



# **Handbook of Operating Procedures**

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## **FINANCIAL CONFLICTS OF INTEREST IN RESEARCH**

### **A. Purpose**

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-Pan American.

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 (PHS), 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.

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.

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

### **B. Persons Affected**

Covered individuals include all who, regardless of title or position, are responsible for the design, conduct, or reporting of research, including a principal investigator, co-investigator, or project director.

A student enrolled at the institution 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.

Other institutions, and their employees and students, who participate in University research carried out in cooperation with or through a subrecipient (e.g., a subcontractor, contractor, or collaborator) are also covered by this policy.

### **C. Policy**

The policy of The University of Texas-Pan American is:

1. Disclosure of Significant Financial Interests Related to Institutional Responsibilities



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- a. As often as required by Section F.2, a covered individual shall complete or update a financial interest disclosure statement that:
  - i. identifies all research in which the covered individual is engaged at the time of the disclosure; and
  - ii. discloses, as provided by Section F.1, each significant financial interest of the individual and covered family members that reasonably appears to be related to the individual's institutional responsibilities.
- b. Doubts pertaining to required disclosures are to be resolved as follows:
  - i. a student who is in doubt about whether the student is a "covered individual" must request a determination by the conflict of interest official identified in Section E.
  - ii. in determining whether research or a financial interest should be disclosed, the covered individual should resolve the doubt in favor of disclosure.
  - iii. 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. Collaborators and Contractors**

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

### **3. 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.

### **4. Education**



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- a. A covered individual must complete training in regard to this policy and applicable policies, regulations, and laws before engaging in research at the institution.
- b. 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.

### **5. Additional Disclosures Required Upon Request**

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

### **6. 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 in accordance with Section C.7 of this policy.

### **7. Management Plan Design and Agreement**

- a. 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:
  - i. public disclosure of the conflict of interest in presentations and publications;



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- ii. for human subjects research, direct disclosure of the conflict of interest to research participants;
  - iii. 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;
  - iv. modification of the research plan;
  - v. change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
  - vi. divestiture or reduction of the financial interest; or
  - vii. 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:
- i. 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
  - ii. clearly identify each specific person responsible for monitoring compliance with the management plan.

### **8. PHS Specific Regulations**

The University will comply with additional regulations specific to research funded by PHS. These include:

- a. Public posting of information regarding specific financial conflicts of interest on the Internet.
- b. 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.
- c. 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 Code of Federal Regulation (CFR) Part 50, Subpart F, and 45 CFR Part 94. In general, those regulations require a Financial Conflict of Interest Report regarding those interests that the institution determines are financial conflicts of interest, including financial conflicts of interest of sub-recipients. The reporting will include specified information sufficient to enable the awarding component to understand the nature



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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.

- d. 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.
- e. 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.

### **D. Definitions**

1. *Covered family member.*
  - a. a spouse;
  - b. 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
  - c. 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. *Institutional responsibilities.* 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



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institutional panel such as an Institutional Review Board (IRB) or Data and Safety Monitoring Board (DSMB).

3. *Research.* Any systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge. The term includes both basic and applied research and product development.
4. *Significant Financial Interests.*
  - a. The following interests of a covered individual or covered family member are considered to be significant financial interests subject to the exclusions provided by Section D.4.c, *but only in regard to interests that reasonably appear to be related to the individual's institutional responsibilities:*
    - i. **PAYMENTS RECEIVED FROM OR EQUITY INTEREST IN A PUBLICLY TRADED ENTITY:** where the total amount 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, 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;
    - ii. **PAYMENTS RECEIVED FROM A NON-PUBLICLY TRADED ENTITY OR EQUITY INTEREST IN A NON-PUBLICLY TRADED ENTITY:** where any equity interest is held in an entity that is not publicly traded, or where the total amount of payments received in the preceding twelve months from an entity that is not publicly traded, when aggregated, exceed \$5,000, including:
      - a) salary; and
      - b) any payment for services other than salary, such as consulting fees, honoraria, or paid authorship;
    - iii. **INTELLECTUAL PROPERTY AND ROYALTIES;**
    - iv. **TRAVEL:** reimbursed or sponsored travel in the preceding twelve months;
    - v. **GIFTS:** where the value of a single gift that the covered individual received in the preceding twelve months exceeds \$250 in value, or multiple gifts from a single entity in the aggregate exceed \$250 in value, other than gifts from a covered family member; and



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- vi. **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.
- b. 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.
- c. The following interests are not significant financial interests:
  - i. 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;
  - ii. 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;
  - iii. 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;
  - iv. 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
  - v. 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.

### **E. Responsibilities**

The Executive Director for Audit Compliance and Consulting Services shall serve as the institutional 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.

The conflict of interest official shall perform the duties required by this policy and other duties as assigned by the President.

The conflict of interest official; the Vice Provost for Research and Sponsored Projects; and the appropriate IRB, Institutional Animal Care and Use Committee (IACUC), Institutional



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Biosafety Committee (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.

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.

### **F. Procedures**

1. Covered individuals shall report for each significant financial interest required to be disclosed under this policy.
  - a. The value of the interest, within the following ranges:
    - i. \$0 - \$4,999;
    - ii. \$5,000 - \$9,999;
    - iii. \$10,000 - \$19,999;
    - iv. amounts between \$20,000 - \$100,000 by increments of \$20,000; or
    - v. amounts above \$100,000 by increments of \$50,000.

Value is determined as follows:

- i. for publicly traded equity interests- market value;
  - ii. for payments for services- amounts received during the preceding twelve months;
  - iii. for royalty income- the amount of royalty income that the covered individual or covered family member received or had the right to receive in the preceding twelve months;
  - iv. for reimbursed or sponsored travel- actual cost of travel during the preceding twelve months, or reasonable estimate if actual cost is not known;
  - v. for gifts- actual cost of gifts received over the last twelve months, or reasonable estimate if actual cost is not known;
  - vi. for fiduciary positions- amounts of remuneration or reimbursement for expenses received during the preceding twelve months.
- b. The name and principal address for the source or entity.
  - c. Descriptive information:
    - i. 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;





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- ii. a description of intellectual property rights held and any agreements to share in royalties related to those rights;
    - iii. the purpose of reimbursed or sponsored travel, the identity of the sponsor/organizer, the destination, and the duration;
    - iv. fiduciary position and responsibility the covered individual held in a for-profit or nonprofit entity in the preceding twelve months, and the name and principal address of the entity.
  - d. 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. When to Disclose; Period Covered by Statement
  - a. A covered individual shall submit or update a financial interest disclosure statement:
    - i. not later than the 30<sup>th</sup> day of initial employment, covering the twelve months preceding the date of disclosure;
    - ii. annually not later than March 1; and
    - iii. not later than the 30<sup>th</sup> day after acquiring a new financial interest as defined under Section D.4, such as receiving payments, an equity interest, intellectual property rights, or royalties that 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 30<sup>th</sup> 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.
- 3. Written Agreements with Collaborators and Contractors
  - a. 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.



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- b. 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.
  - c. 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.
4. 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 at least once every four years.
  - c. 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 completed the training at another institution of The University of Texas System within the last four years.
5. Disclosure Statement Review; Determination of Financial Conflict of Interest
- a. The appropriate conflict of interest official shall review each financial interest disclosure statement and make two determinations:
    - i. whether any significant financial interest disclosed is related to research in which the covered individual is engaged; and
    - ii. 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 official reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.



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### 6. Management Required for Financial Conflicts of Interest

- a. If the conflict of interest official determines that a covered individual has a financial conflict of interest, the official, in cooperation with the covered individual and other appropriate individuals designated by the conflict of interest official, shall develop a management plan governing that conflict of interest.
- 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 60<sup>th</sup> day after the filing of the disclosure statement:
  - i. review the disclosure statement to determine if a financial conflict of interest exists; and
  - ii. 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 60<sup>th</sup> day after learning of the interest:
  - i. determine whether the significant financial interest is a financial conflict of interest; and
  - ii. 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 120<sup>th</sup> day after determining noncompliance:
  - i. 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
  - ii. 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, notifying the PHS, and submitting a mitigation report as required by federal regulation.



## **FINANCIAL CONFLICTS OF INTEREST IN RESEARCH**

7. Posting of Information Regarding Specific Financial Conflicts of Interest in Research Funded by PHS
  - a. For each financial conflict of interest in PHS-funded research 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:
    - i. the covered individual's name;
    - ii. the covered individual's title and role with respect to the research;
    - iii. the name of the entity in which the significant financial interest is held;
    - iv. the nature of the significant financial interest that constitutes a financial conflict of interest; and
    - v. 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:
    - i. \$0 - \$4,999;
    - ii. \$5,000 - \$9,999;
    - iii. \$10,000 - \$19,999;
    - iv. amounts between \$20,000 - \$100,000 by increments of \$20,000; or
    - v. amounts above \$100,000 by increments of \$50,000.
  - 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 60<sup>th</sup> 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.



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- 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.
8. Availability of Information Regarding Specific Financial Conflicts of Interest in Research Not Funded by PHS
- a. For each financial conflict of interest in research not funded by PHS that is found to exist by the conflict of interest official, the institution 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, measureable way, including a covered individual who is the project director or principal investigator:
    - i. the covered individual's name;
    - ii. the covered individual's title and role with respect to the research;
    - iii. the name of the entity in which the significant financial interest is held;
    - iv. the nature of the significant financial interest that constitutes a financial conflict of interest; and
    - v. 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:
    - i. \$0 - \$4,999;
    - ii. \$5,000 - \$9,999;
    - iii. \$10,000 - \$19,999;
    - iv. amounts between \$20,000 - \$100,000 by increments of \$20,000; or
    - v. amounts above \$100,000 by increments of \$50,000.
  - 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 available under this section and for which the information was not previously available, the institution 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.
  - d. The information required by this section must remain available for three years after its most recent update.



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### 9. 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:
  - i. the date of creation;
  - ii. 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
  - iii. 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.
- 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.

### 10. Audits

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

### 11. Posting of this Policy

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

## G. Review

The Divisional Heads for this policy are the Provost and Vice President for Academic Affairs, and the Vice President for Business Affairs. This policy shall be reviewed every five years or sooner if necessary by the following Stakeholders:

1. Vice Provost for Research and Sponsored Projects – Senior Reviewer



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2. Faculty Senate
3. Academic Affairs Executive Team
4. Executive Director of Audits, Consulting, and Compliance Services
5. Executive Director for Business and Rural Development