



Promoting Objectivity in Research by Managing, Reducing or Eliminating Financial Conflicts of Interest

I. Policy Statement

This policy governs the disclosure of individual financial interests and the management and reporting of individual financial conflicts of interest in research performed on behalf of Texas Southern University (“University”).

This policy provides requirements for the disclosure of financial interests that comply with the disclosure requirements of federal regulations of the U.S. Department of Health and Human Services (HHS) and the HHS Public Health Service (PHS), but this policy is not limited in application to PHS-funded research. Rather, this policy applies broadly to research performed at, or on behalf of the University, without regard to whether the research has external funding and, if externally funded, regardless of the funding source.

This policy applies in addition to general University policies, such as policies on standards of conduct, MAPP reference 02.05.05 - Ethics & Conflicts of Interest Policy.

If a specific federal law or regulation provides different requirements than this policy, the more stringent requirement applies.

II. Reason for Policy

This policy provides requirements for the disclosure of financial interests that comply with the disclosure requirements of federal regulations. It also establishes the process for the management and reporting of financial conflicts of interest in research.

III. Scope & Audience

This policy applies to covered individuals and covered family members, as defined below in Section IV, during the course of conducting research at, or on behalf of the University.

IV. Definitions (specific to this policy)

Covered Family Member includes:

1. a spouse;



2. a dependent child or stepchild or other dependent, for purposes of determining federal income tax liability during the period covered by the disclosure statement; and
3. a related or non-related, unmarried adult who resides in the same household as the covered individual and with whom the covered individual is financially interdependent as evidenced, for example, by the maintenance of a joint bank account, mortgage, or investments.

If the covered individual is in doubt about whether an individual is a covered family member, the covered individual should resolve the doubt in favor of disclosure.

Covered Individual:

Is an individual who, regardless of title or position, is responsible for the design, conduct, reporting, review, or oversight of research, including a principal investigator, co-investigator, or project director, and who must file and update financial disclosure statements under this policy.

This definition also applies to any student enrolled at the University who is responsible for the design, conduct, or reporting of research as defined in this section. A student's supervising faculty member who is in doubt about whether the student is a covered individual must request a determination by the conflict of interest official appointed under Section 3.01.

Institutional Responsibilities:

Means any of the professional responsibilities of a covered individual performed on behalf of the University, including consultation, teaching, professional practice, research, University committee membership, or service on a University panel such as an Institutional Review Board (IRB) or Data and Safety Monitoring Board (DSMB).

Research:

Means any systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge. The term includes both basic and applied research and product development.

Financial Interest:



Is an interest with monetary value which is subject to disclosure under Section 2.02 of this policy.

Financial Conflict of Interest:

Is a financial interest which:

- a. has been determined by the conflict of interest official as having potential for directly and significantly affecting the design, conduct, or reporting of the research or is in an entity whose financial interest appears to be affected by that research, and
- b. is subject to the University's development of a management plan to avoid any direct and significant impact to the covered individual's research.

Management Plan:

A management plan is a written agreement that may impose conditions and prescribe actions necessary to manage a financial conflict of interest, including an action reducing or eliminating the financial conflict of interest, to ensure that the design, conduct or reporting of the research is free from bias or the appearance of bias.

V. Website (for policy)

http://www.tsu.edu/About/Administration/Division_of_Academic_Affairs_and_Research/research/

VI. Contacts

Contact	Phone	Website
Office of the Associate Vice President for Research/	(713) 313 - 4245/ 7079	http://www.tsu.edu/About/Administration/Division_of_Academic_Affairs_and_Research/research/

VII. Responsibilities & Procedures

Chapter 1. GENERAL PROVISIONS



Sec. 1.01. - Collaborators and Contractors

- a. If research is carried out in cooperation with or through a sub-recipient (sub-recipients or consortium members), the University will enter into a written agreement with the sub-recipient that provides legally enforceable terms requiring that a financial conflicts of interest policy acceptable to the University applies to the researchers of the sub-recipient.
- b. If the policy of the sub-recipient applies to its researchers, the sub-recipient must certify its policy is consistent with the requirements of the university or any applicable federal regulations.
- c. If the policy of the sub-recipient applies to its researchers, the agreement must specify the time periods for the sub-recipient to report identified financial conflicts of interest to the University. The time periods must be sufficient for the University to make any reports required by federal regulation.

Sec. 1.02. - Education

- a. Each covered individual must acknowledge annually that he or she has read this policy and is aware of the covered individual's responsibilities regarding disclosure of financial interests and of applicable federal regulations.
- b. A covered individual must complete training in regard to this policy and applicable policies, regulations, and laws before engaging in research at the University and at least once every two years thereafter. A covered individual who is new to the University must complete the training before engaging in research at the University or provide evidence of having completed the training at another institution within the last four years. A covered individual must complete the training immediately if the University finds that the individual is not in compliance with this policy or the individual's management plan, or if the University revises this policy in a manner that affects the individual's duties.

Chapter 2. DISCLOSURE OF FINANCIAL INTERESTS RELATED TO INSTITUTIONAL RESPONSIBILITIES



Sec. 2.01. - Extent of Disclosure

- a. As often as required by Section 2.05, a covered individual must complete or update a financial interest disclosure statement that:
 1. identifies all research in which the covered individual is engaged at the time of the disclosure; and
 2. discloses, as provided by Section 2.02, each financial interest of the covered individual and covered family members that reasonably appears to be related to the individual's institutional responsibilities.
- b. In determining whether research or a financial interest should be disclosed, the covered individual should resolve the doubt in favor of disclosure.

Sec. 2.02. - Contents of Disclosure: Financial Interests

- a. The following interests are considered to be financial interests and, subject to the exclusions provided by subsection (b) of this section, a covered individual's disclosure statement must include the following information related to the covered individual and covered family members, but only in regard to interests that reasonably appear to be related to the individual's institutional responsibilities:
 1. **PAYMENTS RECEIVED FROM OR EQUITY INTEREST IN A PUBLICLY TRADED ENTITY:** the total amount and source of payments received in the preceding twelve months from a publicly traded entity and the value of any equity interest held in the entity on the date of disclosure that, when aggregated, exceed \$5,000, including:
 - A. as to payments received:
 - i. salary; and
 - ii. any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and



- B. as to equity interests held, any stock, stock options, or other ownership interest or entitlement to such an interest, valued by reference to public prices or other reasonable measures of fair market value;
2. PAYMENTS RECEIVED FROM A NON-PUBLICLY TRADED ENTITY OR EQUITY INTEREST IN A NON-PUBLICLY TRADED ENTITY:
- A. the total amount and source of payments received in the preceding twelve months from an entity that is not publicly traded that, when aggregated, exceed \$5,000, including
 - i. salary; and
 - ii. any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and
 - B. a description of any equity interest held in an entity that is not publicly traded, including any stock, stock options, or other ownership interests or entitlement to such an interest;
3. INTELLECTUAL PROPERTY AND ROYALTIES:
- A. a description of intellectual property rights held and any agreements to share in royalties related to those rights; and
 - B. the amount and source of royalty income that the covered individual or covered family member received or had the right to receive in the preceding twelve months;
4. TRAVEL: reimbursed or sponsored travel in the preceding 12 months, including the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip;
5. GIFTS: the value and source of a single gift that the covered individual received in the preceding twelve months that exceeds \$250 in value, or multiple gifts from a single entity that in the



aggregate exceed \$250 in value, other than gifts from a covered family member; and

6. **FIDUCIARY POSITIONS:** a fiduciary position the covered individual held in a for-profit or nonprofit entity in the preceding twelve months, including a position as a member of the board of directors, an officer, or other executive or management position, for which the individual received any form of remuneration or reimbursement for expenses, and the name and principal address of the entity.
 - A. **Exclusions.** The following interests are not financial interests and need not be disclosed on the disclosure statement:
 - i. salary, royalties, or other remuneration paid by the University to the covered individual, if the covered individual is currently employed or otherwise appointed by the University;
 - ii. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government, an institution of higher education as defined by 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education;
 - iii. income from service on an advisory committee or review panel for a federal, state, or local government, an institution of higher education as defined by 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education;
 - iv. income from investment vehicles, such as mutual funds or retirement accounts, as long as the covered individual does not directly control the investment decisions made in those vehicles; or
 - v. Travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined by 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.



- B. In making disclosures under this section, the covered individual must disclose the value of a financial interest within the following ranges:
1. 0 - \$4,999;
 2. \$5,000 - \$9,999;
 3. \$10,000 - \$19,999;
 4. amounts between \$20,000 - \$100,000 by increments of \$20,000; or
 5. amounts above \$100,000 by increments of \$50,000.
- C. When describing a source, the covered individual must provide the name and principal address for the source.
- D. The covered individual must distinguish among information pertaining to the covered individual and covered family members whose financial interests and activities are also disclosed by the covered individual.
- E. Any appropriate University official, such as, a vice president, dean or department chair, may request further information about a covered individual's travel, including the monetary value of the travel, in order to determine whether the travel constitutes a financial conflict of interest.

Sec. 2.03. Disclosure of Financial Interests of Other Persons: Covered Family Member

In disclosing financial interests, the interest of any legal entity, including a foundation or a trust that is controlled or directed by the individual or by the individual and covered family members, is considered to be the interest of the covered individual or covered family member as if the separate legal entity did not exist.

Sec. 2.04. Text of Documentation to be Provided on Request

If a covered individual discloses payments, intellectual property interests, or royalties, the covered individual must permit review of any related agreement, contract, offer letter, or other documentation on request of:

- a. the President of the University; or



- b. any other person or entity with administrative responsibility in regard to reviewing financial interest disclosure statements or approving a related management plan.

Sec. 2.05. When to Disclose; Period Covered by Statement

- a. A covered individual must submit or update a financial interest disclosure statement:
 - 1. not later than the 30th day of initial employment, covering the 12 months preceding the date of disclosure;
 - 2. annually not later than date mandated by the University;
 - 3. not later than the 30th day after acquiring a new financial interest that requires disclosure under Section 2.02; and
 - 4. within 30 days from date of travel.
- b. A covered individual who is funded under a PHS-funded research project must ensure his or her financial interest disclosure statement is current at the time of application for research funding from the PHS entity, except that an individual who is new to the University and who is planning to participate in an on-going PHS-funded research project must submit the statement not later than the 30th day of initial employment.
- c. The president of the University or the conflict of interest official may require a covered individual to submit additional disclosures.

Chapter 3. DESIGNATED OFFICIAL; DISCLOSURE STATEMENT REVIEW

Sec. 3.01. Monitoring

Monitoring responsibility include the duties required by this policy and other duties that pertain to conflict of interest.

Sec. 3.02. Disclosure Statement Review; Determination of Financial Conflict of Interest

- a. The President of Texas Southern University will designate an individual to serve and review financial disclosure statements and make two determinations:



1. whether any financial interest disclosed is related to research in which the covered individual is engaged; and
 2. if so, whether a financial conflict of interest exists.
- b. A financial conflict of Interest is related to research in which the covered individual is engaged if the conflict of interest official reasonably determines the financial interest appears to be affected by the research or is in an entity whose financial interest appears to be affected by the research.
 - c. A financial conflict of interest exists when the conflict of interest official reasonably determines that a financial interest could directly and significantly affect the design, conduct, or reporting of the research.

Sec. 3.03. No Expenditure of Funds Prior to Review and Determination

Neither the University nor a covered individual may expend research funds unless the conflict of interest official 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 in accordance with Chapter 4 of this policy.

Sec. 3.04. Cooperation with Institutional Committees

The designated official and the appropriate Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), and other relevant University committees will cooperate in the consideration of whether a covered individual has a financial conflict of interest in regard to research and in the development and implementation of a management plan for that conflict of interest.

Chapter 4. MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

Sec. 4.01. Management Required for Financial Conflicts of Interest

- a. If the designated official determines that a covered individual has a financial conflict of interest, the official, in cooperation with the covered individual and other appropriate individuals designated by the conflict of interest official, such as an appointed Objectivity in Research Committee, must develop a management plan governing that conflict of interest.
- b. If research is ongoing and a new covered individual discloses a financial interest related to that research or any other covered individual discloses a new financial interest related



to that research, the conflict of interest official must, not later than the 60th day after the filing of the disclosure statement:

1. review the disclosure statement to determine if a financial conflict of interest exists; and
 2. if a financial conflict of interest exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the research.
- c. If the conflict of interest official learns of a financial interest that was not timely disclosed or was not timely reviewed, the conflict of interest official must, not later than the 60th day after learning of the interest:
1. determine whether the financial interest is a financial conflict of interest; and
 2. if a financial conflict of interest exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the research going forward.
- d. In addition, if a financial conflict of interest was not identified or managed in a timely manner, or if a covered individual fails to comply with a management plan, the conflict of interest official must, not later than the 120th day after determining noncompliance:
1. complete and document a retrospective review and determination as to whether research conducted during the period of noncompliance was biased in the design, conduct, or reporting of the research; and
 2. 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.
- e. For PHS-covered research projects, the retrospective review must cover key elements as 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.

Sec. 4.02. Management Plan Design and Agreement

A management plan must be in the form of a written agreement and must:



- a. provide that the covered individual acknowledges receipt of the plan, understands the requirements of this policy, and understands and agrees to comply with the required actions and other terms of the plan, including the time frames for required actions; and
- b. clearly identify each specific person responsible for monitoring compliance with the management plan.

Sec. 4.03. Monitoring and Compliance

Each person conducting research under a management plan must comply fully and promptly with the plan, and each person identified in the management plan as having responsibility for monitoring compliance with the plan must carefully and fully monitor that compliance.

Chapter 5. WEB POSTING OF FINANCIAL CONFLICT OF INTEREST INFORMATION

Sec. 5.01. Posting of this Policy

This policy and each update is accessible through this website:

http://www.tsu.edu/About/Administration/Division_of_Academic_Affairs_and_Research/research/

Sec. 5.02. Posting of Information Regarding Specific Financial Conflicts of Interest in Research Funded by PHS

- a. For each financial conflict of interest in PHS-funded research that is found to exist, the University will make the following information available to the public through the website in regard to each covered individual who contributes to the scientific development or execution of the research project in a substantive, measureable way, including a covered individual who is the project director or principal investigator:
 1. the covered individual's name;
 2. the covered individual's title and role with respect to the research;
 3. the name of the entity in which the financial interest is held;
 4. the nature of the financial interest that constitutes a financial conflict of interest; and
 5. the approximate value of the financial interest 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.



- b. The approximate dollar value of the financial interest must be provided within the following ranges if it can be determined by reference to public prices or other reasonable measures of fair market value: (See Section 2.02.6 B.)
- c. The University's Office of Research will update the information required by this section periodically and as needed. In addition, for any financial conflict of interest of a covered individual whose information must be posted under this section and for which the information was not previously posted, the University will make the information required by this section available not later than the 60th day after the financial conflict of interest is identified.
- d. The website on which the information is posted must note that the information is current as of the date listed and is subject to updates.
- e. The information required by this section must remain available on the website for three years after its most recent update.
- f. For PHS-funded research, in regard to project directors, principal investigators, and other senior or key personnel, this information must be available through the Internet before expending PHS funds.

Sec. 5.03. Availability of Information Regarding Specific Financial Conflicts of Interest in Research Not Funded by PHS

- a. For each financial conflict of interest in research not funded by PHS that is found to exist, the University will centrally retain and make the following information available to the public, upon request under the Texas Public Information Act (Chapter 552, Government Code), in regard to each covered individual who contributes to the scientific development or execution of the research project in a substantive, measurable way, including a covered individual who is the project director or principal investigator:
 - 1. the covered individual's name;
 - 2. the covered individual's title and role with respect to the research;
 - 3. the name of the entity in which the financial interest is held;
 - 4. the nature of the financial interest that constitutes a financial conflict of interest; and



5. the approximate value of the financial interest 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.
- b. The approximate dollar value of the financial interest must be provided within the following range if it can be determined by reference to public prices or other reasonable measures of fair market value: (See Section 2.02.6. B.)
- c. The University will make the information required by this section available after the financial conflict of interest is identified in accordance with the deadlines provided by the Texas Public Information Act.
- d. The information required by this section must remain available for three years after its most recent update.

Chapter 6. CERTIFICATION AND REPORTS

Sec. 6.01. Certification and Report Requirement

The University will comply with all federal regulations that require certifications and reporting including that each application for funding to the PHS include specific certifications and agreements in regard to this policy and financial conflicts of interest.

Sec. 6.02. Financial Conflict of Interest Report

Before the expenditure of any funds under a PHS-funded research project, the appropriate University official 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 the University 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.

Chapter 7. ENFORCEMENT

Sec. 7.01. Disclosure is a Condition of Employment or Relationship to University



- a. Timely, complete, and accurate disclosure of activities and 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, which may include termination of employment.
- b. For a covered individual who is not an employee of the University, compliance with this policy is a condition of participating with the University in the capacity that qualifies the person as a covered individual. The University may require the individual to execute a document certifying that the individual knows that compliance with this policy is a condition of participation.

Sec. 7.02. Federal Enforcement

- a. Federal regulations, 42 CFR Part 50, Subpart F, and 45 CFR Part 94, require the institution to notify the PHS of instances in which the failure of a covered individual to comply with this policy or a management plan appears to have biased the design, conduct, or reporting of PHS-funded research. The PHS awarding component may take enforcement action or require the institution to take action appropriate to maintaining objectivity in the research. The institution must make information available to HHS or the PHS awarding component as required by federal regulation.
- b. If the HHS determines clinical research funded by PHS to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a covered individual with a financial conflict of interest that was not managed or reported by the institution as required by federal regulation, the institution will require the covered individual involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Chapter 8. ADMINISTRATION OF CONFLICTS POLICIES; RECORDS

Sec. 8.01. Oversight and Authority

The president or his or her designee will 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.

Sec. 8.02. Records



- a. 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 University actions, must be retained for the longer of at least three years after:
 1. the date of creation;
 2. 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
 3. the date of final resolution of any investigation, audit, or similar action involving the records.
- b. The University will provide for a centralized repository for financial interest disclosure statements, management plans, and related records.
- c. The President's designee will provide copies of all guidelines, procedures, and forms used by the University relating to financial conflicts of interest and must ensure that the President receives copies of any revised guidelines, procedures, and forms simultaneously with the implementation of the revision.

Sec. 8.03. Audits

The University will provide for regular audits of financial interest disclosure statements to determine individual and University compliance with this policy

VIII. Form & Tools

None

IX. Frequently Asked Questions

http://www.tsu.edu/About/Administration/Division_of_Academic_Affairs_and_Research/research/

X. Related Information



CONFIDENTIAL

TEMPLATE

RESEARCH CONFLICTS OF INTEREST MANAGEMENT PLAN

FOR _____

(July 23, 2014)

This Research Conflicts of Interest Management Plan (RCOI Management Plan) has been created by the Research Conflicts of Interest Committee (Committee) to assist in managing or reducing real or potential financial conflicts of interest in research that may develop because Dr. _____ (Title/Department/School), holds significant financial interests with _____ while simultaneously participating in research at Texas Southern University (TSU) that is either sponsored by _____ and/or that might appear to affect or be affected by his/her financial interests in _____.

The TSU Research Conflicts of Interest Policy (*reference policy name*) requires significant financial interests (as defined in Attachment A) that create or appear to create financial conflicts of interest in research to be managed, reduced, or eliminated.

DESCRIPTION OF SIGNIFICANT FINANCIAL INTERESTS

Description of company.

Description of the related technology/intellectual property.

Employee's financial interests.

Employee's outside activities (consulting, advising, board service, etc.) for the company.

TSU's financial interests in the company, if applicable.

Description of licensing agreement, if applicable.

SPONSORED RESEARCH

Dr. _____ proposes to participate in research at TSU that is related to his/her financial interests (*current and/or proposed research projects applicable to this Plan will be listed in Attachment B*).

Should Dr. _____ propose to be involved in future related research, his/her participation in the research will mandate that it be reviewed by the Committee and this RCOI Management Plan will be updated accordingly.

RCOI MANAGEMENT PLAN

Dr. _____, the Committee has reviewed your significant financial interests, TSU's financial interests, the licensed technology, and your research. Your participation in research creates a potential conflict that will



be permitted insofar as you agree to this RCOI Management Plan to manage the identified potential financial conflicts of interest in the research.

In addition, the Committee will monitor this RCOI Management Plan on an annual basis to verify you have complied with the terms of the Plan and determine if additional strategies are required to effectively manage any potential financial conflicts of interest in research as needed.

Management of Potential Conflicts in the Conduct of Research:

1. The Committee has reviewed your significant financial interests with _____ and your existing research to determine whether safeguards will be required to promote objectivity in the research, *i.e.* to ensure, to the extent possible, that the design, conduct, and reporting will be free from bias resulting from your financial conflict of interest. The Committee determined that research involving the use, study, or validation of the licensed technology or _____ products creates a potential financial conflict of interest. Other research that does not involve the licensed technology (*e.g.*, research that generates no data that can be used to create or improve the licensed technology) or does not involve _____ products will not require prior review by the Committee in the context of this RCOI Management Plan.

Research that might appear to affect or be affected by your financial interests in _____ (“**conflicted research**”) includes research that is sponsored by _____ and research funded by any external or internal source that uses, studies, or validates the technology licensed to _____ (*e.g.*, _____) including but not limited to research that would result in bringing a product to market. You have informed the Committee that for conflicted research you propose to _____ (*description of safeguards to be provided by the researcher*) _____ as appropriate or each project in order to ensure, to the extent possible, that the design, conduct, and reporting will be free from bias resulting from your financial conflict of interest. The Committee has accepted these methodologies as appropriate for safeguarding the objectivity of the conflicted research.

The Committee has determined that if you propose to participate in new conflicted research projects, a re-evaluation of your methods for mitigating actual or perceived research bias may need to be undertaken. Depending upon the nature of the research, additional safeguards to those described above may be required. You may be asked to provide a description of the planned studies, including statements describing how the proposed studies constitute conflicted research, and the safeguards you will use to ensure objectivity in the design and conduct of the studies and the analysis and interpretation of data. Your participation in the planned studies must be reviewed and approved prior to the initiation of said research.

The Committee determined that the continual and consistent implementation of these safeguards for all conflicted research conducted under this RCOI Management Plan will be required to maintain the objectivity of the research. Notify the Committee of changes in your financial interests or in your Research related to the licensed technology prior to them occurring or when they occur so that any financial conflict of interest in the research maybe re-evaluated and this RCOI Management Plan updated accordingly.



Reporting and Review of Related Significant Financial Interests:

2. You must submit a Research Conflict of Interest (COI) Disclosure Form: 1) when submitting all new research applications to the Office of Sponsored Projects, the Committee for the Protection of Human Subjects, the Animal Welfare Committee, or in association with proposed internal awards, department funds, or gifts; and 2) when new reportable financial interests are obtained by you and/or your covered family members during research award/contract periods.

In addition, when proposing to participate in the design, conduct, or reporting of any other research involving the licensed technology or _____ products, regardless of the funding source or location of where the research is to be conducted, you must submit a Research COI Disclosure Form to the EVPARA for notification purposes.

3. You must submit a new Review and Approval Form when there are revisions in any sponsored research agreement or contract with _____ to ensure a new Research COI Disclosure Form is submitted for the Committee to review.
4. You must provide additional information as requested within ten business days to facilitate disclosure by TSU to sponsors regarding any identified potential financial conflict of interest in research, if required by sponsor guidelines (*e.g.*, federal agencies).
5. You must submit reports as requested by the President, his designee, and/or the Committee that include information about your research program, related significant financial interests, conflicts that may have developed and what steps were taken to minimize and/or eliminate actual or perceived bias in said research. The reports must be submitted annually unless the level of your financial interests or potential conflicts of interest in research requires more frequent monitoring.

AGREEMENT

Dr. _____, by signing below, you are certifying to TSU the following:

I acknowledge the accuracy of the information in this RCOI Management Plan describing my outside activities and financial interests on which this Plan is based.

I have read, understand, and agree to comply with the requirements for managing potential financial conflicts of interest in research as set forth in this RCOI Management Plan.

I understand that an Institutional Conflicts of Interest Management Plan will also be implemented to manage potential conflicts of commitment with my TSU responsibilities that may result from my outside activities with _____.



I understand that failure to comply with applicable federal regulations, state laws, TSU Board of Regents *Rules and Regulations*, TSU policies, and the terms of this RCOI Management Plan may result in the total withdrawal of or limitations to TSU's approval of my activities with _____ and, further, may result in disciplinary action, up to and including termination of my employment at TSU.

I acknowledge that it is my responsibility to inform the TSU Vice President for Academic and Research Affairs in writing within 30 days if any of the facts upon which this RCOI Management Plan is based should change. I understand and agree that any material change in circumstances may require review by the Research Conflicts of Interest Committee and revision of this RCOI Management Plan.

READ, ACKNOWLEDGED, AND AGREED TO:

Employee (Date)

Title/Department

APPROVED: Department Chair (Date)

APPROVED: Dean of College or School (Date)

Provost/Vice President for Research Affairs (Date)