**The University of Texas at Arlington**

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Contents**

I. Title

II. Policy Statement

III. Scope

IV. Rationale

V. Definitions

VI. Policy Standards

VII. Relevant Federal and State Statutes

VIII. Relevant UT System Policies, Procedures and Forms

IX. Who Should Know

X. UT Arlington Office(s) Responsible for Policy

XI. Dates Approved or Amended

XII. Contact Information

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**I. Title**

Section 5-703 Policy for Disclosure, Management, and Reporting of Financial Conflicts of Interest in Research

**II. Policy Statement**

It is the policy of UT Arlington that no proposed, awarded or ongoing research shall be biased by Conflicts of Interest. The University is committed to moving research forward and fostering entrepreneurial spirit while maintaining objectivity and integrity.

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

**III. Scope**

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.

This policy applies to **Covered Individuals** as defined in V: Definitions, Sec. C**. Covered Individuals must disclose Significant Financial Interests as defined within this policy.** UT Arlington Investigators are expected to make reasonable inquiry as to whether their relationships and activities fall within the provisions of this policy.

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.

**IV. Rationale**

UT Arlington’s growing interaction with industry and for-profit enterprises has created new possibilities for the occurrence of conflicts of interest. These conflicts arise when there are opportunities for faculty or staff members to benefit either from the outcome of research or from activities conducted as a UT Arlington Investigator.

UT Arlington’s position is that with clear guidelines and principles, in conjunction with appropriate supervision and monitoring, it is possible for interaction between industry 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.

It is not the intent of this policy to eliminate or prohibit situations involving potential conflicts of interest. This policy is intended to enable Investigators to recognize situations that may pose a conflict of interest, to disclose these situations as required, and to ensure that any potential conflicts of interest are mitigated or managed. An integral part of this policy is a disclosure mechanism whereby Investigators regularly review their activities. This policy is intended to maintain the professional autonomy of researchers inherent in the self-regulation of research and scholarship.

**V. Definitions**

1. **Research is defined as** 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).

1. **Investigator** is defined as 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.

1. **Covered Individual** is defined as any Investigator (see definition above) who proposes or conducts:

**1.** sponsored research,

**2.** non-exempt human subject research, and/or

**3.** animal research.

1. **Covered Family Member** is defined, for the purposes of this policy, as an Investigator’s spouse and dependent children.
2. **Sponsored Research** is defined as any research for which a proposal is submitted or awarded by a sponsor for extramural funding, or any gift designated for research received by UT Arlington. Sponsored research (both awards and gifts) can include research, training, and instructional projects involving funds, materials, or other compensation from external sources.
3. **Human Subject Research** is defined as Research (see V: Definitions, Sec. A.) that involves obtaining data from a living individual through [intervention or interaction](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102) with the individual, or obtaining data that is [identifiable private information](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102). This policy does not apply to human subject research that has been determined by the University’s IRB to be [exempt](http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c2). (Note: Both exempt and non-exempt [Human Subject Research](http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1) requires review by the University’s IRB: <http://www.uta.edu/ra/oric/human/sops.htm>.)
4. **Animal Research** is defined as any live, vertebrate animal used or intended for use in research, training, experimentation, teaching, exhibition, biological testing, or for related purposes. (Note: Animal Research requires review and approval by the University’s IACUC: <http://www.uta.edu/ra/oric/animal/>.)
5. **Investigator’s Institutional Responsibilities** are defined as an individual’s professional responsibilities and activities on behalf of the Institution, including but not limited to: research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards.
6. **Financial Interest** is defined as anything of monetary value, whether or not the value is readily ascertainable.
7. **Remuneration** is defined as salary or any payment for services not otherwise identified as salary (*e.g.,* consulting fees, honoraria, paid authorship).
8. **Equity Interest** is defined as any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
9. **Significant Financial Interest is defined as the following:**
   1. A financial interest consisting of one or more of the following interests of the Investigator (and 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 Covered Individual must report a financial interest in which the value of any remuneration (see V: *Definitions*, Sec. J.) received from the entity in the twelve months preceding the disclosure and the value of any equity interest (see V: *Definitions*, Sec. K.) 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 Covered Individual must report a financial interest in which the value of any remuneration (see V: *Definitions*, Sec. J.) received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds **$5,000**, or when the Investigator holds **any** equity interest (see V: *Definitions*, Sec. K.);
      3. **Intellectual Property:** A Covered Individual must report intellectual property rights and interests (*e.g.,* patents, copyrights), upon receipt of income related to such rights and interests.
      4. **Reimbursed or Sponsored Travel:** A Covered Individual that submits to or is awarded funding by the PHS must report the occurrence of 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, and there are additional exclusions that do apply.** Many types of University travel do not require disclosure (see exclusion details below in L: *Significant Financial Interest*, Part 2.).
10. The term *significant financial interest* **does not include** the following types of financial interests:   
    * 1. salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution 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 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.
      6. travel not meeting the exceptions in part (e) above, but is valued at less than $5,000 per entity that reimburses or sponsors the travel.
11. **Conflict of Interest (COI) is defined** as a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.
12. **COI Disclosure refers to the University’s conflict of interest disclosure form available here:** [**http://www.uta.edu/ra/oric/coi/index.htm**](http://www.uta.edu/ra/oric/coi/index.htm)**. Covered Individuals must submit a COI Disclosure annually, or within 30 days of a newly identified or reportable Significant Financial Interest (***see V: Definitions, Sec****.* L.).**
13. **PHS** means 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).
14. **Institutional Official (IO)** is the individual designated as responsible for ensuring compliance with federal and state regulations pertaining to conflict of interest. The IO is responsible for the delegation of authority for the establishment and enforcement of relevant University policies and procedures including solicitation of disclosures, review and determination of financial conflicts of interest, management of identified financial conflicts of interest, and reporting of financial conflicts of interest as required by federal regulations. The President or his/her designee is the Institutional Official (IO) for the research conflict of interest program at The University of Texas at Arlington.

**VI. Policy Standards**

1. **Accessibility**

In accordance with PHS Title 42, Part 50, Subpart F, the Institution will maintain this policy as up-to-date, make the policy available on its publicly accessible website, and make information related to conflicts of interest available upon request.

1. **COI Disclosures**
2. **Timing**
   * 1. **Initial Disclosure:**
        1. **Covered Individuals conducting PHS-sponsored research, Non-Exempt Human Subject Research, or Animal Research:** Covered Individuals must submit or have a current COI Disclosure on file *no later than* the time of application for sponsorship or at the time of research protocol submission (i.e., submission to the Institutional Review Board or the Institutional Animal Care & Use Committee).
        2. **Covered Individuals conducting research not included in part 1 above:** Covered Individuals must submit or have a current COI disclosure on file prior to the expenditure of sponsor funds.
        3. **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 project.
     2. **Subsequent Disclosures:** Following initial disclosure, Covered Individuals must submit an updated Disclosure at least annually**, or within 30 days of discovering or acquiring a new reportable Significant Financial Interest (**see V: *Definitions*, Sec. L.**).**
3. **Content of COI Disclosure**
4. 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 interest and of applicable federal regulations.
5. Covered Individuals must report each Significant Financial Interest (see V: *Definitions*, Sec. L.) of the individual and covered family members that reasonably appears to be related to the individual’s institutional responsibilities (see V: *Definitions*, Sec. H.)
6. Disclosure updates (annual or more frequently) shall include any significant financial interest that was not disclosed initially, and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).
7. **Management Plans**

If the Institutional Official or his/her designee determines that a covered individual has an actual or potential financial conflict of interest, the official, in cooperation with the Covered Individual and other appropriate designees, shall develop a management plan governing that conflict of interest. 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 regulation (e.g., PHS 42 CFR Part 50, Subpart F).

1. **Collaborators and Contractors in PHS-Funded Research**

**In 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 conflict of interest policy of the contracting party *or* UT Arlington’s 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 financial conflicts of interest to the University.
2. ***If UT Arlington’s conflict of interest 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 this institution. In addition, the agreement must specify the time periods for the Investigators to submit a COI Disclosure to the University.
3. In accordance with federal regulation, UT Arlington will provide reports to the PHS awarding component of all financial conflicts of interest prior to the expenditure of funds and within 60 days of any subsequently identified financial conflict of interest.
4. **Education**
5. 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 the institution and at least once every four years thereafter.
6. A Covered Individual who is new to the institution must complete the training *before engaging in PHS research* at the institution or provide evidence of having completed the training at another institution within the last four years.
7. An Investigator with an active management plan (regardless of sponsorship) must complete training at initiation of the plan and at least once every four years thereafter for the duration of the plan’s activity.
8. A Covered Individual must complete 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 requirements of Covered Individuals, or as otherwise determined by the Institutional Official.
9. **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 financial conflicts of interest. 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 CFR Part 50, Subpart F, and 45 CFR Part 94. The institution will comply with PHS requirements for conducting, documenting, and reporting retrospective reviews where applicable.

1. **Enforcement**

Compliance with the terms of this policy is required as a condition of conducting research as an employee, representative, collaborator, or student of this institution. Consequences for violation of this policy are described and enforced by the University of Texas Board of Regents Rule 30103, Standards of Conduct: <http://www.utsystem.edu/bor/rules/30000Series/30103.pdf>

1. **Records**

Records will be maintained in accordance with federal and state regulations and the institution’s policies and procedures for records and information management and retention:

[http://www.uta.edu/policy/rim/.](http://www.uta.edu/policy/rim/)

**VII. Relevant Federal and State Statutes**

* PHS Federal Regulations ([42 CFR Part 50 Subpart F, 45 CFR Part 94](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=223ed9c7ebfa72579c62af8c29fd4fff&rgn=div6&view=text&node=42:1.0.1.4.22.6&idno=42))
* Texas Government Code ([Chapter 572 Section 572.051](http://www.statutes.legis.state.tx.us/docs/gv/htm/gv.572.htm))
* Protection of Human Subjects ([45 CFR Part 46](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html), [21 CFR Part 50](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50))
* Humane Care and Use of Laboratory Animals ([PHS Policy on Humane Care and Use of Laboratory Animals](http://grants.nih.gov/grants/olaw/references/phspol.htm), [Animal Welfare Act](http://www.aphis.usda.gov/animal_welfare/awa_info.shtml))

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

* UT System Board of Regents' Rules and Regulations: [30103 (Standards of Conduct)](http://www.utsystem.edu/bor/rules/30000Series/30103.pdf), [30104 (Conflict of Interest)](http://www.utsystem.edu/bor/rules/30000Series/30104.pdf), [Series 90000 (Rules for Intellectual Property)](http://www.utsystem.edu/bor/rules/90000Series/Complete90000.pdf)
* [UT System Policy UTS 110: Employees of The University of Texas System: Financial Disclosure and Conflict of Interest Statement](http://www.utsystem.edu/bor/procedures/policy/policies/uts110.html)
* [UT Arlington Conflicts of Interest Policy](http://www.uta.edu/policy/hop/adm/5/508) (institutional conflicts of interest and commitment)
* [UT Arlington Intellectual Property Policy](http://www.uta.edu/policy/hop/adm/5/702)
* [UT Arlington Policy of Service on Outside Boards](http://www.uta.edu/policy/hop/adm/5/506)
* [UT Arlington Policy on Faculty Outside Employment](http://www.uta.edu/policy/hop/adm/6/1000)
* [UT Arlington Policy on Staff Outside Employment](http://www.uta.edu/policy/hop/adm/5/505)
* [UT Arlington Policy on Records Management and Retention](http://www.uta.edu/policy/hop/adm/5/402)
* UT Arlington Statement of Principles and Policies Regarding Human Subjects in Research: <http://www.uta.edu/policy/hop/adm/5/705>
* UT Arlington COI Disclosure Form: <http://www.uta.edu/ra/oric/coi/index.htm>

**IX. 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.

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

The President or his/her designee is the Institutional Official (IO) for the research conflict of interest program at The University of Texas at Arlington. The conflict of interest program is coordinated and maintained by Research Administration – Office of Regulatory Services.

**XI. Dates Approved or Amended**

November 2012

**XII. 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](mailto:regulatoryservices@uta.edu)

817-272-3723

<http://www.uta.edu/uta/research.php>