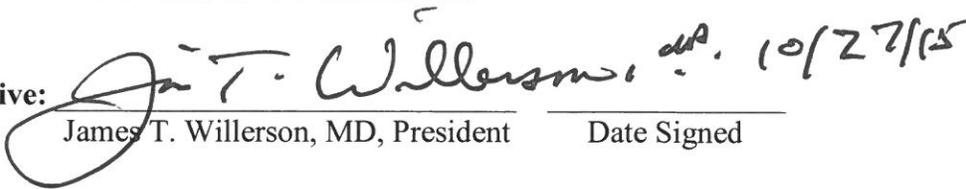


RESEARCH CONFLICTS OF INTEREST

Approval of Responsible Executive:


James T. Willerson, MD, President

Date Signed

Effective Date: August 24, 2012

Reviewed: October 2015

Next Review Date: August 2018

PURPOSE

Texas Heart Institute ("Institute") is committed to ensuring that financial interests of investigators and the Institute do not affect, or appear to affect, the design, conduct or reporting of research or compromise the protection of human subjects. Therefore, members of the Institute community conducting research using public or private funding from any source must disclose potential conflicts of interest and, when appropriate, work cooperatively with designated Institute staff to develop and implement plans to manage, reduce or eliminate conflicts of interest. The purpose of this policy is to describe the Institute's procedures for identifying, reporting, evaluating, and managing financial relationships that could affect or appear to affect the objectivity or integrity of research conducted by investigators and research staff employed or affiliated with the Institute. Such procedures shall comply with requirements established by the United States Department of Health and Human Services, Public Health Service (PHS) (Title 45 CFR Part 50, Subpart F), for research funding.

SCOPE

These policies and procedures apply to all investigators, employees, affiliated staff and others who manage, oversee and conduct research for Texas Heart Institute.

DEFINITIONS

Research is a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. Research encompasses basic and applied research and product development.

Covered Individual is an individual, including the principal investigator, co-investigator, project director, and any other person identified as senior/key personnel in a grant application, research protocol, or report, and others who direct or can materially influence the Research. The principal investigator is responsible for determining if other research staff (e.g., research nurses, research coordinators, data managers, graduate students, postdoctoral fellows, etc.) are Covered Individuals. Hereinafter, the term "Investigator" (when capitalized in this Policy) shall have the same meaning as the term Covered Individual.

PHS Awarding Component is the organizational unit of the U.S. Public Health Service ("PHS") that funds the Research.

Covered Family Member, for purposes of disclosure, includes (1) a spouse; (2) a dependent child or stepchild; (3) any other person financially dependent on the covered individual; and (4) any other person with whom the covered individual has joint financial interests such that an objective third party could reasonably conclude that the covered individual's decisions or other exercise of professional responsibilities at the institution could be influenced by the effect of that action on the person's financial interest. A person described by Subdivision (3) or (4) is a covered family member without regard to whether a legal or biological family relationship exists with the covered individual. If the covered individual is in doubt, the covered individual should resolve the doubt in favor of disclosure.

With regard to the definitions above, 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.

Significant Financial Interest (SFI) is a financial interest consisting of one or more of the following interests of the Covered Individual or Covered Family Member that reasonably appears to be related to the Investigator's institutional responsibilities:

- For any publicly traded entity, the total value of any remuneration (including salary, consulting fees, honoraria, paid authorship) received from the entity in the 12 months preceding the disclosure and the value of any equity interest (any stock, stock option, or other ownership interest based on fair market value) in the publicly traded entity as of the date of disclosure exceeds \$5,000.
- For any non-publicly traded entity, the total value of any remuneration received from the entity in the 12 months preceding the disclosure exceeds \$5,000, or equity interest (e.g., stock, stock option, or other ownership interest) of any amount in the non-publicly traded entity.
- Intellectual property rights, upon receipt of income related to such rights and interests.
- Remuneration or payment for expenses for service as an officer, director or fiduciary for a for profit or nonprofit entity in the preceding 12 months.
- Gifts received in the preceding 12 months that exceed \$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 the value and source of the gifts.
- Reimbursed or sponsored travel in the preceding 12 months (see exclusions noted below).

The following are not considered SFI and are excluded from reporting:

- Salary, royalties, or other remuneration paid by the Institute to the covered individual, if the covered individual is currently employed or otherwise appointed by the Institute.
- 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.
- Income from service on advisory committees or review panels 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.

- 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.
- Travel reimbursed or 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.

CEO is the Chief Executive Officer or, if this position is vacant, the President of Texas Heart Institute.

PROCEDURES

A. Education

The covered individual must complete training related to this policy and applicable policies, regulations, and laws at least once every 4 years. A covered individual who is new to the institution must satisfy this training requirement before engaging in Research at the Institute.

A covered individual must complete the training immediately if the institution finds that the individual is not in compliance with this policy or the individual's management plan, or if the institution revises this policy in a manner that affects the individual's duties.

The CEO is responsible for ensuring that appropriate faculty, staff, trainees, and other persons participate in training in regard to this policy and applicable laws.

Each covered individual must acknowledge annually that the individual is aware of and has read this policy and is aware of the covered individual's responsibilities regarding disclosure of significant financial interests and of applicable federal regulations.

B. Research Conflicts of Interest Disclosure by Covered Individuals

A covered individual shall submit or update a financial interest disclosure statement that identifies all Research projects in which the covered individual is engaged at the time of the disclosure. The disclosure statement will identify each significant financial interest of the individual and covered family member that reasonably appears to be related to the individual's institutional responsibilities. The financial disclosure should be submitted according to the following schedule:

- Not later than the 30th day of initial employment, covering the 12 months preceding the date of disclosure;
- Annually not later than November 15; and
- Not later than 30 days after acquiring a new financial interest that requires disclosure, such as receiving payments, an equity interest, intellectual property rights, or royalties that would require disclosure on an annual financial interest statement.

A covered individual who is planning to participate in a PHS-funded Research project shall submit a financial interest disclosure statement not later than the time of application for PHS-funded Research, except that an individual who is new to the institution and who is planning to participate in an on-going PHS-funded Research project shall submit the statement not later than the 30th day of initial employment.

The President or the CEO may require a covered individual to submit additional disclosures.

If a covered individual discloses payments, intellectual property interests, or royalties, the covered individual must provide a copy of any related agreement, contract, offer letter, or other documentation upon request from the President, CEO, or any other person or entity with administrative responsibility for reviewing financial interest disclosure statements or approving a related management plan.

In making disclosures under this section, the covered individual shall:

- disclose dollar amounts in rounded, whole dollars;
- when describing a source, provide the name and principal address for the source; and
- distinguish among information pertaining to the covered individual and covered family members whose financial interests and activities are also disclosed by the covered individual.

C. Investigator Research Conflicts of Interest Certification

All grants and research contracts submitted through the Office of Research Administration ("ORA") and Research requiring review by an Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) must include a completed Research Conflicts of Interest Certification for all key personnel responsible for the design, conduct or reporting of the proposed Research. The principal investigator ("PI"), defined as the individual who has primary responsibility for design, management and reporting of applicable Research, is responsible for identifying key personnel who must complete the certification and ensuring completion of the certifications.

Covered Individuals initiating Research not reviewed by the IRB or the IACUC, and not requiring the review and approval of ORA, should disclose any potential research conflicts of interest directly to the CEO using the Research Conflict of Interest Disclosure form.

Investigators and/or related colleagues or staff who indicate potential conflicts in the Research Conflict of Interest Certification Form must complete a Research Conflict of Interest Disclosure Form. This disclosure must be submitted with the Certification to the ORA and forwarded to the CEO for review.

D. Third Party Identification of Potential Research Conflicts of Interest

Although investigators are responsible for certifying whether significant financial interests exist, and, as applicable, disclosing such potential conflicts of interest with their Research, third parties (e.g., other employees, department directors, administrative persons, or representatives of pharmaceutical companies) may also report potential conflicts of interest. Such reports may be made directly to the Office of the CEO (Compliance@texasheart.org) or to the ORA (ResearchAdmin@texasheart.org) via email or anonymously via phone (832-355-3400).

E. Review Process

The CEO will send each financial interest disclosure statement to the RCOI Advisory Group, which will review the information and provide an assessment to the CEO as to whether any significant financial interest disclosed is related to Research in which the covered individual is engaged. A significant financial interest is related to Research in which the covered individual is

engaged if the RCOI Advisory Group or the CEO reasonably determines that 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.

If the RCOI Advisory Group or the CEO determines that the significant financial interest disclosed is related to Research in which the covered individual is engaged, the CEO, in consultation with the President will determine whether a financial conflict of interest exists and propose to the President a management plan to manage, reduce or eliminate the financial conflict of interest. A financial conflict of interest exists when the CEO agrees with the RCOI Advisory Group determination that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the Research.

The CEO or President makes the final determination regarding what actions are required to manage, reduce or eliminate conflicts of interest. If the Research involves human research subjects, appropriate information will also be made available to the IRB to consider in its review of the clinical research application as provided in (G) below.

The approval of the President is required for employees who are pursuing sponsored research agreements or licensing agreements for intellectual property with entities where they have equity or serve as a board member, officer or key employee.

F. Management of Financial Conflicts of Interest

The CEO is responsible for overseeing the development and implementation of research conflict of interest management plans. He/she may delegate these oversight responsibilities to the RCOI Advisory Group, but management plans developed by the RCOI Advisory Group must be approved by the CEO or President prior to implementation.

While evaluation and management of the potential conflict is the goal, it is recognized that some conflicts may not be manageable. Nonetheless, when the investigator has a unique capability and must be involved with a critical research project to ensure its proper performance, it may be appropriate for the Research to go forward with a well-defined and carefully monitored management plan.

Neither the institution nor a covered individual may expend research funds unless the CEO 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.

A management plan may impose any condition and prescribe any action 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. Examples of conditions or actions that may be prescribed include, but are not limited to:

- public disclosure of the conflict of interest in presentations and publications;
- for human subjects research, direct disclosure of the conflict of interest to research participants;

- appointment of an independent monitor with authority to take measures to protect the design, conduct, and reporting of Research against bias, or the appearance of bias, resulting from the conflict of interest;
- modification of the Research plan;
- change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;
- divestiture or reduction of the financial interest; or
- severance of relationships that create an actual or potential financial conflict of interest.

The management plan must be in the form of a written agreement and must provide that the covered individual acknowledges receipt of the plan and understands the requirements of this policy and the required actions and other terms of the plan, including the time frames for required actions; and clearly identify each specific person responsible for monitoring compliance with the management plan. Each person conducting Research under a management plan shall comply fully and promptly with the plan, and each person identified in the management plan as having responsibility for monitoring compliance with the plan shall carefully and fully monitor that compliance.

If Research is ongoing and a new covered individual discloses a significant financial interest related to that Research or any other covered individual discloses a new significant financial interest related to that Research, the CEO shall, 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, after consultation with the President, an interim management plan or implement other interim measures to ensure the objectivity of the Research.

Research continuation may be allowed in the face of a conflict depending upon (1) the nature of the science, (2) the specific financial interest, (3) the magnitude of the interest and the degree to which it is related to the Research, and (4) the extent to which the interest is amenable to effective oversight and management.

In cases where sponsored research agreements or licensing agreements for intellectual property are made with an entity where an employee owns an interest or serves as an employee, officer or member of the board of directors, the plan must also be approved by the President.

The RCOI Advisory Group will review existing management plans on an annual basis to ensure that conflicts continue to be managed appropriately.

G. Research Involving Human Participants

While the thresholds for disclosure are the same for all types of Research, additional diligence in evaluation and management is required for Research with potential risks to human subjects or with potential implications for medical care and the practice of medicine. The RCOI Advisory Group applies the rebuttable presumption standard when reviewing financial conflicts of interest in human subjects research, i.e., individuals with significant financial interests may not conduct the Research unless there are compelling circumstances. Compelling circumstances include factors such as unique investigator expertise; unique institutional resources; unique access to particular patient populations; nature of science; level of risk for human subjects; and degree to which financial interests and Research are linked. While this policy is consistent with

simultaneous review of a given Research proposal by both RCOI Advisory Group and the IRB, the RCOI Advisory Group review process will be completed and the report forwarded to the IRB before the protocol receives final review and approval. IRB may request revision of the recommended management plan if it feels the conflict cannot be managed or the proposed plan is insufficient. These two committees will work in conjunction with each other and the RCOI Advisory Group process should provide sufficient information to ensure that, as applicable, conflicts are managed and research participants are informed. The investigator will comply with any requirements regarding RCOI made by the IRB of record for the protocol.

H. Noncompliance with Research Conflicts of Interest Policies

The Institute anticipates that investigators will comply fully and promptly with this policy. The CEO is responsible for investigating instances of non-compliance and determining whether to impose sanctions and what sanctions will be applied. In making these determinations, he/she may consult with the applicable department director, the President, the RCOI Advisory Group or other appropriate individuals.

Examples of non-compliance include, but are not limited to:

- failure to submit required statements or updates;
- failure to provide additional information requested by the CEO or RCOI Advisory Group;
- knowingly filing an incomplete, erroneous or misleading statement;
- failing to comply with conflict of interest management plans; or
- knowingly violating applicable laws or regulations.

If the CEO learns of a significant financial interest that was not timely disclosed or was not timely reviewed, the CEO shall, not later than the 60th day after learning of the interest: (1) determine whether the significant 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.

In addition, if a financial conflict of interest was not timely identified or managed, or if a covered individual fails to comply with a management plan, the CEO shall, not later than the 120th day after determining noncompliance: 1) complete and document a retroactive 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 regarding the covered individual's participation in the Research between the date that the noncompliance is identified and the date the retroactive review is completed.

Failure on the part of an investigator to comply with this policy may result in disciplinary action and/or sanctions; examples of possible sanctions include formal reprimand; non-renewal of appointment; termination of appointment for good cause; and/or any other enforcement action mandated by the applicable government granting agency. An investigator who is the subject of a disciplinary action may appeal such action in accordance with established Institute grievance and/or disciplinary procedures.

For a covered individual who is not an employee of the institution, compliance with this policy is a condition of participating with the Institute in the capacity that qualifies the person as a covered

individual. The Institute may require the individual to execute a document certifying that the individual knows that compliance with this policy is a condition of participation.

For PHS-covered Research projects, the retroactive review shall 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 regulations.

If the failure to comply has resulted in a bias of the design, conduct or reporting of Research, the CEO will take appropriate corrective actions and instruct the Institute's Signing Official, as identified in eraCommons, to promptly notify the PHS Awarding Component of corrective actions to be taken.

If the HHS determines that 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 regulations, 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.

I. Reporting of Research Related Institutional Financial Interests

Significant Institute financial interests developed when the institution receives equity in entities that license its intellectual property are reported by the ORA to the CEO. Financial interests of institutional officials must be disclosed annually to the CEO in the Institute's Disclosure of Conflict of Interest and Related Party Transactions report with the exception of the President who discloses his financial interests to the CEO and the Institute's Board Chairperson. If these individuals have a significant financial interest in a company sponsoring Institute Research, the interests are reported to the CEO.

Covered Individuals also identify institutional financial interests related to their proposed Research, if known, on the applicable Research Conflicts of Interest Disclosure Form.

J. Reporting for PHS-Sponsored Projects

Federal regulations require that each application for funding to the PHS include specific certifications and agreements in regard to this policy and financial conflicts of interest. Federal regulations also require that the institution make the reports required by this policy for PHS-funded Research.

For PHS-sponsored projects, the Signing Official must notify the Awarding Component prior to expending any funds that a conflict of interest exists by submitting a financial conflict of interest report in compliance with 42 CFR Part 50, Subpart F, and 45 CFR Part 94, and must provide assurance the conflict is being managed, reduced or eliminated. The financial conflict of interest report will include 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 Signing Official must file financial conflict of interest reports annually for the duration of the project period as required by federal regulation.

The institution must make information available to HHS or the PHS awarding component as required by federal regulation. Reporting is not required for applications for Phase I support

under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

If conflicts are identified after the initial award is made, the Signing Official must notify the PHS within 60 days of identifying the conflict by filing a financial conflict of interest report as required by federal regulation.

The Signing Official must also promptly notify the PHS Awarding Component of corrective actions taken if an investigator has biased the PHS funded Research.

K. Web Posting of Financial Conflict of Interest Information and Policy

For each covered individual for whom a financial conflict of interest is found to exist by the CEO and 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, the Institute will make information publicly available through a posting on the Internet. This posting will include:

- the covered individual's name;
- the covered individual's title and role with respect to the Research;
- the name of the entity in which the significant financial interest is held;
- the nature of the significant financial interest that constitutes a financial conflict of interest; and
- the approximate value of the significant 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.

The approximate dollar value of the significant financial interest shall be provided within the following ranges if it can be determined by reference to public prices or other reasonable measures of fair market value:

- \$0 - \$4,999;
- \$5,000 - \$9,999;
- \$10,000- \$19,999;
- Amounts between \$20,000 - \$100,000 by increments of \$20,000;
- Amounts above \$100,000 by increments of \$50,000.

The Institute will update the information required by this section annually. 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 Institute will make the information required by this section available not later than the 60th day after the financial conflict of interest is identified.

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.

The information required by this section will remain available on the Internet for three years after its most recent update.

For project directors, principal investigators, and other senior or key personnel on PHS-funded Research, this information must be available on the Internet before PHS funds are expended.

This policy and each update of this policy must be publicly accessible on the Internet.

L. Appeals Process

An investigator may appeal to the CEO if he/she does not concur with the proposed plan for managing/eliminating research conflicts of interest, or if the Research is not permitted to be conducted. A written appeal should be submitted within 30 days of notice of the proposed management plan or denial and include evidence detailing the investigator's concerns and/or compelling circumstances which support his/her claim that the management plan should be revised and/or the Research should go forward.

The CEO will review the appeal and may request the review/advice of the RCOI Advisory. It is, however, the responsibility of the CEO and/or the President to approve, modify or reject any proposed revisions to the conflict of interest management plan. The CEO may also appoint an external ad hoc group to provide an additional level of review in the appeal process and to report its findings and recommendations to the CEO. The decision of the CEO and/or President is final.

M. Contractors and Collaborators

If Research is carried out in cooperation with or through a subcontractor, contractor, or collaborator, including a person identified under federal regulations as a "sub-recipient," the Institute must enter into a written agreement with the contracting party that provides legally enforceable terms that establish whether this policy or the financial conflicts of interest policy of the contracting party applies to the researchers of the contracting party.

If the policy of the contracting party applies to its researchers, the contracting party must certify that its policy is consistent with the requirements of any applicable federal regulations. If the contracting party cannot so certify, the agreement must state that the researchers are subject to this policy as Covered Individuals for disclosing significant financial interests that are directly related to the researcher's work at the Institute.

If the policy of the contracting party applies to its researchers, the agreement must specify the time periods for the contracting party to report identified financial conflicts of interest to the Institute. The time periods must be sufficient for the Institute to make any reports required by federal regulations.

If the policy of the Institute applies to the researchers of the contracting party, the agreement must specify the time periods for the researchers to submit a financial interest disclosure statement to the Institute. The time periods must be sufficient for the Institute to comply with its review, management, and reporting obligations under federal regulations.

N. Records

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 institutional actions, shall be retained in accordance with the Institute's records retention schedule or 3 years after the submission of all required reports relating to a PHS-funded Research project, whichever is later. The Institute will maintain a centralized repository for financial interest disclosure statements, management plans, and related records.

O. Audits

Institute compliance staff, as designated by the CEO, will conduct regular audits of financial interest disclosure statements to determine individual and institutional compliance with this Policy, and submit results of all such audits to the CEO.

CONTACTS

Contact	Telephone	Email/Web Address
Compliance Staff	832-355-3792	Compliance@texasheart.org
Office of Research Administration	832-355-3400	ResearchAdmin@texasheart.org

REFERENCES

- 21 CFR 50, Subpart F- Promoting Objectivity in Research
- 21 CFR Part 94
- NSF Grant Policy Manual Section 510
- 2 CFR part 376—Nonprocurement debarment and suspension (HHS)
- 42 CFR part 50, subpart D—Public Health Service grant appeals procedure
- 45 CFR part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations
- 45 CFR part 79—Program fraud civil remedies
- 45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State, local, and tribal governments

Revision History:

- October 23, 2015
- October 27, 2015