

STANDARD ADMINISTRATIVE PROCEDURE

15.99.01.M1.01

Institutional Conflict of Interest in Human Subjects Research

Approved September 2, 2015

Next scheduled review September 2, 2020

SAP Statement

Texas A&M University is committed to conducting human subjects research in a manner consistent with the highest standards of integrity and ethics and free from any actual or apparent institutional conflict of interest.

Reason for SAP

This SAP sets forth the process by which institutional conflicts of interest in human subjects research are identified and managed or eliminated. This policy applies to individuals engaged in human subjects research and to those who provide oversight, management and/or review of such activities.

Definitions

Conflict of Interest Official means the Conflict of Interest (“COI”) Official designated by the Vice President for Research per University Rule 15.01.03.M1 *Financial Conflict of Interest in Sponsored Research*.

Human Subjects Research - Consistent with University Rule 15.99.01 *Human Subjects Research*, human subjects research occurs when an investigator undertakes a systematic investigation including development, testing and evaluation designed to develop or contribute to generalizable knowledge that involves living individuals and the investigator obtains research data through intervention or interaction with human subjects, or from databases that contain personally identifiable information about human subjects.

Institutional Conflict of Interest – A situation where the financial interests of the University, or a university official acting within his or her authority on behalf of the institution, might affect, or reasonably appear to affect, university processes for the design conduct, review, reporting or oversight of human subjects research.

Significant Financial Interest for University Officials has the meaning set forth in System Regulation 15.01.03 *Financial Conflicts of Interest in Research*.

University Official means an individual who, because of his or her position with the University, has the capacity to affect, or can reasonably appear to affect, University processes for the design, conduct, review, reporting or oversight of human subjects research. Such officials can include the president, the provost and executive vice president, vice presidents, associate vice presidents and vice provosts, deans, department heads, and directors/unit heads of organized research units.

Official Rule/ Responsibilities/ Process

1. GENERAL

- 1.1 The University, including its officials, must balance many competing pressures. It engages in relationships with a variety of sponsors that may lead to financial benefit for the University in many forms, including major gifts, royalty payments and equity from licensing intellectual property, as well as sponsored educational and research agreements.

In addition, industry relationships are essential to advance scientific frontiers and enable the commercial development of academic discoveries to the benefit of the public. Nonetheless, while generally part of legitimate educational, research, and business activities, relationships with commercial entities cannot be allowed to compromise, or appear to compromise, the integrity of the University's primary missions, including the safety and integrity of its research, education, and clinical care. The protection of human research subjects and integrity of the University must remain of highest priority.

- 1.2 This procedure is separate and distinct from other existing rules and procedures on conflict of interest in research including University Rule 15.01.03.M1 *Financial Conflicts of Interest in Sponsored Research* which provides for the disclosure and management of conflicts of interest that are personal to the individual.
- 1.3 To the extent the University maintains intrasystem agreements with System members for human subjects related compliance services, the University's COI Official, or designee, will coordinate with the System member(s) to ensure that Institutional COI in human subjects research is appropriately identified, reviewed, resolved and monitored as set forth in this SAP.

2. INSTITUTIONAL CONFLICT OF INTEREST

- 2.1 An institutional conflict of interest ("Institutional COI") can occur whenever the external financial interests or business relationships of the University or of one of its officials are such that their actions could affect, or could reasonably appear to affect, the design, conduct, review, reporting or oversight of the University's human subjects research. The potential for Institutional COI that could

compromise the integrity of the University's research mission generally arises in one of the three situations described below:

- 2.1.1 when the University, as an institution, has taken an equity interest in a business enterprise in which University employees conduct, or propose to conduct, research that could affect the value of the equity interest in that enterprise;
 - 2.1.2 when the University holds a patent, license, or right to royalties on a process, technique, or production that it licenses to external companies, which in turn use University employees to conduct research on that process, technique or product; or
 - 2.1.3 when a University Official, with the authority to act on behalf of the University and to make decisions that have institution-wide implications, or whose decisions could reasonably be seen as affecting the conduct, review, or oversight of human subjects research, holds a significant financial interest in, consults for, serves on the board of, or is otherwise expected to act for the benefit of an entity that has a financial interest in University sponsored human subjects research.
- 2.2 In addition to those circumstances indicated above, other financial relationships with research sponsors may warrant formal scrutiny, depending on the circumstances. In general, the University should assess the potential for conflict of interest and weigh the magnitude of any risk to the research's integrity.
- 2.3 Although the listed circumstances are potential areas of concern, the goal of this SAP is not to preclude the University from accepting philanthropy from companies that sponsor research, or that own or control products that are being studied or tested. Rather, this SAP is intended to require the University to develop means of identifying and examining such circumstances, and of managing, through disclosure, separation of responsibilities, and as otherwise appropriate, mitigate any actual or apparent conflicts of interest that may result.
3. IDENTIFICATION, REVIEW AND RESPONDING TO INFORMATION REFLECTING INSTITUTIONAL CONFLICT OF INTEREST
- 3.1 The Vice President for Research ("VPR") has the responsibility for overseeing the process for identifying, reviewing, resolving, and monitoring Institutional COI that may arise from the business relationships of either the University or its officials with outside entities in the context of human subjects research. Disclosures that may identify actual or potential institutional conflict of interest shall be handled as provided below.
 - 3.2 Disclosure by the University

3.2.1 The COI Official, or designee, shall obtain from the Texas A&M University System Technology Commercialization Office (“TTC”) quarterly reports that disclose the entities in which the University holds equity positions or from which it has the right to receive royalty payments.

3.2.2 The COI Official, or designee, will obtain bi-annual reports of substantial gifts to the University.

3.3 Disclosure by University Officials

3.3.1 University Officials must furnish written conflict of interest disclosures as may be required by state or federal authorities or by The Texas A&M University System policies or regulations and university rules and procedures. This disclosure will be made at least annually and within thirty (30) days of a change in the individual's financial or business relationship that would require disclosure under such laws or policies. The COI Official, or designee, will coordinate with appropriate institutional offices to identify disclosures which may fall within the scope of this SAP.

3.4 Review of Disclosure Information

3.4.1 The Human Research Protection Program (“HRPP”) assists, supports and reviews all proposed human subjects research and administers the University’s human research protection program. The University’s Conflict of Interest Official, or designee, shall provide HRPP with copies of financial disclosures that are related to human subjects research and meet the definition of “Significant Financial Interest” as set forth in System Regulation 15.01.03, and with copies of the disclosures/reports identified in Sections 3.2 and 3.3 above.

3.4.2 The HRPP, in coordination with the Institutional Review Board(s) (“IRB”), shall review all proposed human subjects research submissions it receives with the disclosure and report information provided by the Conflict of Interest Official, or designee, to identify any actual or potential Institutional COI present in the submissions. The HRPP will refer any research submissions for which an actual or potential Institutional COI has been identified to the Conflict of Interest Official, or designee, for a response per Section 4 below. Once the Institutional COI is resolved, the affected submission will be returned to HRPP for review by the University's IRB.

4. RESPONDING TO INFORMATION REFLECTING POTENTIAL INSTITUTIONAL CONFLICT OF INTEREST

4.1 Actual or Apparent Conflict of Interest of the President, Provost and Executive Vice President, or the Vice President for Research

If the president, provost and executive vice president, or the vice president for research is found to have an actual or apparent Institutional COI, he or she shall either:

4.1.1 totally divest him or herself of the financial interest; and/ or

4.1.2 resign from the board or other position with the external entity that has a financial interest in University-sponsored human subjects research. Proposed research cannot be approved or continued until such action is taken by the affected official.

4.2 All Other Institutional Conflicts of Interest

The VPR shall appoint an Institutional Conflict of Interest Committee (“ICOIC”), which must consult with the VPR and/or the System member, as appropriate, where other actual or apparent Institutional COI are identified to determine whether to:

4.2.1 in cases involving a business entity, require the TCC to divest the University's current equity holdings and/or its right to royalties in that business entity, as well as its right to acquire equity holdings in the future;

4.2.2 propose modifications to the proposed human subjects research that would remove the possibility that the University, or any of its units or officials, would benefit financially from the results of the proposed research;

4.2.3 prohibit the proposed human subjects research, when in the best interests of the public or the University, upon recommendation from the HRPP manager;

4.2.4 direct that the University Official who holds a significant financial interest divest him- or herself of that interest, or remove him- or herself from the decision process involving such research; or

4.2.5 if feasible, develop an Institutional COI management plan.

5. MONITORING THE CONFLICT OF INTEREST PROCESS

5.1 The ICOIC, or as otherwise designated by the VPR, shall monitor the Institutional COI. It shall meet periodically to:

5.1.1 Ensure that University Officials are in compliance with the disclosure obligations of this SAP; and

- 5.1.2 Review and propose to the VPR and/or System member, modifications to the plans for managing Institutional COI.
- 5.2 Any member of the ICOIC who has a financial interest in or serves as a paid consultant for an entity that is involved in a research proposal shall not participate in the review under this SAP.
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Related Statutes, Policies, or Requirements

[System Policy 07.01, *Ethics*](#)

[System Regulation 15.01.03, *Financial Conflict of Interest in Sponsored Research*](#)

[System Regulation 15.99.01, *Use of Human Subjects in Research*](#)

[University Rule 15.01.03.M1, *Financial Conflict of Interest in Sponsored Research*](#)

[University Rule 15.99.01.M1, *Human Subjects Research*](#)

[System Policy 31.05, *External Employment and Expert Witness*](#)

[System Regulation 31.05.01, *Faculty Consulting and External Professional Employment*](#)

[System Regulation 31.05.02, *External Employment*](#)

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