate students must not be held to non-disclosure of any aspect of their research in their meetings with individuals at the Health Science Center (including members of their dissertation advisory committees).
6. Health Science Center facilities, equipment, and personnel should be used only for Health Science Center activities and purposes, as described in the *Handbook of Operating Procedures* (HOP), [Section 10.1.3](#), "Personal Use of University Resources, Equipment, and Assets".
7. A Covered Individual should not participate directly in the negotiation of research agreements, technology license agreements, equipment purchases, or other arrangements between the Health Science Center and an organization in which the individual has a Significant Financial Interest.
8. Research on human subjects should receive especially rigorous review and should be subject to a presumption against permitting the participation of any individual holding a Significant Financial Interest without a compelling reason and, when allowed, without an appropriate management plan approved by the Institutional Review Board (IRB).

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9. The Health Science Center will not accept research funding that is proposed to be sponsored by a small, privately held entity in which the faculty member who would conduct such research has a significant financial interest and/or Board seat or other management position unless the faculty member provides a compelling reason that the conduct of such research should be under the direction of that faculty member and such an arrangement is approved by the Vice President for Research. Faculty who have ownership, managerial, or Board relationships with a start-up are required by this policy, and the Board of Regents ([Rule 90103](#): “Equity Interests” and [Rule 90104](#): “Business Participation and Reporting”) to disclose their interest and implement a conflict of interest management plan. Where the start-up forms from Health Science Center owned, intellectual property, The University of Texas System ["Procedure for Managing Conflicts of Interest"](#) also applies.

General Provisions

Who is Covered: “Covered Individual”

An individual who, regardless of title or position, is responsible for the design, conduct, or reporting of research, including a principal investigator, associate investigator, or project director, must file and update financial disclosure statements under this policy. A person required to file and update financial disclosure statements is referred to in this policy as a “covered individual.”

Collaborators and Contractors

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

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- (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 this institution.
 - (c) If the policy of the contracting party applies to its researchers, the agreement must specify the time periods for the contracting party to report identified financial conflicts of interest to this institution. The time periods must be sufficient for this institution to make any reports required by federal regulation.
 - (d) If the policy of this institution applies to the researchers of the contracting party, the agreement must specify the time periods for the researchers to submit a financial interest disclosure statement to this institution. The time periods must be sufficient for this institution to comply with its review, management, and reporting obligations under federal regulation.

Education

- (a) Each covered individual must acknowledge annually that the individual is aware of and has read this policy and is aware of the covered individual’s responsibilities regarding disclosure of significant financial interests and of applicable federal regulations.
- (b) A covered individual must complete training in regard to this policy and applicable policies, regulations, and laws before engaging in research at the institution and at least once every four years thereafter. A covered individual who is new to the institution must complete the training before engaging in research at the institution or provide evidence of having

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completed the training at another institution of The University of Texas System within the last four years. A covered individual must complete the training immediately if the institution finds that the individual is not in compliance with this policy or the individual’s management plan, or if the institution revises this policy in a manner that affects the individual’s duties.

- (c) The Vice President for Research is responsible for ensuring that appropriate faculty, staff, trainees, and other persons participate in training in regard to this policy and applicable laws.

Disclosures of Significant Financial Interests Related to Institutional Responsibilities

Extent of Disclosure

- (a) As often as required by the [“When to Disclose”](#) section below, a covered individual shall complete or update a financial interest disclosure statement that:
 - (1) identifies all research in which the covered individual is engaged at the time of the disclosure; and
 - (2) discloses, as provided by the [“Contents of Disclosure”](#) section below, each significant financial interest of the individual and covered family members that reasonably appears to be related to the individual’s institutional responsibilities.
- (b) “Institutional responsibilities” means any of the professional responsibilities of a covered individual on behalf of the institution, including research, research consultation, teaching, professional practice, institutional committee membership, or service on an institutional panel such as an Institutional Review Board (IRB) or Data and Safety Monitoring Board (DSMB).
- (c) In determining whether research or a financial interest should be disclosed, the covered individual should resolve the doubt in favor of disclosure.

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Contents of Disclosure: Significant Financial Interests

(a) The following interests are considered to be significant financial interests and, subject to the exclusions provided by Subsection (b) of this section, a covered individual's disclosure statement must include the following information in regard to the covered individual and covered family members, but only in regard to interests that reasonably appear to be related to the individual's institutional responsibilities:

(1) PAYMENTS RECEIVED FROM OR EQUITY INTEREST IN A PUBLICLY TRADED ENTITY: the total amount and source of payments received in the preceding twelve months from a publicly traded entity and the value of any equity interest held in the entity on the date of disclosure that, when aggregated, exceed \$5,000, including:

(A) as to payments received:

(i) salary; and

(ii) any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and

(B) as to equity interests held, any stock, stock options, or other ownership interest or entitlement to such an interest, valued by reference to public prices or other reasonable measures of fair market value;

(2) PAYMENTS RECEIVED FROM A NON-PUBLICLY TRADED ENTITY OR EQUITY INTEREST IN A NON-PUBLICLY TRADED ENTITY:

(A) the total amount and source of payments received in the preceding twelve months from an entity that is not publicly traded that, when aggregated, exceed \$5,000, including

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- (i) salary; and
 - (ii) any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and
- (B) a description of any equity interest held in an entity that is not publicly traded, including any stock, stock options, or other ownership interests or entitlement to such an interest;
- (3) INTELLECTUAL PROPERTY AND ROYALTIES:
- (A) a description of intellectual property rights held and any agreements to share in royalties related to those rights; and
 - (B) the amount and source of royalty income that the covered individual or covered family member received or had the right to receive in the preceding twelve months;
- (4) TRAVEL: reimbursed or sponsored travel in the preceding twelve months, including the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and the value of the travel, if the aggregated value of all payments from the sponsor/organizer (such as salary, consulting fees, honoraria, or paid authorship and travel) exceeds \$5000;
- (5) GIFTS: the value and source of a single gift that the covered individual received in the preceding twelve months that exceeds \$250 in value, or multiple gifts from a single entity that in the aggregate exceed \$250 in value, other than gifts from a covered family member; and
- (6) FIDUCIARY POSITIONS: a fiduciary position the covered individual held in a for-profit or nonprofit entity in the preceding twelve months, including a position as a

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member of the board of directors, an officer, or other executive or management position, for which the individual received any form of remuneration or reimbursement for expenses, and the name and principal address of the entity.

- (b) The following interests are not significant financial interests and need not be disclosed on the disclosure statement:
- (1) salary, royalties, or other remuneration paid by the institution to the covered individual, if the covered individual is currently employed or otherwise appointed by the institution (including salary paid by the Veteran's Administration);
 - (2) income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government, an institution of higher education as defined by [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education;
 - (3) income from service on an advisory committee or review panel for a federal, state, or local government, an institution of higher education as defined by [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education;
 - (4) income from investment vehicles, such as mutual funds or retirement accounts, as long as the covered individual does not directly control the investment decisions made in those vehicles; or
 - (5) travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined by [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

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- (c) In making disclosures under this section, the covered individual shall:
- (1) disclose dollar amounts in rounded, whole dollars;
 - (2) when describing a source, provide the name and principal address for the source; and
 - (3) distinguish among information pertaining to the covered individual and covered family members whose financial interests and activities are also disclosed by the covered individual.
- (d) The conflict of interest official may request further information about a covered individual's travel, including the monetary value of the travel, in order to determine whether the travel constitutes a financial conflict of interest.

Disclosure of Financial Interests of Other Persons: Covered Family Member

- (a) For purposes of disclosure under the "[Contents of Disclosure](#)" section above, "covered family member" includes:
- (1) a spouse;
 - (2) a dependent child or stepchild;
 - (3) any other person financially dependent on the covered individual; and
 - (4) any other person with whom the covered individual has joint financial interests such that an objective third party could reasonably conclude that the covered individual's decisions or other exercise of professional responsibilities at the institution could be influenced by the effect of that action on the person's financial interest.

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- (b) A person described by Subsection (a) (3) or (a) (4) is a covered family member without regard to whether a legal or biological family relationship exists with the covered individual. If the covered individual is in doubt; the covered individual should resolve the doubt in favor of disclosure.
 - (c) In disclosing financial interests, the interest of any legal entity, including a foundation or a trust that is controlled or directed by the individual or by the individual and covered family members is considered to be the interest of the covered individual or covered family member as if the separate legal entity did not exist.

Text of Documentation to be Provided on Request

If a covered individual discloses payments, intellectual property interests, or royalties, the covered individual must provide a copy of any related agreement, contract, offer letter, or other documentation on request of:

- (a) the president of the institution;
- (b) the conflict of interest official; or
- (c) any other person or entity with administrative responsibility in regard to reviewing financial interest disclosure statements or approving a related management plan.

When to Disclose; Period Covered by Statement

- (a) A covered individual shall submit or update a financial interest disclosure statement using the [iDisclose](#) application managed by the Office of the VPR:
 - (1) not later than the 30th day of initial employment, covering the twelve months preceding the date of disclosure;
 - (2) annually not later than March 31; and

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(3) not later than the 30th day after acquiring a new financial interest that requires disclosure under the "[Contents of Disclosure](#)" section, such as receiving payments, an equity interest, intellectual property rights, or royalties would require disclosure on an annual financial interest disclosure statement.

(b) A covered individual who is planning to participate in a PHS-funded research project shall submit a financial interest disclosure statement not later than the time of application for PHS-funded research, except that 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 not later than the 30th day of initial employment.

(c) The president of the institution or the conflict of interest official may require a covered individual to submit additional disclosures.

**Conflict of Interest Official;
Disclosure Statement Review**

Conflict of Interest Official

The conflict of interest official for the institution is the Vice President for Research (VPR). The day-to-day activities of policy compliance will be handled by the Assistant Vice President of Research Operations and the Conflict of Interest Manager. The conflict of interest official (or designee) shall perform the duties required by this policy and other duties as assigned by the President. Service as a conflict of interest official is in addition to any other capacities in which the person serves the institution.

Disclosure Statement Review; Determination of Financial Conflict of Interest

(a) The appropriate conflict of interest official(s), applicable Department Chair/Dean/VP and the Conflict of Interest Committee shall review each financial interest disclosure statement and make two determinations:

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(1) whether any significant financial interest disclosed is related to research in which the covered individual is engaged; and

(2) if so, whether a financial conflict of interest exists.

(b) A significant financial interest is related to research in which the covered individual is engaged if the conflict of interest official reasonably determines that the financial interest appears to be affected by the research or is in an entity whose financial interest appears to be affected by the research.

(c) A financial conflict of interest exists when the conflict of interest officials reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.

No Expenditure of Funds Prior to Review and Determination

Neither the institution nor a covered individual may expend research funds unless the conflict of interest official has determined that no financial conflict of interest exists or that any financial conflict of interest is manageable in accordance with the terms of a management plan that has been adopted and implemented.

Cooperation with IRB

The conflict of interest official and the appropriate IRB shall cooperate in the consideration of whether a covered individual has a financial conflict of interest in regard to human subjects research and in the development and implementation of a management plan for that conflict of interest. The IRB may require additional protections to ensure the safety of human subjects participating in conflicted research.

Management of Financial Conflict of Interest

Management Required for Financial Conflicts of Interest

(a) If the conflict of interest official determines that a covered individual has a financial conflict of interest, the official, in

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cooperation with the covered individual, applicable Department Chair/Dean/VP, the Conflict of Interest Committee and other appropriate individuals designated by the conflict of interest official, shall develop a management plan. Such management plan is required to govern conflicts of interest that have the potential to adversely affect the protection of human subject participants or the integrity of the research.

- (b) If research is ongoing and a new covered individual discloses a significant financial interest related to that research or any other covered individual discloses a new significant financial interest related to that research, the conflict of interest official shall, not later than the 60th day after the filing of the disclosure statement:
 - (1) review the disclosure statement to determine if a financial conflict of interest exists; and
 - (2) if a financial conflict of interest exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the research.
- (c) If the conflict of interest official learns of a significant financial interest that was not timely disclosed or was not timely reviewed, the conflict of interest official shall, not later than the 60th day after learning of the interest:
 - (1) determine whether the significant financial interest is a financial conflict of interest; and
 - (2) if a financial conflict of interest exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the research going forward.
- (d) In addition, if a financial conflict of interest was not timely identified or managed, or if a covered individual fails to comply with a management plan, the conflict of interest official shall, not later than the 120th day after determining noncompliance:

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- (1) complete and document a retrospective review and determination as to whether research conducted during the period of noncompliance was biased in the design, conduct, or reporting of the research; and
 - (2) implement any measures necessary with regard to the covered individual's participation in the research between the date that the noncompliance is identified and the date the retrospective review is completed.
- (e) For PHS-covered research projects, the retrospective review shall cover key elements as specified by federal regulations and may result in updating the Financial Conflict of Interest Report described by the "[Financial Conflict of Interest Report](#)" section below, notifying the PHS, and submitting a mitigation report as required by federal regulation.

Management Plan Design and Agreement

- (a) A management plan may impose any condition and prescribe any action necessary to manage a financial conflict of interest, including an action reducing or eliminating the financial conflict of interest, to ensure that the design, conduct, or reporting of the research is free from bias or the appearance of bias. Examples of conditions or actions that may be prescribed include:
 - (1) public disclosure of the conflict of interest in presentations and publications;
 - (2) for human subjects research, direct disclosure of the conflict of interest to research participants;
 - (3) appointment of an independent monitor with authority to take measures to protect the design, conduct, and reporting of research against bias, or the appearance of bias, resulting from the conflict of interest;
 - (4) modification of the research plan;

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- (5) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - (6) divesture or reduction of the financial interest; or
 - (7) severance of relationships that create an actual or potential financial conflict of interest.

(b) A management plan must be in the form of a written agreement and must:

- (1) provide that the covered individual acknowledges receipt of the plan and understands the requirements of this policy and the required actions and other terms of the plan, including the time frames for required actions; and
- (2) clearly identify each specific person responsible for monitoring compliance with the management plan

Monitoring and Compliance

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

Web Posting of Financial Conflict of Interest Information

Posting of this Policy

This policy and each update of this policy must be publicly accessible through the Internet in the *Handbook of Operating Procedures*, [Chapter 10](#).

Posting of Information Regarding Specific Financial Conflicts of Interest

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- (a) For each financial conflict of interest that is found to exist by the conflict of interest official, the institution will make the following information available to the public through the Internet in regard to each covered individual who contributes to the scientific development or execution of the research project in a substantive, measureable way, including a covered individual who is the project director or principal investigator:
- (1) the covered individual's name;
 - (2) the covered individual's title and role with respect to the research;
 - (3) the name of the entity in which the significant financial interest is held;
 - (4) the nature of the significant financial interest that constitutes a financial conflict of interest; and
 - (5) the approximate value of the significant financial interest by range or, if the dollar value cannot be determined by reference to public prices or other reasonable measures of fair market value, a statement to that effect.
- (b) The approximate dollar value of the significant financial interest shall be provided within the following ranges if it can be determined by reference to public prices or other reasonable measures of fair market value:
- (1) \$0 - \$4,999;
 - (2) \$5,000 - \$9,999;
 - (3) \$10,000 - \$19,999;
 - (4) amounts between \$20,000 - \$100,000 by increments of \$20,000; or
 - (5) amounts above \$100,000 by increments of \$50,000.
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- (c) The institution will update the information required by this section annually. In addition, for any financial conflict of interest of a covered individual whose information must be posted under this section and for which the information was not previously posted, the institution will make the information required by this section available not later than the 60th day after the financial conflict of interest is identified.
 - (d) The website on which the information is posted must note that the information is current as of the date listed and is subject to updates.
 - (e) The information required by this section must remain available on the Internet for three years after its most recent update.
 - (f) For PHS-funded research, in regard to project directors, principal investigators, and other senior or key personnel, this information must be available through the Internet before expending PHS funds.

Certification and Reports to PHS

Certification and Report Required

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

Financial Conflict of Interest Report

Before the expenditure of any funds under a PHS-funded research project, the appropriate institutional officials will make the Financial Conflict of Interest Report to the PHS awarding component in compliance with [42 CFR Part 50, Subpart F, and 45 CFR Part 94](#). In general, those regulations require a Financial Conflict of Interest Report regarding those interests that the institution determines are financial conflicts of interest, including financial conflicts of interest of sub-recipients. The reporting will include specified information sufficient to

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enable the awarding component to understand the nature and extent of the financial conflict and to assess the appropriateness of the management plan related to the conflict of interest. The federal regulations require reporting within a specified period of financial conflicts of interest identified subsequent to an earlier report and require annual updating of reports regarding previously disclosed financial conflicts of interest.

Enforcement

Disclosure is a Condition of Employment or Relationship to Institution

- (a) Timely, complete, and accurate disclosure of activities and financial interests consistent with this policy is a condition of employment at the institution, and a covered individual who does not comply with this policy is subject to discipline, including termination of employment.

- (b) For a covered individual who is not an employee of the institution, compliance with this policy is a condition of participating with the institution in the capacity that qualifies the person as a covered individual. The institution may require the individual to execute a document certifying that the individual knows that compliance with this policy is a condition of participation.

Federal Enforcement

- (a) Federal regulations, [42 CFR Part 50, Subpart F, and 45 CFR Part 94](#), require the institution to notify the PHS of instances in which the failure of a covered individual to comply with this policy or a management plan appears to have biased the design, conduct, or reporting of PHS-funded research. The PHS awarding component may take enforcement action or require the institution to take action appropriate to maintaining objectivity in the research. The institution must make information available to HHS or the PHS awarding component as required by federal regulation.

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- (b) If the HHS determines clinical research funded by PHS to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a covered individual with a financial conflict of interest that was not managed or reported by the institution as required by federal regulation, the institution will require the covered individual involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.
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Administration of Conflicts Policies; Records

Oversight and Authority

The Vice President for Research (VPR) is responsible for overseeing implementation of this policy and may provide additional procedures and supplementary forms, as appropriate, consistent with this policy and applicable sponsor regulations.

Records

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

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	July 2001
Section 10.1	Ethics, Standards of Conduct, and Relationships with External Entities	Revised:	November 2015
Policy 10.1.6	Conflicts of Interest in Research and Disclosure	Responsibility:	Vice President for Research

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- (c) The conflict of interest official, or another person designated by the president, shall provide the chancellor of The University of Texas System with copies of all guidelines, procedures, and forms used by the institution relating to financial conflicts of interest and shall ensure that the chancellor receives copies of any revised guidelines, procedures, and forms simultaneously with the implementation of the revision.

Audits

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

Policies and Relevant Statutes

Individuals subject to this policy should also be aware of and in compliance with the following policies:

Health Science Center:

- HOP [Section 10.1.2](#), Code of Ethics and Standards of Conduct
- HOP [Section 10.1.3](#), Personal Use of University Resources, Equipment, and Assets
- HOP [Section 10.1.4](#), Giving and Receiving Benefits
- HOP [Section 10.1.5](#), Political Activities
- HOP [Section 10.1.9](#), Conflict of Interest, Conflict of Commitment and Outside Activities
- HOP [Section 10.1.11](#), Guidelines for Interactions Between Clinicians and Researchers With Industry

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The University of Texas System:

- [UTS 175](#), Disclosure of Significant Financial Interests and Management and Reporting of Financial Conflicts of Interest in Research

The University of Texas System Board of Regents:

- [Regents' Rules and Regulations, Rule 30104](#), Conflict of Interest, Conflict of Commitment and Outside Activities
- [Regents' Rules and Regulations, Rule 60306](#), Use of University Resources

This policy has also been predicated on the following State of Texas Statutes:

- [Texas Government Code Chapter 572](#) – Personal Financial Disclosure, Standards of Conduct and Conflict of Interest
- Texas Education Code, [Section 51.912](#)
- The Public Health Service and the National Science Foundation promoting objectivity in research (effective October 1, 1995) codified at [42 CFR Part 50 and 45 CFR Part 94](#).