
MANAGEMENT AND REPORTING OF FINANCIAL CONFLICTS OF INTEREST IN RESEARCH

A. Purpose

The Division of Research, Innovation, and Technology Commercialization (Division) utilizes the policies and procedures described below to address the management and reporting of financial conflicts of interest in research conducted at The University of Texas Rio Grande Valley (UTRGV).

B. Scope

These policy statements and procedures apply to all employees, students, trainees, and individual defined as covered individuals and engaged in research under UTRGV's oversight.

C. Policy Statements

1. The primary responsibility of a UTRGV employee must always be to their institutional responsibilities at UTRGV. No covered individual (as defined below) may engage in any outside relationship with an outside entity if that relationship causes or appears to cause bias in the design, conduct, or reporting or research. Covered individuals must disclose and structure their relationships with an outside entity to enable review and management of any possible conflicts of interest, and covered family members will be included in any analysis of a perceived or actual conflict of interest.
2. Covered individuals are expected adhere to the requirements described in these policies and procedures as well as to any management plans developed and overseen by the Division.
3. The Executive Vice President for Research, Graduate Studies, and New Program Development and the Executive Director for Research Compliance and Export Control are responsible for ensuring that the disclosures of covered individuals participating in or planning to participate in U.S. Public Health Service-funded research are timely reviewed, management plans are implemented and monitored, and appropriate records are maintained.
4. These policies and procedures apply in addition to, and not instead of, general UTRGV or University of Texas System policies, such as policies on standards of conduct, as well as [42 CFR Part 50, Subpart F](#) and [45 CFR Part 94](#). If [42 CFR Part 50, Subpart F](#) or [45 CFR Part 94](#) provides different or additional requirements than this document, the more stringent or additional requirement applies.
5. Research funds awarded by the federal government may not be expended if a 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 by the Division.
6. Federal regulations require that each application for funding to the PHS include specific certifications and agreements regarding these policies and procedures and financial conflicts of

interest. Federal regulations also require that UTRGV make the reports required by this policy for PHS-funded research.

7. Before the expenditure of any funds under a PHS-funded research project, the appropriate Division 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 UTRGV 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.
8. 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 UTRGV's actions, shall be retained for the longer of at least three years after the date of creation; 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 the date of final resolution of any investigation, audit, or similar action involving the records.
9. This policy and procedures document will be posted on the Division's website.

D. **Procedures**

1. *Required Disclosure of Financial Interests by Covered Individuals* – Covered individuals are expected to comply with all Outside Activities and Interests reporting requirements and deadlines as [described and managed](#) by the [Institutional Compliance Office](#).
2. *Review and Management Procedures for Reports by Individuals Engaged in Research and Sponsored Projects* – The Division will conduct its reviews of disclosures in accordance with [42 CFR Part 50 \(Subpart F\)](#), [45 CFR Part 94](#), and applicable UTRGV and UT System policies.
 - a. The Research Integrity and Export Controls Officer (RI&ECO) will review disclosures submitted by individuals engaged in research and sponsored projects make two determinations:
 - i. whether any significant financial interest disclosed is related to research or non-research sponsored projects in which the covered individual is engaged; and if so
 - ii. whether a financial conflict of interest exists.
 - b. A significant financial interest is related to UTRGV research in which the covered individual is engaged, or a non-research sponsored project, if the RI&ECO reasonably determines that the financial interest appears to be affected by UTRGV research or non-research sponsored project, or is in an entity whose financial interest appears to be affected by UTRGV research or non-research sponsored project.

- c. A financial conflict of interest exists when the RI&ECO reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of UTRGV research, or in the case of non-research sponsored projects, UTRGV's decisions in carrying out such projects.
 - d. Neither UTRGV nor a covered individual may expend research funds unless the RI&ECO 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.
 - e. The RI&ECO and the appropriate Institutional Review Board shall cooperate in the consideration of whether a covered individual has a financial conflict of interest in regard to human subjects research and in the development and implementation of a management plan for that conflict of interest.
3. *Management of Identified Potential Conflicts* – If the RI&ECO official determines that a covered individual has a financial conflict of interest, the RI&ECO, in cooperation with the covered individual and other appropriate individuals as determined by the Division, shall develop a management plan governing that conflict of interest.
- a. A management plan must be in the form of a written agreement and must provide that the covered individual acknowledges receipt of the plan, understands the requirements of this policy, and agrees to comply with the required actions and other terms of the plan, including the time frames for required actions; and clearly identify each specific person responsible for monitoring compliance with the management plan.
 - b. If research is ongoing and a current or new covered individual discloses a new significant financial interest related to that research, the RI&ECO shall, not later than the 60th 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 one does exist, implement an interim management plan or other interim measures to ensure the objectivity of the research.
 - c. If the RI&ECO learns of a significant financial interest that was not timely disclosed or was not timely reviewed, the RI&ECO shall, not later than the 60th day after learning of the interest, (i) determine whether the significant financial interest is a financial conflict of interest and (ii) if so, implement an interim management plan or implement some 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 RI&ECO shall, not later than the 120th day after determining noncompliance, (i) complete and document a retrospective review and determination as to whether the 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.

6. *Records and Confidentiality*

- a. To the extent permitted by law, information related to conflict of interest disclosures and management will be maintained confidentially. However, such records will be made available upon written request to the agency funding research of the covered individual or other non-research sponsored project at UTRGV; and as otherwise required by law. Where human subject research is contemplated, and a potential or actual conflict exists, the records may be shared with the appropriate IRB. Also, the existence of potential or actual conflicts of interest affecting proposed research and non-research sponsored projects are disclosed in proposals for funding submitted to sponsors. As required by and in accordance with [42 CFR Part 50, Subpart F](#), information related to financial conflicts of interest may be made available to the public through the internet.
- b. All records discussed in this policy may be subject to the Texas Public Information Act. Any written request for records discussed in this policy must be forwarded immediately upon receipt to the Chief Legal Officer.

D. **Definitions**

1. *Compensation* – any form of benefit including but not limited to salary, retainer, honoraria, intellectual property rights and royalties, or promised, deferred, or contingent interest. It also includes sponsored travel or reimbursement.
2. *Conflict of Interest* – means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.
3. *Covered Family Member (of a Covered Individual)* – includes any of the following:
 - a. A spouse;
 - b. A dependent child or stepchild;
 - c. Any other person financially dependent on the individual; and
 - d. Any other person with whom the individual has joint Financial Interests, such that an objective third party could reasonably conclude that the individual’s decisions or other exercise of Institutional Responsibilities could be influenced by their effect on the other person’s Financial Interest.
 - e. Any person may meet the above definition and be identified as a family member without regard to whether a legal or biological family relationship exists
4. *Covered Individual* – 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. The term includes all such individuals who are part-time and non-exempt employees, and non-employee graduate students and post-graduate trainees, but not high school or undergraduate students. The term also includes research collaborators whose potential conflicts of interest with research are not managed by their home institution.
5. *Financial Interest* – anything of monetary value, including without limitation salary or other payments for services (e.g., compensation for consulting; speaking; advising; serving on a Board of Directors or as an officer, trustee, or other executive or management position; editorial compensation; etc.); Investment Interests (e.g., common or preferred stock, options or other derivatives, partnership interests or shares, etc.); intellectual property rights (e.g., patents, copyrights, royalties from such rights, etc.); reimbursements including travel

expenses; gifts; or other income (e.g., any other Compensation or benefit from a single Business Entity not otherwise described above).

6. *Institutional Responsibilities* – any duties or responsibilities of an individual on behalf of UTRGV, including without limitation essential and other functions, Research, Research consultation, teaching, administrative responsibilities, professional practice, institutional committee membership, or service on an Institutional Standing Committee or other convened group.
8. *Research* – a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research as well as product development.
9. *Significant Financial Interest* – has the meaning assigned in 45 CFR §50.603.

D. Related Statutes or Regulations, Rules, Policies, or Standards

UT System Board of Regents’ Rules and Regulations 30104 Conflict of Interest, Conflict of Commitment, and Outside Activities

UTS175 Disclosure of Significant Financial Interests and Management and Reporting of Financial Conflicts of Interest in Research

[42 CFR Part 50, Subpart F](#)

[45 CFR Part 94](#)