I. Discussion Items: (Moderated by Lawrence Rauchwerger)

(a) Finalize proposed draft agenda outline for July 11, 2012 CPI meeting:

- Overview of proposed revisions to System Policy 17.01, IP Management and Commercialization – James Moore, IPCC Chair
- Overview of proposed revisions to System Policy 31.05, External Employment and Expert Witness, and System Regulation 31.05.01, Faculty Consulting, External Employment and Conflicts of Interest – Peter Schuerman (OTC) and Nicholas Chremos (OGC)
- Update on PIFAC – Terry Thomas, PIFAC Chair

(b) Update on TAMUS Regulation on Financial Conflict of Interest (Katherine Rojo del Busto)

(c) Discussion items needed for July 11 CPI EC meeting with the TAMU administration (i.e., law school; DHHS project; TAMU-HSC merger; other?)

(d) Update on OSRS and PIFAC (Terry Thomas)

(e) Update on CONCUR (Terry Thomas)

(f) Discussion of DHHS grant / Recommendation to invite Brett Giroir to future EC meeting to discuss (Terry Thomas)

(g) Update on proposed Texas A&M and HSC merger (Reza Langari)

(h) Review draft July CPI newsletter items

(i) Other business
DRAFT July Newsletter Items

— Summary of May 9, 2012 CPI meeting
— Summary of June 4, 2012 CPI EC meeting with representatives of The Texas A&M University System Office of General Counsel and Office of Technology Commercialization
— Summary of June 5, 2012 CPI EC meeting with the President, Provost and Vice President for Research
— Summary of June 6, 2012 CPI EC meeting research administration representatives from Texas A&M, AgriLife Research, HSC, TEES and TTI
— Preview of July 11, 2012 CPI monthly meeting
— OSRS PI/Faculty Advisory Committee (PIFAC) Update
— Update on Faculty Advisory Committee reviewing matters related to the Texas A&M Health Science Center and Texas A&M University
— Update on Outsourcing Committee
— Texas A&M University Vice President for Research: Testimony to Congress on the Future of Research Universities
— Junkins Selected as Founding Director of TIAS
— Call for Nominations: Trotter Prize
— Update on University Dining
— CONCUR Updates
— Data Management Planning Tool
— 150th Anniversary of the Morrill Act
— Research Compliance and Biosafety Newsletter (June 2012)
— FACULTY-DISCUSS Listserv
— CPI meeting calendar
— TTVN contact information
15.01.03 **Financial Conflict of Interest in the Design, Conduct and Reporting of Sponsored Research and Educational Activities**

Approved July 31, 1996
Revised June XX, 2012
Next Scheduled Review: June XX, 2014

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**Regulation Statement**

The Texas A&M University System (system) recognizes its responsibilities to encourage interaction between its employees and the public and private sectors as an important component of its research activities. The system is committed to conducting research in a manner consistent with the highest standards of integrity and ethics. The system adopts this regulation to promote objectivity in research and to ensure that the research activities conducted by each member are free from bias resulting from financial conflicts of interest.

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**Reason for Regulation**

This regulation implements federal law and regulations adopted by the Public Health Service of the U.S. Department of Health and Human Services and the National Science Foundation to address when a Significant Financial Interest (SFI) reasonably appears to affect or bias the design, conduct or reporting of research.

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**Procedures and Responsibilities**

1. **PURPOSE AND BACKGROUND**

This regulation defines the general procedures required for members to identify, manage and report financial conflicts of interest in research. The purpose of this regulation is to protect the credibility and integrity of system researchers and staff, as well as member universities and agencies themselves, so the public trust and confidence in their research activities are maintained. To that end, this regulation adopts standards for the disclosure, management and reporting of financial conflicts of interest beyond those required by federal law.

Members have a responsibility to identify and manage, reduce or eliminate conflicts of interest that may arise due to financial or other personal interests of an Investigator. Therefore, the system requires Investigators to disclose financial interests related to their Institutional Responsibilities.
2. APPLICABILITY

Except as otherwise provided by federal law, this regulation applies broadly to all Research Activities regardless of the funding source, as well as to Research Activities that do not have external funding.

In addition to the issues addressed in this regulation, there may be ethical considerations that are distinct and separate from financial conflict of interest questions.

3. CONFLICT OF INTEREST OFFICIAL

The member chief executive officer (CEO) shall appoint a Conflict of Interest Official (COI Official) who will be responsible for implementing this regulation. The COI Official shall perform the duties assigned by this regulation and any other duties as assigned by the CEO.

4. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

4.1. Each Investigator, as defined below, must submit or update a Financial Disclosure Statement as required in Section 4.2 of this regulation that:

(a) Identifies all Research or Research Activities in which the Investigator is engaged at the time the Financial Disclosure Statement is submitted; and

(b) Discloses the following information for each SFI held by the Investigator or a Covered Family Member that is reasonably related to the Investigator’s Institutional Responsibilities:

(1) The total amount of salary or other payments received in the preceding twelve months, in rounded, whole dollar amounts;

(2) A description and the value of any equity interest (e.g., stock, stock options, or other ownership interest or entitlement to such an interest) in rounded, whole dollar amounts by reference to public prices or other reasonable measures of fair market value;

(3) A description and the value of any intellectual property or royalty interests in rounded, whole dollar amounts;

(4) The source of the SFI, including the source’s name and principal address; and

(5) For each occurrence of reimbursed or sponsored travel, the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration of the trip. Each member, at its discretion, may require an Investigator to disclose additional information in order to determine whether the travel at issue constitutes a Financial Conflict of Interest (FCOI).

4.2 Investigators shall submit or update a Financial Disclosure Statement to the member’s COI Official:

(a) Within 30 days of the Investigator’s initial employment date;
(b) Annually, not later than August 31st;
(c) Within 30 days after acquiring a new SFI requiring disclosure; and
(d) For those Investigators participating in PHS-funded research, not later than the application date for PHS-funded research, except that an Investigator who will be participating in an ongoing PHS-funded research project must submit a Financial Disclosure Statement within 30 days of the Investigator’s initial employment date.

4.3 Investigators shall also submit or update a separate Financial Disclosure Statement for each Covered Family Member within the time periods specified in Section 4.2.

4.4 Investigators shall use the Financial Disclosure Statement form provided in Appendix B to this regulation.

4.5 An Investigator or Covered Family Member shall provide any additional documentation related to the SFIs disclosed on a Financial Disclosure Statement upon request of a member’s COI Official.

5. REVIEW OF FINANCIAL DISCLOSURE STATEMENTS

5.1 Each member’s COI Official shall review the Financial Disclosure Statement(s) submitted by each Investigator at that member and determine:

(a) Whether an SFI is related to research in which an Investigator is participating; and
(b) Whether an FCOI exists.

5.2 A COI Official may request additional information about an Investigator’s Financial Disclosure Statement to determine if a financial conflict of interest exists.

5.3 An FCOI exists when the COI Official reasonably determines that an SFI held by an Investigator or a Covered Family Member could directly and significantly affect the design, conduct or reporting of the Investigator’s research.

6. CERTIFICATION AND REPORTING

6.1 Federal regulations require members to include specific certifications and agreements regarding this regulation and financial conflicts of interest in each application for funding submitted for PHS-funded research.

6.2 Each member shall comply with the reporting requirements in 42 CFR §50.602 and 45 CFR §94.5, which require members to submit reports to the appropriate federal funding agency within a certain period of time after the member identifies an FCOI related to PHS-funded research.

7. NO EXPENDITURE OF RESEARCH FUNDS

7.1 In cases involving sponsored research, there will be no expenditure of research funds by an Investigator or member unless the COI Official 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.

7.2 In cases of unfunded research, the research shall not begin unless the COI Official 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.

8. MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

8.1 If a COI Official determines that an FCOI exists, the COI Official or designee shall notify the Investigator in writing and work with the Investigator to develop a Management Plan specifying the steps to be taken to manage, reduce or eliminate the FCOI.

8.2 Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate an Investigator’s FCOI include, but are not limited to:

(a) Public disclosure of the FCOI;

(b) For research projects involving human subjects research, disclosure of the FCOI to the participants;

(c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research against bias resulting from the FCOI;

(d) Modification of the research plan or research activities;

(e) Requiring a change in personnel and/or responsibilities for all or a portion of the research activities;

(f) Disqualification of personnel from participation in that portion of the research activities that would be affected by the FCOI;

(g) Reduction or elimination of the financial interest (e.g., sale of an equity interest);

(h) Severance of relationships that create an FCOI.

8.3 A Management Plan must include a description of the following key elements:

(a) The research affected by the FCOI, including if available the project number;

(b) The role and principal duties of the Investigator who has the FCOI;

(c) The conditions or restrictions to be implemented to manage, reduce or eliminate the FCOI;

(d) A statement explaining how the Management Plan will protect the research from bias resulting from the FCOI;

(e) Confirmation of the Investigator’s agreement to abide by the Management Plan;
(f) A statement explaining how the Management Plan will be monitored to ensure compliance and who is responsible for monitoring compliance with the Management Plan; and

(g) Any other information as needed.

8.4 The Management Plan must be signed by the Investigator, the Investigator’s supervisor, and approved by the COI Official.

8.5 In the case of NSF-funded research, if the COI Official determines that imposing conditions or restrictions would be either ineffective or inequitable, and potential negative impacts arising from the FCOI are outweighed by the interests of scientific progress, technology transfer, or the public health and welfare, the COI Official may allow the research to proceed without imposing such conditions or restrictions.

8.6 If an Investigator disagrees with the COI Official’s determination that an FCOI exists, the Investigator may appeal the COI Official’s determination to the CEO, or designee, in writing within 10 business days after receiving the COI Official’s determination. The decision of the CEO, or designee, is final.

9. PUBLIC ACCESSIBILITY

9.1 Each member shall maintain an up-to-date written, enforced FCOI rule and shall make that rule and this regulation available via a publicly accessible website.

9.2 PHS-Funded Research

9.2.1 If a member’s COI Official determines that an FCOI exists that is related to PHS-funded research, the member will make the following information available to the public:

(a) The name of the Investigator;

(b) The title and role of the Investigator in relation to the affected research;

(c) The name of the entity in which the SFI is held;

(d) A description of the SFI that was determined to be an FCOI; and

(e) The approximate dollar value of the SFI. If the dollar value cannot be determined by reference to publicly available prices or another reasonable method, the member shall include a statement to that effect. Dollar values may be provided within ranges, e.g., $0-$4,999; $5,000-$10,000; $10,000-$20,000; $20,000-$50,000; $50,000-$100,000. Amounts over $100,000 may be stated in increments of $50,000.

9.2.2 Members shall make this information available in writing to any requestor within five business days after receipt of a request so long as the following criteria are met:

(a) The SFI was disclosed and is still held by the Investigator;
(b) The member has determined that the SFI is related to PHS-funded research; and

(c) The member’s COI Official has determined that the SFI is an FCOI.

9.2.3 Alternatively, members may make this information available through posting on a publicly accessible website. If a member chooses this option, the member must update the information posted on the website on an annual basis. In addition, for each SFI that is required to be publicly available under this section, the information related to that SFI must be posted on the member’s website within 60 days after the FCOI is identified. The website must contain a statement that the information posted is current and accurate as of the date listed and is subject to updates.

9.2.4 The information required under this section must remain available to any requestor or posted on the Internet for three years after the date of the last expenditure on the research project or, if the research activity is unfunded, three years after the date the project terminates.

9.3 Non-PHS-Funded Research

For each FCOI identified by a member’s COI Official that is not related to PHS-funded research, the member’s COI Official shall retain all information related to the FCOI in a central location and shall make this information available to the public, upon request and as authorized by the Texas Public Information Act, Tex. Gov’t Code, Chapter 552.

9.4 Each member’s COI Official is responsible for coordinating with the member’s public information officer/Coordinator to ensure that all responses to public information requests are made in compliance with federal and state law.

10. RETROSPECTIVE REVIEW

10.1 Noncompliance, Retrospective Review and Documentation for PHS-funded Research

10.1.1 If a member discovers an FCOI related to PHS-funded research that was not timely identified or managed, or if an Investigator fails to comply with a management plan, the member’s COI Official or designee shall, within 120 days after determining noncompliance:

(a) Complete a retrospective review of the Investigator’s research activities and any PHS-funded research project to determine if any PHS-funded research, or portion thereof, conducted during the period of noncompliance, was biased in the design, conduct or reporting of such research; and

(b) Implement any measures necessary, including but not limited to halting the Investigator’s participation in any affected research project, to remediate the noncompliance between the date the noncompliance was identified and the date the retrospective review is completed.
10.1.2 The member’s COI Official or designee shall document each retrospective review, including but not limited to the following key elements:

(a) Project number;
(b) Project title;
(c) Investigator contact(s);
(d) Name of the Investigator with the FCOI;
(e) Entity with which the Investigator has an FCOI;
(f) Reason(s) for the retrospective review;
(g) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
(h) Findings of the review; and
(i) Conclusions of the review (i.e., determination, recommended actions and remedial measures implemented).

10.1.3 If bias is found, the member’s COI Official shall notify the PHS and submit a mitigation report as required by federal law. If necessary, the COI Official shall update the FCOI Reports described in Section 9.2 of this regulation.

10.2 Noncompliance, Retrospective Review and Documentation for All Other Research

If a member’s COI Official discovers an FCOI related to non-PHS-funded research that was not timely identified or managed, the COI Official shall conduct and document a retrospective review as described in Sections 10.1.1 and 10.1.2. If bias is found, the member’s COI Official shall notify the CEO and, if required by law, the COI Official shall also notify the funding agency.

11. RESEARCH THROUGH CONTRACTORS OR SUBRECIPIENTS

11.1 If a member conducts research in cooperation with or through a subrecipient, the member shall enter into a written agreement with the subrecipient to ensure compliance with this regulation and federal law. The written agreement shall incorporate legally enforceable terms that specify whether the FCOI policy of the member or the subrecipient will apply to the subrecipient’s Investigators who will participate in the research and require the subrecipient to cooperate with the member to provide FCOI reports to a sponsoring agency as required by law.

11.2 If the subrecipient’s Investigators must comply with the subrecipient’s FCOI policy, the subrecipient shall certify that its policy complies with federal law. If the subrecipient cannot provide this certification, the agreement shall state that the subrecipient’s Investigators are subject to this regulation’s requirements for disclosing SFIs that are related to the work performed by the subrecipient’s Investigators on behalf of the member.
11.3 If the subrecipient’s FCOI policy applies to its Investigators, the agreement must specify the time periods for the subrecipient to report all identified FCOIs to the member. These time periods shall be sufficient to allow the member to comply with the member’s review and management requirements and all federal reporting requirements.

12. TRAINING, EDUCATION & CERTIFICATION

12.1 Each member is responsible for complying with the training requirements under federal law, see, e.g., 42 C.F.R. §50.604(b); 45 C.F.R. §94.4(b).

12.2 Each Investigator must certify annually that the Investigator is aware of and has read this regulation and any related member rule or procedure and is aware of the Investigator’s responsibilities regarding disclosure of SFIs and of applicable federal regulations.

12.3 Prior to engaging in research on behalf of a member and at least once every four years thereafter, each Investigator shall complete training on this policy and other applicable policies, regulations, rules and laws. In addition, Investigators shall immediately complete training if the system changes this regulation in a manner that affects Investigator requirements.

12.4 An Investigator who is newly employed by a member must complete the requisite training before engaging in any Research or Research Activity on behalf of a member and at least once every four years thereafter.

12.5 If a member’s COI Official determines that an Investigator is not in compliance with this regulation or a management plan agreed upon by the Investigator and the member, the Investigator must immediately complete training on this regulation and other applicable policies, regulations, rules and laws.

12.6 Each member’s COI Official or designee shall document an Investigator’s compliance with applicable training requirements. The COI Official or designee shall maintain all documentation related to an Investigator’s compliance with this training requirement in a central location.

13. ENFORCEMENT

13.1 Violations of this regulation or applicable member rules shall be brought to the attention of the Investigator, who will be given an opportunity to comply. The Investigator shall present a proposal for compliance to the member’s COI Official for review and action within 10 business days of the notification of noncompliance. Failure to comply will constitute an intentional violation as discussed in the following paragraph.

13.2 Repeated or intentional violations of this regulation may be reported to the funding agency and the CEO by the COI Official. Sanctions may be imposed by the CEO or designee and may range from a letter of reprimand up to and including termination.
13.3 Cases, including appeals of impending sanctions, involving Investigators employed by a member shall be processed in a manner consistent with normal system policies and regulations, as well as member rules or procedures.

13.4 Cases, including appeals of impending sanctions, involving Investigators not employed by or affiliated with a member shall be referred to the Investigator’s home institution or organization for processing. However, a member may remove an Investigator not employed by or affiliated with the member from participating in a particular research project or activity until any allegations involving an FCOI are resolved.

14. RECORDKEEPING

The COI Official for each member shall maintain all records related to Investigators’ Financial Disclosure Statements and any FCOI determinations and/or Management Plans in a central location. In cases of sponsored research, these records shall be kept for the longer of 3 years from the date of the last expenditure submitted in the case of sponsored research or as required by applicable federal law, see, e.g., 45 C.F.R. §§74.53(b), 92.42(b). For the case of non-sponsored or unfunded research, these records shall be kept for the longer of 3 years from the date the research ended or as required by law.

15. AUDIT

Each member shall provide for regular audits of SFI disclosure statements and related documents and reports to determine individual and institutional compliance with this regulation.

Related Statutes, Policies, or Requirements

42 C.F.R. Part 50, Subpart F
45 C.F.R. Part 94
21 C.F.R. Parts 54, 312,314, 320,330, 601, 807, 812 and 860

National Science Foundation Grant Policy Manual, Chapter V, §510, eff. July 1, 2005

System Policy 07.01, Ethics

System Policy 15.01, Research Agreements

System Regulation 15.99.03, Ethics in Research and Scholarship

System Policy 31.05, External Employment and Expert Witness

System Regulation 31.05.01, Faculty Consulting, External Employment and Conflicts of Interest
Definitions

Conflict of interest – occurs when an individual’s private interests compete with his/her professional obligations to the system to a degree that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise.

Conflict of Interest (COI) Official – the person designated by the CEO of a member who is responsible for implementing this regulation and the requirements herein for that member.

Contractor – an entity that provides property or services under contract for the direct benefit or use of the Federal Government.

Covered Family Member – includes an Investigator's spouse, dependent child or stepchild, any other person dependent upon the Investigator, and any other person with whom the Investigator has joint financial interests that could be influenced by the Investigator’s actions.

Disclosure of Significant Financial Interests – an Investigator’s disclosure of significant financial interests to the COI Official designated by each member.

Financial Conflict of Interest (FCOI) – a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research or Research Activities.

Examples of FCOIs include, but shall not be limited to:

1. Situations where the Investigator occupies a position in an enterprise doing business in the area of the Investigator’s University.

2. Situations in which an Investigator, while serving as a consultant to an external organization, has access to a colleague’s unpublished, privileged information, such as proposals or papers that have potential value, and the Investigator seeks to provide that information to the external organization.

3. Situations where an Investigator directs students into a research area or other activity from which the investigator intends to realize personal financial gain. A conflict may arise if students are directed to areas of lesser scientific or scholarly merit to enhance the potential for monetary gain or if the financial potential exists only for the investigator.

4. Disclosure or use for personal profit of unpublished information coming from system research or other confidential system sources, or assisting outside organizations by giving them access to such information except as may be authorized by official system policies.

5. Situations in which an Investigator can require others to purchase a product in which the Investigator has a proprietary interest and from which the investigator will receive income.

FCOI Report – an Institution’s report of an FCOI to a federal agency.
Financial Disclosure Statement – the statement that an Investigator is required by this regulation to submit and update to the member’s COI Official on behalf of the Investigator or a Covered Family Member.

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

Institution – any member that submits a proposal or that receives research funding for Research or Research Activities that are subject to this regulation.

Institutional Responsibilities – an Investigator’s professional responsibilities within the Investigator’s field of discipline on behalf of a member, including teaching, research, research consultation, professional practice, committee memberships, and service on panels such as an Institutional Review Board (IRB). This term includes consulting and other external employment approved under System Regulation 31.05.01, Faculty Consulting, External Employment and Conflicts of Interest. However, this term does not include external employment approved under System Regulation 31.05.02, External Employment.

Investigator – the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of Research or Research Activities.

Manage – taking action to address an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI – a project director or principal Investigator of a sponsored research project; for purposes of this regulation, the PD/PI is included in the definitions of senior/key personnel and Investigator.

Research or Research Activities – any systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research, scholarship (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). The term also includes educational activities funded by the National Science Foundation (NSF) or proposed for funding by NSF.

Senior/Key Personnel – the PD/PI and any other person identified as senior/key personnel by a member in a grant application, progress report, or any other report submitted to a federal agency by the member pursuant to the requirements in this regulation.

Significant Financial Interest – a financial interest, including but not limited to one or more of the following interests, of the Investigator (and those of the Investigator’s Covered Family Members) that reasonably appears to be related to the Investigator’s Institutional Responsibilities:

(a) With regard to any publicly traded entity, a Significant Financial Interest exists if 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. 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 includes any stock, stock option, or other
ownership interest, as determined through reference to public prices or other reasonable measures of fair market value:

(b) With regard to any non-publicly traded entity, a **Significant Financial Interest** exists if 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 (or the Investigator’s Covered Family Member) holds any equity interest (e.g., stock, stock option or other ownership interest); or

(c) Intellectual property and royalty interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(d) The occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities; provided, however, that this does not include 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.

(e) Gifts, when the value of a single gift received by the Investigator or a covered family member in the preceding twelve months exceeds $250, or when the aggregated value of multiple gifts received from a single entity within the preceding twelve months exceeds $250, excluding gifts received from a covered family member.

(f) Any fiduciary position held by an Investigator or a covered family member 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 Investigator or covered family member received any form of remuneration or reimbursement for expenses.

The term **Significant Financial Interest** does not include:

(a) Salary, royalties or other remuneration paid by a member to the Investigator if the Investigator is currently employed or otherwise appointed by the member, including intellectual property rights assigned to the system or its member and agreements to share in royalties related to such rights;

(b) 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;

(c) 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;

(d) 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; or
(e) 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.

Appendices

Appendix A – Model Rule Template for System Members
Appendix B – Model Template for Financial Disclosure Statement

Contact Office

Office of General Counsel/System Ethics & Compliance Office
(979) 458-6120

1. PURPOSE AND BACKGROUND

1.1 The System recognizes its responsibilities as a public organization to encourage interaction between its employees and the public and private sectors as an important component of its research, instructional and service activities. The System encourages the recruitment, retention and recognition of individuals with creative abilities who can contribute to technology transfer and interactions with the business community and public entities consistent with their primary commitment to the System. The System and its employees are also committed to conducting themselves and their activities in a manner consistent with the highest standards of integrity and ethics.

1.2 These guidelines define the general regulations and procedures regarding conflicts of interest in relation to sponsored research. Their purpose is to protect the credibility and integrity of System researchers and staff, as well as component universities and agencies themselves, so that public trust and confidence in their sponsored research activities are maintained. System components have a responsibility to manage, reduce or eliminate any actual or potential conflicts of interest that may arise due to a financial or other personal interest of an investigator. Therefore, the System requires that investigators disclose any significant financial interest that might create a real or potential conflict of interest in relation to a sponsored project.

1.3 These guidelines apply specifically to research conducted under contracts and grants from the National Science Foundation (NSF) and the Public Health Service (PHS); however CEOs may, at their option, extend the application of these guidelines to all sponsored research.

1.4 In addition to issues addressed in these regulations, there may be ethical considerations that are distinct and separate from conflict of interest questions.
2. DEFINITIONS

2.1 A potential conflict of interest occurs when an individual's private interests compete with his/her professional obligations to the System to a degree that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. This regulation is to address such conflicts when a significant financial interest reasonably appears to affect or bias the design, conduct or reporting of research or educational activities funded or proposed for funding to sponsoring agencies.
2.2 *Investigator* means the principal investigator/project director, co principal investigator, and any other person affiliated with the System who has authority and responsibility for the design, conduct or reporting of research or educational activities funded or proposed for funding to sponsoring agencies. In this context, "Investigator" also includes the investigator's spouse and dependent children.

2.3 **Significant Financial Interest**

2.3.1 Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria from profit making enterprises); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). These regulations adhere to the definitions put forth in the guidelines of the National Science Foundation and the Department of Health and Human Services, which say that the possibility of a potential conflict of interest exists when financial interests in business enterprises or entities meet the following conditions:

1. An equity interest that when aggregated for the Investigator and the Investigator’s spouse and dependent children, meets both of the following tests: exceeds $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and represents more than a five percent ownership interest in any single entity, or

2. Salary, royalties or other payments that when aggregated for the Investigator and the Investigator’s spouse and dependent children over the next twelve months, are expected to exceed $10,000.

2.3.2 The term does not include:

1. Salary, royalties or other remuneration from the System;

2. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

3. Income from service on advisory committees or review panels for public or nonprofit entities.

2.3.3 Examples of Conflict of Interest, include, but are not limited to, the following:

Example 1. Situations where a substantial body of research that could and ordinarily would be conducted by the investigator within a System component is diverted elsewhere.

Example 2. Situations where the investigator occupies a position in an enterprise doing business in the area of the investigator's University.
Example 3. Relationships that might enable investigators to influence a System component's interactions with outside organizations in ways that may lead to personal gain, to the taking of improper advantage by anyone, or the improper diversion of a System component's assets from the primary missions of a System component, including the time and talents of faculty and staff.

Example 4. Situations in which an investigator, while serving as a consultant to an external organization, has access to a colleague’s unpublished, privileged information, such as proposals or papers that have potential value, and the investigator seeks to provide that information to the external organization.

Example 5. Situations where an investigator directs students into a research area or other activity from which the investigator intends to realize personal financial gain. A conflict may arise if students are directed to areas of lesser scientific or scholarly merit to enhance the potential for monetary gain or if the financial potential exists only for the investigator.

Example 6. Disclosure or use for personal profit of unpublished information coming from System research or other confidential System sources, or assisting outside organizations by giving them access to such information except as may be authorized by official System policies.

Example 7. Consultation that imposes obligations that conflict with the System Policy on patents (System Policy 17.02) or with a System component's obligations to research sponsors.

Example 8. Situations in which an investigator can require others to purchase a product in which the investigator has a proprietary interest and from which the investigator will receive income.

3. GUIDELINES

Each component university and agency of the System that performs research or educational activities funded by grants and contracts shall establish rules and procedures for the disclosure by researchers of financial interests that might reasonably appear to be directly and significantly affected by the research or educational activities funded under the grant or contract. Such rules and procedures shall address the following issues related to the disclosure and review of such interests.
3.1—Disclosure of Financial Interests

The possibility of a potential conflict of interest should be noted and disclosed by the investigator at the earliest possible stage, and no later than at the time of proposal submission. If a potential conflict of interest does exist with a proposed or funded project, each investigator is required to disclose the following information about any entity which would reasonably appear to have a financial interest that would be directly and significantly affected by the research or educational activities being funded:

(1) the names of affected corporations, both for profit and not for profit, for which the person serves as a member of the governing board in the capacity of a director, advisory director, trustee, or otherwise;

(2) the names of affected corporations for which the person serves as an officer;

(3) the name of affected partnerships, limited partnerships, proprietorships, or other business associations of which the person is a partner, general or limited partner, joint venturer, or owner;

(4) the amount of any compensation received for services related to (1), (2), and (3) above, including any benefits, direct or indirect (reported by range of amounts) and benefits received for intellectual property rights (e.g., patents, copyrights, and royalties from such rights);

(5) affected business entities in which the person holds a controlling interest or is the principal shareholder;

(6) whether the person is employed by any affected business entities described in (1) through (5) above that have any relationship to the System or any of its components, and a brief description of such relationship.

3.1.1—The information should be provided for investigators, their spouses, and their dependent children.

3.1.2—Questions regarding specific potential conflict of interest situations may be clarified by consulting with an individual or office designated by the CEO. The System Office of General Counsel may be consulted when needed.

3.1.3—Each investigator shall complete separate Significant Financial Interests Disclosure Forms for himself/herself, his/her spouse and his/her dependent children, attaching all required supporting documentation.
3.1.4 All pertinent Significant Financial Interests must be disclosed at the time each proposal with potential conflict of interest is submitted for internal routing. Annual updates must be filed by all investigators by August 31 of each year, by filing a supplemental disclosure form through the Department Head and College Dean to the Director of Sponsored Projects.

3.1.5 Subawardees, contractors, or collaborators included in proposals submitted by the component shall certify that their organization has a Conflict of Interest Policy in compliance with the Federal regulations prior to the submission of the proposal.

3.2 Review of Disclosure

3.2.1 The CEO shall designate an officer who shall conduct an initial review of all financial disclosures to determine if any disclosed Significant Financial Interest could affect the design, conduct or reporting of the proposed sponsored project. If the initial determination is made that there may be a potential for conflict of interest covered by this Regulation, the investigator will be notified and the Disclosure packet will be referred to the component Conflict of Interest Review Committee (CIRC).

3.2.2 Conflict of Interest Review Committee members and chair are appointed by the CEO or designee. The CIRC shall be composed of researchers representing a cross section of disciplines and a research administrator.

3.2.3 The CIRC shall determine what conditions or restrictions, if any, should be imposed by the institution to manage actual or potential conflicts of interest arising from disclosed Significant Financial Interests.

3.2.4 Prior to consideration by the CIRC, the Investigator, in cooperation with the Investigator's supervisor, shall develop and present to the CIRC a Resolution Plan detailing the proposed steps that will be taken to manage, reduce or eliminate any actual or potential conflict of interest presented by the Significant Financial Interest. The Resolution Plan shall include as appropriate:

1. public disclosure of Significant Financial Interests;
2. review of research protocol by independent reviewers;
3. monitoring of research by independent reviewers;
4. modifying the research plan;
5. disqualification from participating in all or a portion of the research funded;
6. divestiture of significant financial interests; and
(7) severance of relationships that create actual or potential conflicts of interest.

3.2.5 The CIRC shall review the Resolution Plan and approve it, or where appropriate, add or delete conditions or restrictions.

3.2.6 If the CIRC determines that imposing the above referenced conditions or restrictions would be inequitable, or that the potential negative impacts that may arise from a Significant Financial Interest are outweighed by interests of scientific progress, technology transfer or the public health and welfare, the CIRC may recommend that the research go forward without imposing such conditions or restrictions but managed with appropriate monitoring of the research to ensure that the financial interest does not bias the project. In cases where the Investigator feels that the CIRC decision was unfair, the case may be appealed to the CEO who shall make the final decision regarding resolution. All non-resolved conflicts will be immediately reported to the funding agency or agencies.

3.2.7 The approved Resolution Plan shall be incorporated into a Memorandum of Understanding (MOU) that details the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the Business Enterprise or Entity. The Memorandum of Understanding shall be signed by the Investigator, the Investigator's supervisor and the Chairperson of the CIRC. Actual or potential conflicts of interests will be satisfactorily managed, reduced or eliminated in accordance with these Guidelines prior to the expenditure of any funds under the award, or these actual or potential conflicts of interest will be disclosed to the sponsoring agency for action.

3.2.8 A CEO may establish a plan for review that does not involve a standing CIRC, provided all elements of disclosure and review are observed and that an ad hoc committee is named to handle unresolved questions of financial conflict.

3.3 Record Keeping

Records of Investigator financial disclosures and of actions taken to manage actual or potential conflicts of interest shall be retained by the System component until 3 years after the termination or completion of the award to which they are related, or the resolution of any government action involving those records.

3.4 Enforcement

3.4.1 Apparent oversights or violations of this regulation and applicable university or agency rules shall be brought to the attention of the Investigator, who will be afforded an opportunity to comply. The Investigator shall present the proposed correction to the CIRC for review and action within 30 calendar days of the notification. Failure to comply will constitute an intentional violation, as discussed in the following paragraph.
3.4.2 Repeated or intentional violations of this regulation may be reported to the funding agency and the CEO by the CIRC if not corrected. Sanctions may be imposed by the CEO and may range from a letter of reprimand to the removal of an Investigator from an ongoing project.

3.4.3 Cases that involve investigators affiliated with a System component and which include the possibility of scientific or academic misconduct shall be processed in a manner consistent with System Regulation 15.99.03, “Ethics in Research and Scholarship.

3.4.4 Cases that involve investigators not affiliated with a System component and which include the possibility of scientific or academic misconduct shall be processed in a manner consistent with their home institution's or organization's policies and procedures.

3.4.5 Appeals of impending sanctions for investigators shall follow normal System or component procedures. These may include a request for a hearing by the Committee on Academic Freedom, Responsibility and Tenure, as provided in the System Policy 12.01, Academic Freedom, Responsibility and Tenure.

3.4.6 Appeals of impending sanctions for investigators not affiliated with a System component shall follow the appeals process at their home institution or organization.

CONTACT FOR INTERPRETATION: Office of General Counsel

HISTORY: New (no previous APRM)
Rule Statement

[Insert System Member] is committed to conducting research and educational activities in a manner consistent with the highest standards of integrity and ethics. This rule is adopted to promote objectivity in research and to ensure that the research and educational activities are conducted in a manner free from bias resulting from financial conflict of interest.

Reason for Rule

This rule implements the requirements of system regulation 15.01.03.

Procedures and Responsibilities

1. APPOINTMENT OF CONFLICT OF INTEREST OFFICIAL

   The [President/CEO] appoints [insert title] or his or her designee as the Conflict of Interest Official (COI Official) for [insert system member name]. The COI Official shall perform the duties established in system regulation 15.01.03 relating to the review of financial interest disclosures and the management and reporting of financial conflicts of interest.

2. DISCLOSURE AND REVIEW

   Each Investigator shall submit Financial Disclosure Statements to the [insert system member] COI Official as required in system regulation 15.01.03.

   2.1 In accordance with system regulation 15.01.03 and federal law, the COI Official will review all financial disclosure statements by Investigators and determine whether any disclosed SFI is related to the Investigator’s research and whether a Financial Conflict of Interest (FCOI) exists. If an FCOI exists, the COIOfficial will develop a Management Plan specifying the actions that will be taken to manage, reduce or eliminate the FCOI. All FCOIs identified by the COI Official
will be satisfactorily managed, reduced or eliminated prior to the expenditure of any sponsored research funds or prior to the start of an unfunded Research Activity.

2.2 In accordance with system regulation 15.01.03, the COI Official may appoint a Conflict of Interest Review Committee (CIRC) to assist in the determination of whether an FCOI exists. If the COI Official appoints a CIRC, the CIRC must be composed of Investigators representing a cross-section of disciplines and at least one research administrator. The COI Official and/or CIRC may involve the Investigator to assist in determining whether an SFI is related to the Investigator’s Research or Research Activities. The System Ethics and Compliance Officer and/or the Office of General Counsel may be consulted as appropriate.

3. MONITORING

Each Investigator conducting Research under a Management Plan shall comply fully and promptly with the Plan. The COI Official shall be responsible for conducting periodic reviews of Financial Disclosure Statements and Management Plans to determine individual and institutional compliance. The COI Official shall report instances of noncompliance as required in system regulation 15.01.03 and federal law.

4. TRAINING AND CERTIFICATION

Investigators shall complete training as required in system regulation 15.01.03. In addition, each Investigator shall annually certify that the Investigator is aware of and has read system regulation 15.01.03 and this rule and is aware of the Investigator’s responsibilities regarding disclosure of SFIs and applicable federal regulations.

5. PUBLIC ACCESSIBILITY

5.1 The COI Official shall ensure that this rule is available through a publicly accessible website.

5.2 [System Members choose either Option A or Option B, as written below, not both]

**OPTION A: PHS-Funded Research**

If the COI Official determines that a Financial Conflict of Interest exists that is related to PHS-funded research, the COI Official will make the following information available to the public through the [insert System Member] website:

(a) The name of the Investigator;
(b) The title and role of the Investigator in relation to the affected research;
(c) The name of the entity in which the SFI is held;
(d) A description of the SFI that was determined to be an FCOI; and
(e) The approximate dollar value of the SFI. If the dollar value cannot be
determined by reference to publicly available prices or another reasonable
method, the system member shall include a statement to that effect. Dollar
values may be provided within ranges, e.g., $0-$4,999; $5,000-$10,000;
$10,000-$20,000; $20,000-$50,000; $50,000-$100,000. Amounts over
$100,000 may be stated in increments of $50,000.

The COI Official shall ensure that the information posted to the [insert system
member] website complies with federal law and system regulation 15.01.03.

**OPTION B: PHS-funded Research**

If the COI Official determines that a Financial Conflict of Interest exists that is
related to PHS-funded research, the COI Official shall coordinate with the [public
information officer/coordinator] to make the following information available in
writing to any requestor within five business days after receipt of a request, so
long as the Investigator still holds the SFI:

(a) The name of the Investigator;
(b) The title and role of the Investigator in relation to the affected research;
(c) The name of the entity in which the SFI is held;
(d) A description of the SFI that was determined to be an FCOI; and
(e) The approximate dollar value of the SFI. If the dollar value cannot be
determined by reference to publicly available prices or another reasonable
method, the system member shall include a statement to that effect. Dollar
values may be provided within ranges, e.g., $0-$4,999; $5,000-$10,000;
$10,000-$20,000; $20,000-$50,000; $50,000-$100,000. Amounts over
$100,000 may be stated in increments of $50,000.

5.3 Non-PHS-funded Research

For all public information request related to non-PHS funded research, the COI
Official shall coordinate with the [public information coordinator/officer] to
ensure that responses to requests comply with Texas Government Code, Chapter
552.

6. OTHER CONSIDERATIONS

In addition to the issues addressed in system regulation 15.01.03 and this rule, there
may be other ethical considerations that are separate and distinct from conflict of interest
questions, including but not limited to those relating to external employment and conflict
of commitment. The primary responsibility of employees of [insert system member] is
the accomplishment of the duties and responsibilities assigned to the employee’s position
of appointment. External consulting or other outside employment should not interfere
with those duties and responsibilities as set forth in system policies and related
regulations.
Related Statutes, Policies, or Requirements

42 C.F.R. Part 50, Subpart F

45 C.F.R. Part 94

21 C.F.R. Parts 54, 312,314, 320,330, 601, 807, 812 and 860

National Science Foundation Grant Policy Manual, Chapter V, §510, eff. July 1, 2005

Supplements:

System Policy 15.01 – Research Agreements
System Regulation 15.01.03 – Financial Conflict of Interest in Research

Cross reference:

System Policy 07.01 – Ethics
System Policy 31.05 – External Employment and Expert Witness
System Regulation 31.05.01 – Faculty Consulting, External Employment and Conflicts of Interest
System Regulation 31.05.02 – External Employment

Definitions (Optional)

Definitions of terms used in this rule are found in System Regulation 15.01.03.

Contact Office (Required)

Contact Office
(XXX) XXX-XXXX
FINANCIAL DISCLOSURE STATEMENT
as required by System Regulation 15.01.03

Name: 

Date: 

Title: 

College/Department: 

- If statement is made on behalf of a Covered Family Member, use the following format for the “Title” field: “Covered Family Member, [spouse, son, or daughter of (insert Investigator Name)].”

RESEARCH OR RESEARCH ACTIVITY

<table>
<thead>
<tr>
<th>Project #</th>
<th>Project Title &amp; Description</th>
<th>Funding Agency/Entity</th>
<th>Budget (in whole $)</th>
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- If research is unfunded, use “N/A” for the “Funding Agency/Entity” field and “$0” for “Budget” field. If necessary add additional rows or pages.

SIGNIFICANT FINANCIAL INTERESTS (SFIs)

<table>
<thead>
<tr>
<th>Source</th>
<th>Description (e.g., salary, royalty interest, sponsored travel)</th>
<th>Value (in whole $)</th>
<th>Related to Research?</th>
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- If necessary add additional rows or pages.

CERTIFICATION

I certify that the information provided in this form is true and correct to the best of my knowledge. I further certify that I have read System Regulation 15.01.03 – Financial Conflict of Interest in Research and rule 15.01.03. _1 – Financial Conflict in Interest in Research and that I am aware of my responsibilities and applicable federal regulations regarding disclosure of Significant Financial Interests.

Signature: ________________________________ Date: ________________________________