Research Conflict of Interest - UTDPP1029

This policy governs the disclosure of individual Financial Interests and the management and reporting of individual Financial Conflicts of Interest in funded research managed by The University of Texas at Dallas (“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 (PHS), and the National Science Foundation (NSF). It also applies to such other research as might be funded by agencies, public or private, that a reasonable person could construe as presenting a likelihood of bias in the conduct of the funded research that could adversely affect the reputation of the university.

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 or state law or regulation provides different requirements than this policy, the federal or state requirement applies.

Rationale

This policy provides requirements for the disclosure of Financial Interests that comply with the disclosure requirements of federal regulations. It also establishes the process for the management and reporting of apparent Financial Conflicts of Interest in research to assure that these conflicts are properly disclosed in resulting reports and publications.

Scope

This policy applies to Covered Individuals and covered family members, as defined below in Section IV, during the course of conducting funded research managed by the University.

Definitions

Covered Family Member includes:

1. a spouse;
2. a dependent as defined for 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.

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.

Covered Individual is an individual who, regardless of title or position, is responsible for the
design, conduct, reporting, review, or oversight of research, including a principal investigator, co-investigator, or project director.

This definition also applies to any student enrolled at the University who is responsible for the design, conduct, or reporting of research managed by the university under a grant or contract. A student's supervising faculty member 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 3.01.

Institutional Responsibilities means any of the professional responsibilities of a Covered Individual performed on behalf of the University, including consultation, teaching, professional practice, research, University committee membership, or service on a University panel such as an Institutional Review Board (IRB) or Data and Safety Monitoring Board (DSMB).

Research, for purposes of this policy, means any systematic investigation, study, or experiment designed to produce results that will be represented to the public as based upon evidence available to others beside the author and in principle replicable by others beside the author. The term includes both basic and applied research and product development.

Financial Interest is an interest with monetary value which is subject to disclosure under Section 2.02 of this policy.

Financial Conflict of Interest is a Financial Interest which has been determined by the conflict of interest official as having potential for directly and significantly affecting the design, conduct, or reporting of the research or is in an entity whose Financial Interest appears to be affected by that research.

Management Plans are written agreements that 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.

Contacts

Office of Research/Conflict of Interest Official (for research)
Phone: 972-883-4579 and 972-883-4718
Website: https://research.utdallas.edu/orc/conflict-of-interest

Responsibilities and Procedures

Chapter 1. General Provisions

Sec. 1.01. Collaborators and Contractors

1. If research is carried out in cooperation with or through a subrecipient (subrecipients or consortium members), the University will enter into a written agreement with the subrecipient that provides legally enforceable terms requiring that a Financial Conflicts of Interest policy acceptable to the University applies to the researchers of the subrecipient.
2. If the policy of the subrecipient applies to its researchers, the subrecipient must certify its policy is consistent with the requirements of any applicable federal regulations.

3. If the policy of the subrecipient applies to its researchers, the agreement must specify the time periods for the subrecipient to report identified Financial Conflicts of Interest to the University. The time periods must be sufficient for the University to make any reports required by federal regulation.

Sec. 1.02. Education

1. Each Covered Individual must acknowledge annually that he or she has read this policy and is aware of the applicable federal regulations.

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

Chapter 2. DISCLOSURE OF FINANCIAL INTERESTS RELATED TO INSTITUTIONAL RESPONSIBILITIES

Sec. 2.01. Extent of Disclosure

1. As often as required by Section 2.05, a Covered Individual must complete or update a Financial Interest disclosure statement that:
   
   1. identifies all funded research in which the Covered Individual is engaged at the time of the disclosure that is likely to present, to a reasonable person, an appearance of conflict of interest such that the results of that research are unlikely to be objective or reliable; and
   
   2. discloses, as provided by Section 2.02, each Financial Interest of the Covered Individual and covered family members that reasonably appears to be related to the Covered Individual's institutional responsibilities as required to fulfill the terms set forth by the funding entity.

2. In determining whether research or a Financial Interest should be disclosed, the Covered Individual should resolve the doubt in favor of disclosure.

Sec. 2.02. Contents of Disclosure: Financial Interests

1. The following interests are considered to be 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 related 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 as required to fulfill the terms set forth by the funding entity:
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:

   1. as to payments received:

      1. salary; and
      2. any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and

   2. 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:

   1. 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

      1. salary; and
      2. any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and

   2. 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:

   1. a description of intellectual property rights and any agreements to share in royalties related to those rights; and

   2. the amount and source of royalty income above the stated minima 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 of the trip;

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 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 remuneration, and the name and principal address of the entity.
2. Exclusions. The following interests are not 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 University;
   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), a non-profit scientific society registered under 501(c) under IRS rules, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

3. In making disclosures under this section, the Covered Individual must disclose the value of a Financial Interest as being within the following ranges:
   
   1. $0 - $4,999;
   2. $5,000 - $9,999;
   3. $10,000 - $19,999;
   4. between $20,000 - $100,000 by increments of $20,000; or
   5. above $100,000 by increments of $50,000.

4. When describing a source, the Covered Individual must provide the name and principal address for the source.

5. The Covered Individual must distinguish among information pertaining to the Covered Individual and covered family members whose Financial Interests and activities are also disclosed by the Covered Individual.

6. Any appropriate University official, such as the conflict of interest official, a vice president, dean or department chair, 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.

Sec. 2.03. Disclosure of Financial Interests of Other Persons: Covered Family Member

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.

Sec. 2.04. Text of Documentation to be Provided on Request

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:

1. the president of the University;
2. the conflict of interest official; or,
3. the Research Integrity Committee.

Sec. 2.05. When to Disclose; Period Covered by Statement

1. A Covered Individual must 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 date mandated by the University;
   3. not later than the 30th day after acquiring a new Financial Interest that requires disclosure under Section 2.02; and
   4. within 30 days from date of travel.
2. A Covered Individual who is funded under a PHS-funded research project must ensure his or her Financial Interest disclosure statement is current at the time of application for research funding from the PHS entity, except that an individual who is new to the University and who is planning to participate in an on-going PHS-funded research project must submit the statement not later than the 30th day of initial employment.
3. The president of the University or the conflict of interest official may require a Covered Individual to submit additional disclosures.

Chapter 3. CONFLICT OF INTEREST OFFICIAL; DISCLOSURE STATEMENT REVIEW

Sec. 3.01. Conflict of Interest Official

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

Sec. 3.02. Disclosure Statement Review; Determination of Financial Conflict of Interest

1. The appropriate conflict of interest official will review each Financial Interest disclosure statement and make two determinations:
   1. whether any Financial Interest disclosed is related to research in which the Covered Individual is engaged; and,
   2. whether the Financial Interest of the individual could directly and significantly affect the design, conduct, or reporting of the research.
2. If both determinations are affirmative, the conflict of interest official or Research Integrity Committee will decide:
1. whether the university has an interest in establishing a management plan; and
2. if so, whether the plan should involve disclosure requirements, adjustment of Financial Interests, or adjustments of the research in consultation with the funding agencies.

3. A financial conflict of interest is related to research in which the Covered Individual is engaged if the conflict of interest official reasonably determines 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.

Sec. 3.03. No Expenditure of Funds Prior to Review and Determination

The University may not 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 Chapter 4 of this policy.

Sec. 3.04. Cooperation with Institutional Committees

The conflict of interest official and the appropriate Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), and other relevant University committees will 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.

Chapter 4. MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

Sec. 4.01. Management Required for Financial Conflicts of Interest

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 the Research Integrity Committee, must develop a management plan governing that conflict of interest that shall specify the actions that have been, and shall be, taken to manage such conflict of interest.

2. For Financial Conflicts of Interests managed by the University related to research funded by entities other than PHS, the University should follow guidelines provided by the funding agency or customary and traditional usage in the concerned discipline, with attention to statements of ethics and principles of disciplinary associations.

3. Management of Financial Conflicts of Interests Related to PHS-Funded Research

1. If PHS-funded research is ongoing and a new Covered Individual discloses a Financial Interest related to that research or any other Covered Individual discloses a new Financial Interest related to that research, the conflict of interest official must, not later than the 60th day after the filing of the disclosure statement as make a determination as required by Section 3.02 of this policy and, if a financial conflict of interest exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the PHS-funded research.

2. If the conflict of interest official learns of a Financial Interest related to PHS-funded
research that was not timely disclosed or was not timely reviewed, the conflict of interest official must, not later than the 60th day after learning of the interest make a determination as required by Section 3.02 of this policy and, if a financial conflict of interest exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the PHS-funded research.

3. In addition, if a financial conflict of interest related to PHS-funded research was not identified or managed in a timely manner, or if a Covered Individual fails to comply with a management plan, the conflict of interest official must, not later than the 120th day after determining noncompliance complete and document a retrospective review and determination as to whether PHS-funded research conducted during the period of noncompliance was biased in the design, conduct, or reporting of the research, and implement any measures necessary with regard to the Covered Individual's participation in the PHS-funded research between the date that the noncompliance is identified and the date the retrospective review is completed. The retrospective review must 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.

Sec. 4.02. Management Plan Design and Agreement

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, 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.

Sec. 4.03. Monitoring and Compliance

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

Chapter 5. WEB POSTING OF FINANCIAL CONFLICT OF INTEREST INFORMATION

Sec. 5.01. Posting of this Policy

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

Sec. 5.02. Availability of Information Regarding Specific Financial Conflicts of Interest in Research Not Funded by PHS

For Financial Conflicts of Interests managed by the University related to research funded by entities other than PHS, the University will post the following information on the internet: the name of the researcher, the title of the project, the source of funding, and a brief description of the management plan.
Sec. 5.03. Posting of Information Regarding Specific Financial Conflicts of Interest in Research Funded by PHS

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:
   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 Financial Interest is held;
   4. the nature of the Financial Interest that constitutes a financial conflict of interest; and
   5. the approximate value of the 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. The approximate dollar value of the Financial Interest must be provided within the following ranges if it can 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.

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.

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.

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

6. This information must be available through the Internet in regard to project directors, principal investigators, and other senior or key personnel before expending PHS funds.

Chapter 6. CERTIFICATION AND REPORTS

Sec. 6.01. Certification and Report Requirement

The University will comply with all federal regulations that require certifications and reporting including that each application for funding to the PHS include specific certifications and agreements in regard to this policy and Financial Conflicts of Interest.
Sec. 6.02. PHS Financial Conflict of Interest Report

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 subrecipients. 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.

Chapter 7. ENFORCEMENT

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.

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.

Chapter 8. ADMINISTRATION OF CONFLICTS POLICIES; RECORDS

Sec. 8.01. Oversight and Authority

The president or his or her designee will 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.

Sec. 8.02. Records

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, must 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.

2. The University will provide for a centralized repository for Financial Interest disclosure statements, management plans, and related records.

3. The conflict of interest official, or another person designated by the president, will 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 must ensure that the chancellor receives copies of any revised guidelines, procedures, and forms simultaneously with the implementation of the revision.

Sec. 8.03. Audits

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

**Policy Form**

Conflict of Interest and Commitment Disclosure Portal

**Relevant Federal and State Statutes**

National Science Foundation (Award and Administration Guide Chapter IV.A)

PHS Federal Regulations (42 CFR Part 50 Subpart F)

PHS Federal Regulations (45 CFR Part 94)


**Relevant UT System Policies, Procedures, and Forms**

UT System Board of Regents' Rules and Regulations 30103 (Standards of Conduct)

UT System Board of Regents' Rules and Regulations 30104 (Conflict of Interest)

UT System Board of Regents' Rules and Regulations 60306 (Use of University Resources)

UT System Board of Regents' Rules and Regulations Series 90000 (Rules for Intellectual Property)

UT Systemwide Policy 175: Disclosure of Significant Financial Interests and Management and Reporting of Financial Conflicts of Interest in Research

UT Dallas Intellectual Property Policy

UT Dallas Policy on Records Management and Retention

**Policy History**

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