

Policy RA-PO2

Policy for Disclosure, Management, and Reporting of Conflicts of Interest in Research

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I. **Title**

Policy for Disclosure, Management, and Reporting of Conflicts of Interest (COI) in Research

II. **Policy**

A. Policy Statement

1. It is the policy of The University of Texas at Arlington (UTA) that no proposed, awarded or ongoing Research shall be biased by a COI. The University is committed to moving Research forward and fostering entrepreneurial spirit while maintaining objectivity and integrity.
2. The President has designated the Vice President of Research as the Research Conflict of Interest Official (RCIO) responsible for overseeing implementation of this policy and to provide additional procedures and supplementary forms, as appropriate to identify, manage, remedy, reduce, or eliminate COIs with respect to Research.

B. Scope

1. This policy governs the disclosure of Significant Financial Interests and the management and reporting of COIs in Research performed at the University. COIs related to an employee's status as a state employee are addressed in UTA's HOP Policy 5-508, Conflict of Interests, Conflict of Commitment, and Outside Activities.
2. This policy will apply to any other potential Conflicts of Interest (financial or otherwise) related to research, at the discretion of the RCIO or his/her designee.

3. This policy only applies to Covered Individuals. Covered Individuals must disclose Significant Financial Interests as defined within this policy. Timely, complete, and accurate disclosure of activities and Significant 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 as set forth in Section II.I herein.
4. If a specific federal law, sponsor term, or governing regulation provides different requirements than this policy, the more stringent requirement applies. All related UTA procedures and forms will support this policy as currently published in the University's Handbook of Operating Policies.

C. Rationale

1. UTA's research interactions with a variety of sponsoring agencies, including those of industry and for-profit enterprises creates possibilities for the occurrence of COIs. These conflicts arise when there are opportunities for faculty or staff members to personally or professionally benefit either from the outcome of Research or from activities conducted as a UTA Investigator.
2. It is UTA's position that with clear guidelines and principles, in conjunction with appropriate supervision and monitoring, it is possible for interaction between sponsoring agencies and the University to take place in a manner that is consistent with the highest traditions of scientific Research and in a way that energizes scientific creativity.
3. This policy is intended to enable Investigators to recognize situations that may pose a COI, to disclose these situations as required, and to ensure that any potential COI is mitigated or managed if possible. This policy is intended to maintain the professional autonomy of Investigators inherent in the self-regulation of Research and scholarship.

D. Policy Standards

1. Accessibility: UTA will maintain this policy as up-to-date and inform each Investigator of this policy. In accordance with Public Health Service (PHS) Title 42, Part 50, Subpart F, UTA will make information related to the conflicts of interest of PHS funded Investigators available upon request, within 5 business days. Public access to submit a request will follow federal requirements and is available at <http://www.uta.edu/research/administration/departments/rs/conflict-of-interest/phs-information-requests.php>.
2. COI Disclosures
 - a. Timing
 - i. Initial Disclosures
 - I. **Covered Individuals Conducting PHS-Sponsored Research, Greater than Minimal**

Risk Human Subject Research, or Animal Research: Must submit or have a current COI Disclosure on file no later than the time of application for sponsorship or at the time of the Research protocol submission [(i.e., submission to the Institutional Review Board (IRB) or the Institutional Animal Care & Use Committee (IACUC)].

II. **Covered Individuals Conducting Research not Included in Part I Above:** Must submit or have a current COI Disclosure on file prior to the expenditure of sponsor funds.

III. **New Covered Individuals:** When an Investigator becomes a Covered Individual (e.g., is added to an ongoing Sponsored Research project or a human/animal subject protocol), the individual must submit or have a current COI Disclosure on file before engaging in the Research.

ii. **Subsequent Disclosures:** Following initial disclosure, Covered Individuals must submit an updated COI Disclosure at least annually, or within 30 days of discovering or acquiring a new reportable Significant Financial Interest. The President or the RCIO may require additional disclosures for clarity or transparency.

b. Content of COI Disclosure

i. Each Covered Individual must acknowledge at least annually, via the COI Disclosure, that the individual is aware of and has read this policy, and is aware of a Covered Individual's responsibilities regarding disclosure of Significant Financial Interests and of applicable federal regulations. If a Covered Individual discloses Remuneration, Intellectual Property interest or royalties, related documents may be requested and reviewed by the President, the RCIO, or any other person with administrative responsibility for reviewing the COI Disclosure or management plans. Significant Financial Interests will be disclosed in reportable ranges.

ii. Covered Individuals must report each Significant Financial Interest that reasonably appears to be related to the individual's UTA institutional responsibilities through disclosure in UTA's online Research COI Disclosure form:
<https://mentis.uta.edu/public/#coi/disclosure/my>.

iii. Disclosure updates (annual or more frequent) will include any Significant Financial Interest that was not disclosed initially, and will include updated information regarding

any previously disclosed Significant Financial Interest (e.g. the updated value of a previously disclosed Equity Interest).

- c. Review of the COI Disclosure will result in a determination of whether a Significant Financial Interest is related to Research in which the Covered Individual has engaged or will engage and if so whether a COI exists. The RCIO or his/her designee will determine a COI exists if the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of Research. The RCIO, his/her designee or the Research Conflict of Interest Committee shall cooperate in the consideration of whether a Covered Individual has a COI in regard to Research and in the development and implementation of a management plan. Information will be shared with the IRB, IACUC or other committees and offices as needed.
- E. Management Plans: If the RCIO determines a Covered Individual has an actual or potential COI, the RCIO or designee, in cooperation with the Covered Individual, shall develop a management plan to mitigate or eliminate a potential COI. The management plan shall be implemented before expenditure of funds in Sponsored Research and before approval of a protocol when Research involves human or animal subjects. Where applicable, the content of management plans will meet the minimum requirements of federal regulations (e.g. PHS 42 CFR Part 50, Subpart F). Management plans will be monitored to ensure appropriate follow up and compliance.
1. If a COI was not timely identified or managed, or if a Covered Individual fails to comply with a management plan, the RCIO will complete a retrospective review to determine if Research was biased during the period of noncompliance and implement measures needed to address any issues identified. For PHS-funded Research, this retrospective review will be completed within 120 days.
 2. For PHS-covered Research, the management plan will cover elements 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.
 3. A management plan may impose conditions and prescribe actions, including reducing or eliminating the COI. Examples of actions are modification of the Research and divestiture or reduction of the Significant Financial Interest.
 4. If the failure of an Investigator to comply with this policy or the management plan has biased the design, conduct, or reporting of PHS-funded Research, UTA will notify the PHS awarding component, who may then consider the situation and, as necessary, take appropriate action or refer the matter to UTA for further action.
- F. Collaborators and Contractors Public Health Service (PHS) funded Research: For Research for which a proposal is submitted to or awarded by PHS, if the Research is carried out in cooperation with another entity through formal

agreement with the University (such as a subcontractor or collaborator), the written agreement with the contracting party will provide legally enforceable terms that establish whether the COI policy of the contracting party or UTA's COI policy applies to the Investigators of the contracting party:

1. **If the policy of the contracting party applies to its Investigators**, the contracting party must certify that its policy is consistent with the requirements of any applicable federal regulations, and the agreement must specify the time periods for the contracting party to report identified COIs to the University.
2. **If UTA's COI policy applies to the Investigators of the contracting party**, the agreement must state that the Investigators are subject to this policy as Covered Individuals for disclosing Significant Financial Interests that are directly related to the Investigator's work at UTA. In addition, the agreement must specify the time periods for the Investigators to submit a COI Disclosure to UTA.
3. In accordance with federal regulations, UTA will provide reports to the PHS awarding component of all COIs prior to the expenditure of funds and within 60 days of any subsequently identified COI.

G. Education

1. A Covered Individual who submits to, or is awarded funding by the PHS must complete training in regard to applicable policies, regulations, disclosure of Significant Financial Interests, and Investigator responsibilities, before engaging in PHS Research at UTA and at least once every two years thereafter.
2. A Covered Individual who is new to UTA must complete the training before engaging in PHS Research at UTA or provide evidence of having completed the training at another institution within the prior two years.
3. An Investigator with an active management plan (regardless of sponsorship) must complete training at initiation of the plan and at least once every two years thereafter for the duration of the plan's activity.
4. A Covered Individual must complete training immediately, but in any event no less than thirty (30) business days, if UTA finds that the individual is not in compliance with this policy or the individual's management plan, or if UTA revises this policy in a manner that affects the requirements of Covered Individuals, or as otherwise determined by the RCIO.

- H. Certification and Reports to PHS: Federal regulations require that each application for funding to the PHS include specific certifications, agreements, and reports in regard to this policy and COIs. Before the expenditure of any funds under a PHS-funded Research project, the appropriate UTA officials will submit COI report to the PHS awarding component in compliance with 42 CFR Part 50, Subpart F, and 45 CFR Part 94. UTA will comply with PHS requirements for conducting, documenting, and reporting retrospective reviews where applicable. Reporting will include specified information sufficient to

enable the awarding component to understand the nature and extent of the COI and to assess the appropriateness of the management plan.

- I. **Enforcement:** Compliance with the terms of this policy is required as a condition of conducting Research as a UTA employee, representative, collaborator, or student. Violation of this policy may result in any appropriate disciplinary action allowed under UTA policies and procedures or Regents' Rules, including up to termination of employment.
- J. **Records:** Records will be maintained in accordance with federal and state regulations and UTA's policies and procedures for records and information management and retention located at <https://www.uta.edu/legalaffairs/rim/>. Records will include documentation of COI Disclosures, management plans, and training. Records are maintained by the Office of Regulatory Services.

III. **Definitions**

Animal Research: any live, vertebrate animal used or intended for use in Research, training, experimentation, teaching, exhibition, biological testing, or for related purposes. Animal Research requires prior review and approval by the University's IACUC: <http://www.uta.edu/ra/oric/animal>.

COI Disclosure: the University's COI Disclosure form available at <https://mentis.uta.edu/public/#coi/disclosure/my>. Covered Individuals must submit a COI Disclosure annually, or within 30 days of a newly identified or reportable Significant Financial Interest.

Conflict of Interest (COI): a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research. Covered Family Member: an Investigator's spouse, dependent children, or other dependents for purposes of determining federal income tax liability during the period covered by the COI Disclosure.

Covered Individual: any Investigator who proposes or conducts:

- Sponsored Research;
- Greater than Minimal Risk Human Subject Research; and/or
- Animal Research

Equity Interest: any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Financial Interest: anything of monetary value, whether or not the value is readily ascertainable.

Human Subject Research: Research that involves obtaining data from a living individual through intervention or interaction with the individual, or obtaining data that is identifiable private information. All Human Subject Research requires review by the University's IRB. For more information see <http://www.uta.edu/research/administration/departments/rs/human-subjects-irb/index.php>.

Research Conflict of Interest Official (RCIO):the President has designated the Vice President of Research as the individual responsible for ensuring compliance with this policy and federal and state regulations pertaining to COIs in Research. The RCIO is responsible for the establishment and enforcement of relevant university policies and procedures including solicitation of COI Disclosures, review, determination and management of COIs, and reporting COIs as required by federal regulations.

Investigator: any person, regardless of title, position, or employment status who is responsible for the design, conduct, or reporting of Research at, on behalf of, or in collaboration with the University. This may include (but is not limited to): faculty, staff, students, adjunct faculty, collaborators or consultants.

Investigator's Institutional Responsibilities:an individual's professional responsibilities and activities on behalf of the University, including but not limited to: Research, Research consultation, teaching, professional practice, university committee memberships, and service on panels such as the IRB

PHS: the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

Remuneration: salary or any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

Research:a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied Research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).**Significant Financial Interest:**

- A. A Financial Interest consisting of one or more of the following interests of the Investigator or the Investigator's Covered Family Members that reasonably appears to be related to the Investigator's Institutional Responsibilities:
 1. **Remuneration or Equity Interest in a publicly traded entity:** A Financial Interest in which the value of any Remuneration received from the entity in the twelve months preceding the disclosure and the value of any Equity Interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000;
 2. **Remuneration or Equity Interest in a non-publicly traded entity:** A Financial Interest in which the value of any Remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator holds any Equity Interest;
 3. **Intellectual Property:**Any receipt of income for Intellectual property rights and interests (e.g. patents, copyrights);
 4. **Reimbursed or Sponsored Travel:**Any reimbursed or sponsored travel in the twelve months preceding the disclosure in which the value (aggregated per entity that reimburses or sponsors the travel) exceeds \$5,000. This does not apply to Investigators who do not receive PHS funding;

- B. The term Significant Financial Interest does not include the following types of financial interests:
1. Salary, royalties, or other Remuneration paid by UTA to the Investigator or Covered Family Member if the Investigator or Covered Family Member is currently employed or otherwise appointed by UTA, including Intellectual Property rights assigned to UTA and agreements to share in royalties related to such rights;
 2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator or Covered Family Member does not directly control the investment decisions made in these vehicles;
 3. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined at 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;
 4. Income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education as defined at 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;
 5. Travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 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; and
 6. Travel not meeting the exceptions in part (5) above, but is valued at less than \$5,000 per entity that reimburses or sponsors the travel.

Sponsored Research: any Research for which a proposal is submitted or awarded by a sponsor for external funding, or any gift designated for Research received by UTA. Sponsored Research (both awards and gifts) can include Research, training, and instructional projects involving funds, materials, or other compensation from external sources

IV. **Relevant Federal and State Statutes**

PHS Federal Regulations (42 CFR Part 50 Subpart F, 45 CFR Part 94).

Texas Government Code (Chapter 572 Section 572.051).

Protection of Human Subjects (45 CFR Part 46, 21 CFR Part 50).

Humane Care and Use of Laboratory Animals (PHS Policy on Humane Care and Use of Laboratory Animals, Animal Welfare Act).

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

UT System Regents' [Rules and Regulations](#), Rule 30103, Standards of Conduct.

UT System Regents' *Rules and Regulations*, Rule 30104 Conflict of Interest.

UT System *Regents' Rules and Regulations*, Rule 90101 Intellectual Property: Preamble, Scope, Authority.

UT System Policy UTS110 Employees of the University of Texas System: Financial Disclosure and Conflict of Interest Statement

UT System Policy UTS175 Disclosure of Significant Financial Interests and Management and Reporting of Financial Conflicts of Interest in Research.

UTAHOP Policy 5-508 Conflicts of Interest, Conflicts of Commitment, and Outside Activities

UTA HOP Policy 5-702 Intellectual Property Policy

UTA HOP Policy 5-506 Policy of Service on Outside Boards

UTA Policy on Staff Outside Employment

UTA Policy on Records Management and Retention

UTA Statement of Principles and Policies Regarding Human Subjects in Research: <http://www.uta.edu/policy/hop/adm/5/705>

UTA COI Disclosure Form: <https://mentis.uta.edu/public/#coi/disclosure/my>

UTA COI Operating Procedures: <http://www.uta.edu/research/administration/departments/rs/conflict-of-interest/operating-procedures.php>

UTA Policy 5-706 Policy Regarding Animals Used in Research, Teaching, and Testing Activities <https://www.uta.edu/policy/hop/5-706>

VI. **Who Should Know**

This policy impacts all individuals that design, conduct, or report Research at, on behalf of, or in collaboration with the University. This may include (but is not limited to): faculty, staff, students, adjunct faculty, collaborators, consultants, contractors, or subcontractors

VII. **UT Arlington Office(s) Responsible for Policy**

The Vice President of Research

VIII. **Dates Approved or Amended**

April 30, 2018

- IX. **Contact Information**All questions concerning this policy, COI Disclosures, management plans, or reports should be directed to Research Administration - Office of Regulatory Services:regulatoryservices@uta.edu. 817-272-2723.