

Disclosure of Significant Financial Interest and Management and Reporting of Financial Conflict of Interest in Research

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Chapter:	Chapter 2
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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 The University of Texas at El Paso (University).

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 University, 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 University policies, such as policies on standards of conduct, as well as other policies governing disclosure of activities and financial interests.

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

2.1 General Provisions

2.1.1 Who is Covered: “Covered Individual”

2.1.1.1 An individual who, regardless of title or position, is responsible for the design, conduct, or reporting of research, including a principal investigator, co-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.”

2.1.1.2 A student enrolled at the University who is responsible for the design, conduct, or reporting of research that is not PHS-funded is considered to be a “covered individual” under this policy only if the student has a significant financial interest that appears to be affected by the research or is in an entity whose financial interest appears to be affected by the research. A student who is in doubt about whether the student is a “covered individual” must request a determination by the conflict of interest official appointed under Section 2.3.1.

2.1.2 Collaborators and Contractors

2.1.2.1 If research is carried out in cooperation with or through a subrecipient (e.g. a subcontractor, contractor, or collaborator), this University will 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.

2.1.2.2 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 University.

2.1.2.3 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 University. The time periods must be sufficient for this University to make any reports required by federal regulation.

2.1.2.4 If the policy of this University 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 University. The time periods must be sufficient for this University to comply with its review, management, and reporting obligations under federal regulation.

2.1.3 Education

2.1.3.1 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.

2.1.3.2 A covered individual must complete training in regard to this policy and applicable policies, regulations, and laws before engaging in research at the University and at least once every four years thereafter. A covered individual who is new to the

University 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. A covered individual must complete the training immediately if the University finds that the individual is not in compliance with this policy or the individual's management plan, or if the University revises this policy in a manner that affects the individual's duties.

2.2 Disclosure of Significant Financial Interests Related to University Responsibilities

2.2.1 Extent of Disclosure

2.2.1.1 As often as required by Section 2.2.5, a covered individual shall complete or update a financial interest disclosure statement that:

- (A) identifies all research in which the covered individual is engaged at the time of the disclosure; and
- (B) discloses, as provided by Section 2.2.2, each significant financial interest of the individual and covered family members that reasonably appears to be related to the individual's institutional responsibilities.

2.2.1.2 *"Institutional responsibilities"* means any of the professional responsibilities of a covered individual on behalf of the University, including research, research consultation, teaching, professional practice, University committee membership, or service on an institutional panel such as an Institutional Review Board (IRB).

2.2.1.3 In determining whether research or a financial interest should be disclosed, the covered individual should resolve the doubt in favor of disclosure.

2.2.2 Contents of Disclosure: Significant Financial Interests

2.2.2.1 The following interests are considered to be significant financial interests and, subject to the exclusions provided by Subsection 2.2.2.2 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

(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 12 months, including the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration;

- (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 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.

2.2.2.2 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 University to the covered individual, if the covered individual is currently employed or otherwise appointed by the institution;
- (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.

2.2.2.3 In making disclosures under this Section 2.2.2, the covered individual shall disclose the value of a significant financial interest within the following ranges:

(A) \$0 - \$4,999;

(B) \$5,000 - \$9,999;

(C) \$10,000 - \$19,999;

(D) amounts between \$20,000 - \$100,000 by increments of \$20,000; or

(E) amounts above \$100,000 by increments of \$50,000.

2.2.2.4 When describing a source, the covered individual shall provide the name and principal address for the source.

2.2.2.5 The covered individual shall distinguish among information pertaining to the covered individual and covered family members whose financial interests and activities are also disclosed by the covered individual.

2.2.2.6 The conflict of interest official and /or conflict of interest committee 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.

2.2.3 Disclosure of Financial Interests of Other Persons: Covered Family Member

2.2.3.1 For purposes of disclosure under Section 2.2.2, "covered family member" includes:

(1) a spouse;

(2) a dependent child or stepchild or other dependent, for purposes of determining federal income tax liability during the period covered by the disclosure statement; and

(3) a related or non-related, unmarried adult who resides in the same household as the covered individual and with whom the covered individual is financially interdependent as evidenced, for example, by the maintenance of a joint bank account, mortgage, or investments.

2.2.3.2 If the covered individual is in doubt about whether an individual is a covered family member, the covered individual should resolve the doubt in favor of disclosure.

2.2.3.3 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.

2.2.4 Text of Documentation to be Provided on Request

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

- (A) the President of the University;
- (B) the conflict of interest official;
- (C) conflict of interest committee; or
- (D) any other person or entity with administrative responsibility in regard to reviewing financial interest disclosure statements or approving a related management plan.

2.2.5 When to Disclose; Period Covered by Statement

2.2.5.1 A covered individual shall submit or update a financial interest disclosure statement:

- (1) not later than the 30th day of initial employment, covering the 12 months preceding the date of disclosure;
- (2) annually not later than April 30; and
- (3) not later than the 30th day after acquiring a new financial interest that requires disclosure under Section 2.02, such as receiving payments, an equity interest, intellectual property rights, or royalties that would require disclosure on an annual financial interest disclosure statement.

In addition, before a covered individual begins employment in any outside work or activity or receives from an outside source any compensation, or serves on any outside board, a description of the nature and extent of the employment or activity and the range of any compensation must be timely disclosed and approved [by the president or his or her designee]. (Sec. 5.1, Regents' Rule 30104.)

2.2.5.2 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 University 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.

2.2.5.3 The President of the University, the conflict of interest official and/or conflict of interest committee may require a covered individual to submit additional disclosures.

2.3 Conflict of Interest Official; Conflict of Interest Committee; and Disclosure Statement Review

2.3.1 Conflict of Interest Official

2.3.1.1 The President of the University or his or her designee shall appoint a conflict of interest official to perform the duties required by this policy and other duties as assigned by the President.

2.3.2 Conflict of Interest Committee

2.3.2.1 The conflict of interest official may consult with an appointed conflict of interest committee in carrying out the duties to be performed and assigned by this policy.

2.3.3 Disclosure Statement Review; Determination of Financial Conflict of Interest

2.3.3.1 The appropriate conflict of interest official shall review each financial interest disclosure statement and make two determinations:

- (1) whether any significant financial interest disclosed is related to research in which the covered individual is engaged; and
- (2) if so, whether a financial conflict of interest exists.

2.3.3.2 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.

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

2.3.4 No Expenditure of Funds Prior to Review and Determination

2.3.4.1 Neither the University 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 in accordance with Section 2.4 of this policy

2.3.5 Cooperation with Institutional Committees

2.3.5.1 The conflict of interest official, conflict of interest committee, IRB, IACUC, IBC, and other relevant committees shall cooperate in the consideration of whether a covered individual has a financial conflict of interest in regard to research and in the development and implementation of a management plan for that conflict of interest.

2.4 Management of Financial Conflict of Interest

2.4.1 Management Required for Financial Conflicts of Interest

2.4.1.1 If the conflict of interest official determines that a covered individual has a financial conflict of interest, the official, in cooperation with the covered individual and other appropriate individuals designated by the conflict of interest official and/or conflict of interest committee, shall develop a management plan governing that conflict of interest.

2.4.1.2 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.

2.4.1.3 If the conflict of interest official and/or conflict of interest committee 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.

2.4.1.4 In addition, if a financial conflict of interest was not timely identified or managed, or if a covered individual fails to comply with a management plan, the conflict of interest official shall, not later than the 120th day after determining noncompliance:

- (1) complete and document a retrospective review and determination as to whether research conducted during the period of noncompliance was biased in the design, conduct, or reporting of the research; and
- (2) implement any measures necessary with regard to the covered individual's participation in the research between the date that the noncompliance is identified and the date the retrospective review is completed.

2.4.1.5 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, notifying the PHS, and submitting a mitigation report as required by federal regulation.

2.4.2 Management Plan Design and Agreement

2.4.2.1 A management plan may impose conditions and prescribe actions 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;
- (5) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (6) divestiture or reduction of the financial interest; or

- (7) severance of relationships that create an actual or potential financial conflict of interest.

2.4.2.2 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 understands and agrees to comply with 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.

2.4.3 Monitoring and Compliance

2.4.3.1 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.

2.5 Web Posting of Financial Conflict of Interest Information

2.5.1 Posting of this Policy

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

2.5.2 Posting of Information Regarding Specific Financial Conflicts of Interest in Research Funded by PHS

2.5.2.1 For each financial conflict of interest in PHS-funded research that is found to exist by the conflict of interest official, the University 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:

- (A) the covered individual's name;
- (B) the covered individual's title and role with respect to the research;
- (C) the name of the entity in which the significant financial interest is held;

(D) the nature of the significant financial interest that constitutes a financial conflict of interest; and

(E) 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.

2.5.2.2 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:

(A) \$0 - \$4,999;

(B) \$5,000 - \$9,999;

(C) \$10,000 - \$19,999;

(D) amounts between \$20,000 - \$100,000 by increments of \$20,000; or

(E) amounts above \$100,000 by increments of \$50,000.

2.5.2.3 The University 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 University will make the information required by this section available not later than the 60th day after the financial conflict of interest is identified.

2.5.2.4 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.

2.5.2.5 The information required by this section must remain available on the Internet for three years after its most recent update.

2.5.2.6 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.

2.5.3 Availability of Information Regarding Specific Financial Conflicts of Interest in Research Not Funded by PHS

2.5.3.1 For each financial conflict of interest in research not funded by PHS that is found to exist by the conflict of interest official, the University will centrally retain and make the following information available to the public, upon request under the Texas Public

Information Act (Chapter 552, Government Code), in regard to each covered individual who contributes to the scientific development or execution of the research project in a substantive, measurable way, including a covered individual who is the project director or principal investigator:

- (A) the covered individual's name;
- (B) the covered individual's title and role with respect to the research;
- (C) the name of the entity in which the significant financial interest is held;
- (D) the nature of the significant financial interest that constitutes a financial conflict of interest; and
- (E) 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.

2.5.3.2 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:

- (A) \$0 - \$4,999;
- (B) \$5,000 - \$9,999;
- (C) \$10,000 - \$19,999;
- (D) amounts between \$20,000 - \$100,000 by increments of \$20,000; or
- (E) amounts above \$100,000 by increments of \$50,000.

2.5.3.3 The University 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 available under this section and for which the information was not previously available, the University will make the information required by this section available after the financial conflict of interest is identified in accordance with the deadlines provided by the Texas Public Information Act.

2.5.3.4 The information required by this section must remain available for three (3) years after its most recent update.

2.6 Certification and Reports to PHS

2.6.1 Certification and Report Required

2.6.1.1 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 University make the reports required by this policy for PHS-funded research.

2.6.2 Financial Conflict of Interest Report

2.6.2.1 Before the expenditure of any funds under a PHS-funded research project, the appropriate University 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 University determines are financial conflicts of interest, including financial conflicts of interest of sub-recipients. The reporting will include specified information sufficient to enable the awarding component to understand the nature and extent of the financial conflict and to assess the appropriateness of the management plan related to the conflict of interest. The federal regulations require reporting within a specified period of financial conflicts of interest identified subsequent to an earlier report and require annual updating of reports regarding previously disclosed financial conflicts of interest.

2.7 Enforcement

2.7.1 Disclosure is a Condition of Employment or Relationship to University

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

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

2.7.2 Federal Enforcement

2.7.2.1 Federal regulations, 42 CFR Part 50, Subpart F, and 45 CFR Part 94, require the University 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 University to take action appropriate to maintaining objectivity in the research. The University must make information available to HHS or the PHS awarding component as required by federal regulation.

2.7.2.2 If the HHS determines clinical research funded by PHS to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a covered individual with a financial conflict of interest that was not managed or reported by the University as required by federal regulation, the University 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.

2.8 Administration of Conflicts Policies; Records

2.8.1 Oversight and Authority

2.8.1.1 The President or his or her designee shall appoint a conflict of interest official who is responsible for overseeing implementation of this policy and who may provide additional procedures and supplementary forms, as appropriate, consistent with this policy and applicable sponsor regulations.

2.8.2 Records

2.8.2.1 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 University actions, shall be retained for the longer of at least three years after:

- (A) the date of creation;
- (B) 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
- (C) the date of final resolution of any investigation, audit, or similar action involving the records.

2.8.2.2 The University will provide for a centralized repository for financial interest disclosure statements, management plans, and related records.

2.8.2.3 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 University 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.

Institutions will provide data reported in accordance with UTS 175 to UT System administration upon request.

2.8.3 Audits

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