University of Houston System ADMINISTRATIVE MEMORANDUM

SECTION: General Administration NUMBER: 01.G.03

AREA: Research

SUBJECT: Financial Conflict of Interest in Research

1. PURPOSE

The University of Houston System ("System") is committed to maintaining a Research environment that adheres to the highest ethical standards for Research. This commitment includes compliance with regulatory requirements set forth by the Public Health Service (PHS) agencies (including the National Institutes of Health (NIH)), the National Science Foundation (NSF), the Department of Energy (DOE), the National Aeronautics and Space Administration (NASA), and other regulatory bodies. It is the responsibility of the System to promote objectivity in Research through the establishment of a conflict-of-interest policy for both individual researchers as well as the System as a whole.

The purpose of this policy is to protect the credibility and integrity of System researchers and staff, as well as the universities and agencies themselves, so the public trust and confidence in their Research activities are maintained.

2. POLICY

- 2.1. Individuals have a responsibility to identify and manage, reduce, or eliminate Financial Conflicts of Interest that may arise due to their role as Research Investigators. Therefore, the System requires all individuals meeting the definition of Investigator, as defined in this policy, to disclose certain financial interests related to their Institutional Responsibilities.
- 2.2. All Significant Financial Interests held by Investigators and their spouse and dependent children, as well as certain travel paid by a third party and certain procurement activities, must be disclosed under the procedures described in this policy.
- 2.3. Universities within the System may establish additional disclosure guidelines, consistent with this policy.

3. DEFINITIONS

3.1. <u>Designated Official (DO)</u>: The individual at each University responsible for the solicitation and review of disclosures of Significant Financial Interests from each Investigator who is participating in or is planning on participating in Research.

- 3.2. <u>Entity</u>: Any domestic or foreign, public or private, organization (excluding a federal agency).
- 3.3. <u>Financial Conflict of Interest (FCOI)</u>: A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research. Similarly, a Significant Financial Interest that would reasonably appear to be affected by the Research, or that is in an Entity whose financial interests would reasonably appear to be affected by the Research.
- 3.4. <u>Institutional Responsibilities</u>: Investigators' professional responsibilities on behalf of the University, including but not limited to, activities such as Research, Research consultation, teaching, professional practice, institutional committee memberships, and service on institutional panels. All expectations, duties and responsibilities referred to in the University Faculty Handbook are considered Institutional Responsibilities.
- 3.5. <u>Investigator</u>: The project director or principal Investigator, and any other persons, regardless of title or position, who are responsible for the design, conduct, or reporting of Research or educational activities funded or proposed for funding. This may include, but is not limited to, faculty, staff, students, adjunct faculty, or subrecipients (collaborators, consultants, contractors, or subcontractors). With respect to Research funded by the DOE, this also includes any person who participates in the purpose, design, conduct, or reporting of the project.

 In addition, any Research team member who indicates a financial interest related to the submission of a human or animal Research protocol will be asked to complete a certification.
- 3.6. <u>Management Plan</u>: A written agreement that may impose conditions and prescribe actions necessary to manage an FCOI, to ensure that the design, conduct, or reporting of the Research is free from bias or the appearance of bias, including an action reducing or eliminating the FCOI.
- 3.7. <u>Research</u>: A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge.
- 3.8. <u>Significant Financial Interest (SFI)</u>: Anything of monetary value, whether the value is readily ascertainable, that 1) is related to the Investigator's Institutional Responsibilities; and 2) belongs to the Investigator or the Investigator's spouse or dependent children. This includes:
 - Remuneration in excess of \$5,000 from a publicly-traded Entity during the preceding 12 months. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship);
 - Equity interest (stock, stock options, private equity or other ownership interest) in a publicly traded Entity valued in excess of \$5,000 at the time of certification;
 - Any combination of the above two items (equity and income) that exceeds \$5,000 during the preceding 12 months;

- Venture or other capital financing;
- Any amount of equity (stock, stock options, or other ownership interest) in a non-publicly traded Entity, including a start-up company;
- Remuneration that exceeds \$5,000 from a non-publicly traded Entity in the past 12 months; or
- Intellectual property rights and interests (e.g. patents and copyrights), upon receipt of such income related to such rights and interests, if in excess of \$5,000 paid by any source other than the Investigator's current institution.

Significant Financial Interest does NOT include:

- Salary, royalties or other remuneration paid by the institution to the Investigator, if the Investigator is currently employed or otherwise appointed by the institution;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency within the United States¹, U.S. institution of higher education as defined at 20 U.S.C. § 1001(a), U.S. academic teaching hospital, U.S. medical center, or U.S. Research institute that is affiliated with a U.S. institution of higher education;
- 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;
- Income from service on advisory committees or review panels for a federal, state or local government agency within the United States¹, U.S. institution of higher education as defined at 20 U.S.C. § 1001(a), U.S. academic teaching hospital, U.S. medical center, or U.S. Research institute that is affiliated with a U.S. institution of higher education; or
- Intellectual property rights assigned to the institution and agreements to share in royalties related to such rights.

4. PROCEDURE

- 4.1. All Investigators must certify their knowledge of and compliance with this policy by completing a Conflict of Interest Certification at least annually. A current Conflict of Interest Certification must be on file prior to the submission of a new proposal. In the event an Investigator is added after the time of application for an award, the Investigator must make such disclosures prior to participating in the project. Certifications and associated disclosures must also be actively updated or confirmed to be accurate:
 - Prior to expenditure of any funds for a new award;
 - If unrelated to proposals for funding, at the time of submission of human or animal protocols if financial relationships related to the Research exist; and/or

¹ Investigators, including subrecipient Investigators, must disclose all financial interests received from a foreign institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country) as detailed here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-160.html.

• Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

4.2. A disclosure MUST include:

- The Investigator's current or pending relationship with the outside enterprise or Entity in which an SFI exists,
- The relationship of the Research (or NSF-funded educational activity) to the enterprise or Entity,
- The means by which the Investigator proposes to address actual or potential conflicts of interest that arise from the Investigator's Institutional Responsibilities and financial interests (or spouse's or dependent children's financial interests), and
- The dollar amount of the financial interest in specified ranges.
- 4.3. <u>Disclosures of Foreign Significant Financial Interest</u>: Investigators, including subrecipients, must disclose all foreign SFIs (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign Entity, including foreign institutions of higher education or foreign governments (which includes local, provincial, or equivalent governments of another country) when such interests meets the threshold for disclosure (e.g., income in excess of \$5,000).

4.4. Travel:

With some exceptions, federally funded Investigators must disclose reimbursed or sponsored travel paid for by a third-party Entity, including non-profit organizations, as well as foreign entities, foreign government, and foreign institutions of higher education. Disclosure is not required for travel sponsored by or reimbursed by a U.S. government agency, a U.S. institution of higher education or a Research institute affiliated with such, a U.S. medical center, or a U.S. academic teaching hospital.

Travel disclosures must include, at a minimum: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

4.5. <u>Procurement</u>:

In accordance with <u>Texas Government Code Section 2261.252</u> and <u>SAM 02.A.08</u>, all institutional employees who are involved in procurement or contract management must disclose any potential conflict of interest with a private vendor. For example, a potential conflict of interest exists if the employee plans to purchase, or recommend or approve the purchase of, goods or services for the University from an Entity with which they or a family member have a direct or indirect financial or other interest.

5. RESPONSIBILITIES

5.1. Institutional Responsibilities

The DO is responsible for the solicitation and review of disclosures of SFIs from each Investigator at the institution. The DO may delegate this solicitation/review responsibility to another individual or a committee.

The DO or delegate will determine whether an Investigator's submitted SFI could directly and significantly affect the Research or is in an Entity whose financial interest could be affected by the Research. If it is determined that either of these conditions is valid, an FCOI exists. In the case of an FCOI, and prior to the expenditure of any Research funds, the DO or delegate will work with the Investigator, Chair, and Dean to develop a Management Plan to manage or eliminate the conflict, and to ensure to the extent possible that the Research is free of bias or the appearance of bias.

Additional Institutional Responsibilities:

- Maintenance of an up-to-date, written, enforced System Research FCOI policy and if applicable, University Research FCOI policy, made available through the publicly accessible website.
- Notification to Investigators of new regulations and revised institutional policy/Investigator responsibilities.
- Reporting all required information regarding FCOI to federal sponsors.
- Responding to public information requests for information concerning SFIs.
- Maintenance/retention of all required FCOI records per funding agency requirements.

5.2. Investigator

- Being familiar with and abiding by federal regulations, the System Research FCOI policy, and if applicable, the University Research FCOI Policy.
- Ensuring that FCOI training is completed prior to utilizing Research funds and at least once every four years.
- Filing an FCOI Certification and disclosure (if appropriate) to the institution annually and updating it (if appropriate) within the timelines required by this policy.
- Confirming agreement to and complying with any Management Plan issued by the institution; retaining documentation that demonstrates compliance with the Management Plan, such as but not limited to: notices to journal editors or conference audiences, consent forms from human subjects Research, and notices to laboratory personnel.

5.3. College Deans, Department Chairs, and Center Directors

- Ensuring that Investigators submit and update annual certifications and disclosures.
- Ensuring that the assigned Management Plan monitor adheres to the monitor reporting timeline as determined by the DO or delegate.
- As acknowledgers of the Investigator's disclosures and signatories to the Management Plan, College Deans, Department Chairs, and Center Directors are encouraged to provide input with regard to additional factual information,

- concerns, or any conditions or restrictions that might be imposed by the institution to manage, reduce, or eliminate such conflict of interest.
- Ensuring that required Management Plans are carried out and monitored until the completion of the Research.

6. AWARDEES AND SUBRECIPIENTS

When the University is the primary awardee of a collaborative PHS, NSF, NASA, or DOE funded project, it must assure that the financial interests of all subrecipients are reviewed and eliminated or managed properly. During the proposal stage and during the negotiation of a subaward, all subrecipients/potential subrecipients of PHS, NSF, NASA, or DOE funding will be required to certify the following in writing via a Letter of Compliance:

- The subrecipient institution has a policy in place to review and manage SFIs that meets regulatory requirements. For DOE awards, the subrecipient institution shall make such policy available via a publicly accessible website or, if the subrecipient does not have a public website, it shall make its written policy available to any requestor within five business days of a request.
- The subrecipient's policy applies to the sub-awarded portion of the Research project, and
- The subrecipient agrees that the identification and Management Plan of any FCOI identified will be submitted to the awardee University for required reporting purposes. If the sub-awardee institution does not have a compliant FCOI program in place, the agreement must indicate that the subrecipient will follow the University FCOI policy, including the pre-award and annual submission of a Certification (and disclosure, if applicable) to the University DO (or delegate) within 30 days of the submission of the proposal. In the event a non-federal Entity seeks to add an Investigator after the time of application, the non-federal Entity must require the Investigator make such disclosures prior to participating in a project funded under a DOE award.

7. RECORD RETENTION

Each University is responsible for the maintenance and retention of all financial disclosure documentation and of all actions taken to resolve conflicts of interest for the longer of three years from the date of the last expenditure submitted in the case of sponsored Research, until the resolution of any funding agency action involving those records, or as required by applicable federal law, e.g., 45 CFR 74.53(b) and 92.42 (b).

8. PUBLIC ACCESSIBILITY

When an FCOI in PHS-funded Research has been identified, the following will be made available within five business days of a public information request:

- Investigator's name;
- Investigator's title and role with respect to the Research project;
- Name of the Entity in which the SFI is held;
- Nature of the SFI that constitutes an FCOI; and

• Approximate value of the SFI 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.

9. COMPLIANCE

There will be no expenditure of sponsored Research funds by an Investigator unless the DO or delegate has determined that no FCOI exists or that any identified FCOI is manageable under the terms of a Management Plan that has been adopted and implemented.

Failure of any Investigator to comply with this policy shall constitute grounds for disciplinary action. Disciplinary action may vary upon the severity of the violation. A range of examples includes, but is not limited to, the requirement for additional training/monitoring for minor violations up to the imposition of restrictions on an Investigator's participation in sponsored Research for severe or continuing violations.

10. REVIEW AND RESPONSIBILITY

	Responsible P	arty:	Interim Vice Chancellor for Research
11.	Review: APPROVAL		Every five years
	Approved:	Interin	/Claudia Neuhauser/ n Vice Chancellor for Research
		Chanc	/Renu Khator/ ellor
	Date:		January 22, 2024

12. REFERENCES AND RELATED STATUTES, POLICIES, OR REQUIREMENTS

<u>Texas Government Code § 572.051</u> – Standards of Conduct and Conflict of Interest Provisions

<u>Texas Government Code § 2261.252</u> – Disclosure of Potential Conflicts of Interest; Certain Contracts Prohibited

<u>SAM 01.G.01</u> – Sponsored Research Activities

<u>SAM 02.A.08</u> – Outside Activities/Interests Disclosures

SAM 02.A.29 – Ethical Conduct of Employees

Department of Energy (FAL 2022-02)

Department of Health and Human Services Code of Federal Regulations:

<u>42 CFR Part 50; 45 CFR Part 94</u> - Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and

Responsible Prospective Contractors

21 CFR Part 54 - Financial Disclosure By Clinical Investigators

National Institutes of Health (NIHGPS FY2023: 4.1.10)

National Science Foundation Proposal & Award Policies & Procedures Guide (NSF 23-1:

Chapter IX-Recipient Standards)

National Aeronautics and Space Administration (GIC 23-07)