PART C
CONFLICTS OF INTEREST FOR INVESTIGATORS IN HUMAN SUBJECTS RESEARCH

[All terms in Bold are defined either in Part A or this Part C.]

I. Applicability

This Part C of the policy applies to Investigators involved in research involving human subjects.

II. Principles

Federal law and policy require that for federally-funded research studies, the university hosting the research gather information related to each Investigator’s Research Financial Interests (as defined below) that may be affected by the research itself. Although these requirements originated in a concern for assuring the integrity of federally-funded research data, the University is also concerned, as are various professional organizations, with the possible influence of such Research Financial Interests on research integrity and on the safety and welfare of human subjects involved in research protocols, regardless of the source of research funding. The University’s policy in this regard is consistent with prevailing standards for professional conduct, which require that physicians and other licensed professionals not exercise undue influence over patients and clients and act at all times in the best interests of their patients and clients. The University is also concerned about Leadership Roles of Investigators in entities that sponsor research. The University’s policies therefore incorporate those concerns as well.

Consistent with federal laws and the ethical principles of human subjects research, the University seeks to ensure that its Investigators can carry out their responsibilities to protect the rights and welfare of human subjects participating in research projects at the University. Since the University recognizes that Conflicts of Interest may occur during research, this policy is intended to assist Investigators in determining when they have Conflicts of Interest in research, and to guide them in disclosing all potential conflicts and in cooperating with the management or elimination of the conflicts, where necessary. The guidelines and mechanisms, as applied to Investigators and Subrecipient PHS Investigators (as defined below) participating in PHS-Funded Research, are intended to comply with the PHS-Funded Research conflict of interest regulations outlined at 42 C.F.R. Part 50 Subpart F and at 45 C.F.R. Part 94 and should be interpreted consistently with those regulatory requirements and any implementing guidance.

While this policy governs Conflicts of Interest of Investigators, the policy does not regulate disputes between two or more Investigators or between one or more Investigators and the University. Such disputes are to be resolved according to the University’s established dispute resolution procedures.
III. Communication and Training

**Investigators** who may or will participate in human subjects research will receive a copy of this policy, specific information about their obligations to disclose Research Financial Interests, and PHS-Funded Research conflict of interest regulations.

These **Investigators** will also receive training on these topics (i) immediately upon employment or association with the University; (ii) every four years afterwards; (iii) when this policy is revised; and (iv) if and when the University finds that an Investigator is non-compliant with this policy or with a management plan implemented to address a Conflict of Interest.

IV. Process

A. **Timing**

(1) Human Subjects Research-Related Financial and Leadership Disclosure Form C. A Human Subjects Research-Related Financial and Leadership Disclosure Form C (Form C) must be submitted on an annual basis and in response to certain events.

(a) All **Investigators** who may or will participate in human subjects research must complete Form C by January 31st of each year.

(b) Newly hired or affiliated **Investigators** who may or will participate in human subjects research must submit Form C within 60 days of employment or association and at least three weeks prior to the scheduled meeting date of the University’s IRB at which the IRB will review the Investigator’s research protocol. Newly hired or affiliated **Investigators** may not submit any research protocol for review by the IRB before they have submitted Form C to the COI Committee. **Investigators** must thereafter comply with the annual filing deadline of January 31st.

(c) Any **Investigator** who may or will participate in human subjects research must promptly, but no later than 30 days, after the acquisition or discovery of any new Leadership Role or Research Financial Interest or the material modification of any Leadership Role or Research Financial Interest provide an updated Form C.

(d) An **Investigator** planning to participate in PHS-Funded Research must submit Form C prior to the submission of an application for PHS-Funded Human Subjects Research (as defined below).

(2) Other Disclosures.

(a) ** Investigators** must also forward to the COI Committee without delay any amendments or changes that they make to any reports of Research Financial Interests that are submitted to any Sponsor (as defined below) of the research.
In the application for **IRB** approval of a human subjects research protocol, and at the time of continuing review of the protocol, each **Investigator** must attest using the Tulane University Investigator Conflict of Interest Attestation Form that he or she has supplied the **COI Committee** with a complete Conflicts of Commitment and Interest Disclosure Form, including Form C (and any required updates thereto), and must indicate whether the research he or she is conducting could be affected by any of his or her **Research Financial Interests** and/or **Leadership Roles**. The **IRB** will forward a copy to the **COI Committee**. The **IRB** may not approve a human subjects research protocol until each **Investigator** has provided this required information and the **COI Committee** has determined that there is no **Conflict of Interest** or provided assurance regarding management or elimination of the conflict. If, at the time for continuing review of a study, all necessary information has not been provided, no new subjects shall be enrolled in the study. Unless the **IRB** determines that it is in the best interests of the previously enrolled subjects to continue the study and their participation, the study shall not be authorized to continue, and shall not be allowed to continue until such time as all required information has been provided.

**B. Information Required**

Form C requires **Investigators** to report any and all **Leadership Roles** and **Research Financial Interests**. In addition, this form requires **Investigators** to report any and all **Leadership Roles** and **Research Financial Interests** that the **Investigator**’s **Immediate Family** may have in any research or health care-related organization, including any not-for-profit or tax-exempt healthcare related companies or foundations. Further information may be requested by the **COI Committee**. **Investigators** must append to Form C a copy of every report of their **Research Financial Interests** that they are required to submit to any **Sponsor** of research.

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1. The applicable definition of **Immediate Family** can be found in the Definitions section of Part A of the Policy. Pursuant to relevant federal law, the Policy defines the term **Immediate Family** differently for members of the Tulane University Medical Group and other health care providers. Such members and health care providers must refer to the definition of **Immediate Family** that can be found in Part B of this policy regarding such definition. Note that for purposes of evaluating **Vendor** relationships, **Immediate Family** also includes parents, siblings, parents-in-law, and siblings-in-law.

2. All **Investigators** currently conducting research must complete and file an initial Conflicts of Commitment and Interest Disclosure Form, including, in the case of **Investigators** involved in human subjects research, Form C. In the case of an **Investigator**’s receipt of **Research Financial Interests** from any research or health care-related organization, the University may request disclosure from such organization(s) to determine the source of the **Research Financial Interests**.

3. This includes, but is not limited to, financial disclosure reports that must be made to **Sponsors** pursuant to regulations of the United States Food and Drug Administration.
C. **Submission of Forms**

**Investigators** must submit completed disclosure forms through an electronic online process. The online submissions are forwarded to their department chair or the dean if the unit does not have a departmental chair structure. Supervisors, chair or deans, as applicable, are responsible for reviewing the completed Form C prior to its submission to the University’s COI Committee. A list of names of individuals who have not provided the required Form C will be forwarded to the Senior Vice President responsible for their unit.

D. **Review by the COI Committee**

1. **Timing**
   
   (a) **Review of Annual Disclosure Forms.** As promptly as practicable after the January 31st filing deadline, the **COI Committee** will review disclosures and reports, determine whether a conflict exists and implement a management plan if necessary. The **COI Committee** may ask that an **Investigator** who has a potential conflict provide additional information or discuss the matter with the **COI Committee** in person.

   (b) **Review of New and Updated Disclosure Forms.** Within 60 days of receiving an updated disclosure form or a disclosure form from a newly hired or affiliated **Investigator**, the **COI Committee** will complete its review, determine whether a **Conflict of Interest** exists and implement a management plan if necessary.

   (c) **Review of Disclosure Forms from IRB.** As promptly as practicable after receiving a disclosure form from the **IRB**, the **COI Committee** will complete its review, determine whether a **Conflict of Interest** exists and implement a management plan if necessary.

   (d) **PHS-Funded Research.** The **COI Committee** must review current disclosures and reports prior to the expenditure of any funds for **PHS-Funded Research**.

2. **Nature of Review**

   (a) **Generally.** The **COI Committee** will review all disclosures to determine whether any disclosed **Research Financial Interests** or **Leadership Roles** constitute a **Conflict of Interest** with regard to an **Investigator**’s research, that is, whether any disclosed **Research Financial Interest** or **Leadership Role** could compromise or could reasonably be perceived to compromise the **Professional Interests** of the **Investigator**. If one or more **Conflicts of Interest** are identified in this process, then the **COI Committee** shall examine those conflicts to assess the degree of risk they carry with regard to research integrity and the safety and welfare of human subjects. The more significant the **Research Financial Interest** or **Leadership Role** of the **Investigator** in the research being conducted by
that Investigator, the greater the potential risk that the conflicts may inappropriately influence research outcomes and/or subject safety and welfare.

(b) **PHS-Funded Research.** The COI Committee will additionally review the disclosures of Investigators involved in PHS-Funded Research to determine whether any Research Financial Interest is: (i) related to PHS-Funded Human Subjects Research; and (ii) a PHS Financial Conflict of Interest (as defined below). If the Research Financial Interest could be affected by the PHS-Funded Human Subjects Research project or is held in an entity whose financial interest could be affected by the PHS-Funded Human Subjects Research project, the Research Financial Interest will be considered related to the PHS-Funded Human Subjects Research project.

(c) **Guidelines.** The University will maintain guidelines for the COI Committee to assist the committee in assessing whether any Financial Interest is related to PHS-Funded Human Subjects Research and whether any PHS Financial Conflict of Interest exists. The guidelines will be developed and updated by the COI Committee.

(3) **Response**

(a) **Generally.** If the COI Committee determines that a Conflict of Interest exists, and the Conflict of Interest consists of a financial interest that is $10,000 or less, then the COI Committee will endeavor to work with the Investigator to manage, reduce or eliminate the Conflict of Interest.

(b) **Per se Conflicts of Interest.** The COI Committee shall deem any Research Financial Interest that exceeds $10,000 and is related to human subjects research to be a per se Conflict of Interest. An Investigator with a per se Conflict of Interest may not participate in the related human subjects research unless the conflicting interest is eliminated or reduced to $10,000 or below. (Note that the reduced Research Financial Interest might still be deemed a Conflict of Interest, necessitating action under subparagraph (a) above.) If, for any reason, the Conflict of Interest cannot be reduced to $10,000 or less or eliminated altogether, the Investigator will be disqualified from participating in the research, subject only to (1) a showing of compelling and necessary reasons for being permitted to participate, and (2) a COI Committee established management plan consistent with maintaining the integrity of the research and the safety of human subjects participating in the research.

(c) **Compelling and Necessary Reasons.** The showing of compelling and necessary reasons required to justify participation in human subjects research by an Investigator with a per se Conflict of Interest is within the discretion of the COI Committee but should be substantial. The COI
Committee may, for example, require a showing of such factors as: that the Investigator has special expertise regarding the particular drug, device, or method under investigation that uniquely qualifies that Investigator to conduct the investigation; that the University has facilities or equipment that are needed for the research and unavailable at most other institutions in the United States; or that the Investigator or the University is particularly well situated to enroll study subjects because of the patient population of University-affiliated health care providers or of the Investigator.

(d) Notification. The COI Committee shall promptly notify the Investigator and the IRB of its finding(s) regarding whether the Research Financial Interest and/or Leadership Role of the Investigator constitutes a Conflict of Interest, and if so, the method(s) the committee recommends for addressing any such Conflict of Interest.

(4) Continuing Review. At each continuing review, the IRB shall consult with the COI Committee regarding any changes in the Research Financial Interests and/or Leadership Roles of the Investigator, and regarding any changes in management strategies recommended by the COI Committee.

E. Management or Elimination of Conflicts

(1) Generally. Subject to the provisions concerning per se Conflicts of Interest, the COI Committee will develop and implement a management plan to manage, reduce or eliminate any identified Conflict of Interest. While the COI Committee will endeavor to work with the Investigator in developing the management plan, the COI Committee may require, if necessary, that the Investigator comply with a particular management plan for managing a conflict.

(2) Management Plan. The COI Committee’s findings and/or management strategy will be based upon an assessment of the seriousness of the Conflict of Interest, and the likelihood that the Conflict of Interest could in fact influence persons to make inappropriate, unfair or unwise decisions in their conduct or oversight of human subjects research. Methods of controlling or managing Conflicts of Interest include but are not limited to:

(a) Public disclosure of the conflicting Research Financial Interest or Leadership Role to Sponsors and research subjects (i.e., during the informed consent process) and during presentations or publication of the research;

(b) Appointment of an independent monitor capable of taking measures to protect the research from bias resulting from the conflict;

(c) Providing independent monitoring of the subject recruitment and/or informed consent processes;
(d) Requiring independent monitoring and oversight of subject-researcher interactions, data gathering, data analysis, and/or data reporting;

(e) Modifying the research plan;

(f) Eliminating the conflict by: changing the responsibilities of conflicted Investigators; referring the study to non-conflicted Investigators at the University; or referring the study to another site at which Investigators are not conflicted;

(g) Eliminating the conflict by divesting or sequestering the conflicting Research Financial Interest or relinquishing the Leadership Role;

(h) Requiring that investments posing a Conflict of Interest in a research study be “frozen” for a designated period of time lasting beyond the termination of the study, with the Investigator allowed neither to sell nor transfer those interests until the end of that time period, thus providing for a forced segregation of the research study and its results from the Investigator’s conflicting Research Financial Interest;

(i) Arranging for review of all adverse events, including review of subject records on a comprehensive, periodic or sampled basis to assure that reports of adverse events have been timely and properly made; and/or

(j) Adopting procedures for a routine periodic updating of information relating to the Conflict of Interest, if it appears that the Conflict of Interest might change in any appreciable way over the course of a research study.

Other methods may be used consistent with any applicable law and guidance. The COI Committee will monitor compliance with the management plan until the completion of the plan or the end of any Conflict of Interest (e.g., the completion of the PHS-Funded Research project).

(3) IRB Review. The IRB shall review the findings and management strategies of the COI Committee. The IRB may accept the management strategies, or may strengthen them. If the IRB elects to strengthen the management strategies, it must document its reasons for doing so and submit a copy of its written report to the COI Committee. The IRB must promptly notify the Investigator in writing of its determination regarding the Investigator’s real or perceived Conflict of Interest; the Investigator must then comply with the management strategies as modified by the IRB.

F. Expedited Action – Research Financial Interests in PHS-Funded Human Subjects Research

If the University identifies a Research Financial Interest of an Investigator involved in PHS-Funded Human Subjects Research that was not timely disclosed or reviewed in accordance
with this policy, the following actions must occur within 60 days: (i) the **Investigator** must fully disclose the **Research Financial Interest** to the **COI Committee** through the submission of an updated Form C; (ii) the **COI Committee** must review the **Research Financial Interest** and determine whether it is a **Conflict of Interest** as defined in Part A of the policy; (iii) the **COI Committee** must review the **Research Financial Interest** and determine whether it is: (1) related to the human subjects research and (2) a **PHS Financial Conflict of Interest**; and (iv) the **COI Committee** must implement a management plan, if necessary.

If a **Conflict of Interest** of a financial nature or a **PHS Financial Conflict of Interest** is identified, the **COI Committee** will complete and document a **Retrospective Review** (as defined below) of the **PHS-Funded Human Subjects Research** within 120 days to determine if the research was biased. Depending on the findings of the review, the **COI Committee** will update any reports previously submitted under Section IV.G (Reporting of Conflicts). If the **COI Committee** determines that the research was biased, the **COI Committee** will notify the Office of Sponsored Projects Administration. The Office of Sponsored Projects Administration will then promptly notify the Public Health Service entity funding the research and submit a **Mitigation Report** (as defined below) developed by the **COI Committee** in consultation with the Office of Sponsored Projects Administration.

**G. Reporting of Conflicts**

(1) **PHS-Funded Human Subjects Research.** The Office of Sponsored Projects Administration will provide to the Public Health Service entity funding any **PHS-Funded Human Subjects Research** project an initial report on any financial **Conflict of Interest** or **PHS Financial Conflict of Interest** as follows: (i) prior to the expenditure of funds for a **PHS-Funded Human Subjects Research** project (unless the conflict is eliminated before such expenditure); (ii) within 60 days of any such conflict arising in an ongoing **PHS-Funded Human Subjects Research** project; and (iii) as required under Section IV.F (Expedited Action). The Office of Sponsored Projects Administration will provide an annual update on previously reported conflicts of interest for the duration of the **PHS-Funded Human Subjects Research** project.

The initial report will identify: (i) the **PHS-Funded Human Subjects Research** project and **Investigator**; (ii) the entity with which the **Research Financial Interest** is held; (iii) the nature and value of the **Research Financial Interest**; (iv) in the case of a **Conflict of Interest** as defined in Part A of the policy, how the **Research Financial Interest** could compromise or reasonably appear to compromise the **Professional Interests** of the **Investigator**; (v) in the case of a **PHS Financial Conflict of Interest**, how the **Research Financial Interest** relates to the **PHS-Funded Human Subjects Research** project and the basis for the determination that a **PHS Financial Conflict of Interest** exists; and (vi) a description of the management plan in place to address the conflict of interest.

Information to be reported concerning the management plan will include: (i) the role and duties of the **Investigator** with the conflict of interest; (ii) the conditions of the management plan; (iii) how the management plan will protect the research
from bias; (iv) the Investigator’s agreement to the management plan; and (v) how the management plan will be monitored.

Annual updates to the report will include information on the current status of the conflict of interest and any changes to the management plan.

(2) Public Disclosure. If the Investigator of a PHS-Funded Human Subjects Research project who is the project director, principal investigator or otherwise identified by the University as senior/key personnel on the grant application has been determined by the COI Committee to have a Conflict of Interest of a financial nature or a PHS Financial Conflict of Interest, (where the conflict of interest was disclosed and is still held by the project director, principal investigator or senior/key personnel), then, the University will, prior to the University’s expenditure of any funds under a PHS–funded research project, ensure public accessibility as provided herein to certain information about such conflicts of interest, by providing in writing, within five days of a valid request (http://tulane.edu/counsel/upload/Request-for-Report-of-Financial-Conflict-of-Interest-2.pdf): (i) the name, title and role of the individual with the Research Financial Interest; (ii) the entity with which the Research Financial Interest is held; and (iii) the nature and approximate value of the Research Financial Interest. When the University responds to such a request, the University will indicate in its written response that, “The information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the University’s identification of a new financial conflict of interest; updates are not provided automatically, but may be requested”. Such information regarding Conflicts of Interest of a financial nature and PHS Financial Conflicts of Interest is to be retained and available for three years from the date that the information was most recently updated and will be updated annually and within 60 days of the receipt of any new information.

H. Other Reporting and Corrective Action

(1) Non-Compliance. If the COI Committee determines that the failure of an Investigator to comply with this policy or a management plan appears to have biased the design, conduct or reporting of PHS-Funded Human Subjects Research, the Office of Sponsored Projects Administration will promptly notify the Public Health Service entity funding the research of the corrective action taken or to be taken. The COI Committee will ensure compliance with any additional corrective actions imposed by the Public Health Service entity funding the research.

(2) Disclosure. If the U.S. Department of Health and Human Services determines there has been non-compliant management or reporting of a Conflict of Interest of a financial nature or of a PHS Financial Conflict of Interest related to PHS-Funded Human Subjects Research to evaluate the safety and effectiveness of a drug, medical device or treatment, the COI Committee will require the Investigator to disclose the conflict of interest in each public presentation of the
PHS-Funded Human Subjects Research and to request addenda adding the disclosure of the conflict of interest to previously published presentations of the PHS-Funded Human Subjects Research.

I. **PHS Subrecipients**

The University shall require any PHS Subrecipient by contract to either comply with this policy or to comply with its own financial conflicts of interest policy if such policy is compliant with the PHS-Funded Research conflict of interest regulations. If the PHS Subrecipient will comply with this policy, Subrecipient PHS Investigators will be treated as Investigators for purposes of Section IV (Process) of Part C of this policy. Subrecipient PHS Investigators, however, will not have to provide information regarding Leadership Roles or Secondary Commitments on Form C. If the PHS Subrecipient will comply with its own conflicts of interest policy, the University will report any financial conflicts of interest related to PHS-Funded Human Subjects Research of Subrecipient PHS Investigators that have been reported by the PHS Subrecipient to the Public Health Service entity funding the research in accordance with Section IV.G (Reporting of Conflicts). Additional information on implementation of these provisions will be set forth in the University Subrecipient Monitoring Policy.

J. **Certification**

1. **PHS-Funded Human Subjects Research.** The Office of Sponsored Projects Administration is responsible for certifying to the Public Health Service that the University: (i) has a written, up-to-date and enforced administrative process to manage conflicts of interest; (ii) promotes and enforces compliance for Investigators involved in PHS-Funded Human Subjects Research and manages conflicts of interest; (iii) provides ongoing reports to the Public Health Service; (iv) agrees to make information concerning disclosures of Investigators involved in PHS-Funded Human Subjects Research and review of the disclosures available to the U.S. Department of Health and Human Services upon request; and (v) fully complies with federal regulations at 42 C.F.R. Part 50 Subpart F and 45 C.F.R. Part 94.

2. **National Science Foundation Research.** In the case of National Science Foundation funding applicants, the Office of Sponsored Projects Administration is responsible for certifying to the National Science Foundation that all identified conflicts have been reviewed by the COI Committee and have been satisfactorily managed, reduced or eliminated prior to the University’s expenditure of any funds under the National Science Foundation award.

K. **Appeal of the COI Committee Decision**

1. **Generally.** Investigators who disagree with the COI Committee’s findings and/or management strategy may appeal in writing to the Senior Vice President responsible for that Investigator’s unit. A copy of the appeal must be sent to the COI Committee. The COI Committee will promptly notify the IRB of the
appeal. The applicable Senior Vice President may agree with the COI Committee’s findings and/or management strategy, or may amend such findings and/or strategy by, for example, strengthening or weakening the management strategies. The applicable Senior Vice President shall promptly notify the Investigator and the COI Committee of the conclusions of his or her review. The COI Committee will forward to the IRB a revised copy of its findings and management strategy should these require amendment as a result of the appeal. The IRB shall suspend its ultimate determination regarding the study pending the resolution of the appeal.

(2) IRB Review. The IRB shall review the findings and management strategies of the applicable Senior Vice President when there has been an appeal. The IRB may accept the management strategies, or may strengthen them. If the IRB elects to strengthen the management strategies, it must document its reasons for doing so and submit a copy of its written report to the COI Committee and to the applicable Senior Vice President. The IRB must promptly notify the Investigator in writing of its determination regarding the Investigator’s Conflict of Interest; the Investigator must then comply with the management strategies as modified by the IRB.

V. Audit and Sanctions for Non-Compliance

At the request of a Senior Vice President of the University, an Investigator may be audited for the purpose of verifying whether the Investigator truthfully and accurately disclosed his or her Leadership Roles, Secondary Commitments and Research Financial Interests in Form C (and in any updates thereto), and for the purpose of verifying whether the Investigator is complying with the actions, if any, that were specified in the written report of the COI Committee (or applicable Senior Vice President where there has been an appeal, or IRB where management strategies were strengthened). An Investigator who fails to file a completed Form C with the COI Committee by the annual deadline, or who fails to comply with any other action specified by the COI Committee or applicable Senior Vice President (as modified by the IRB) will be subject to potential sanctions in accordance with applicable University policy and procedures. These sanctions may include formal admonition or censure; suspension or termination of the Investigator’s eligibility for grant applications and/or IRB approval; non-renewal of appointment; prohibition on expending PHS funds; and/or dismissal.

VI. Confidentiality

All financial and other confidential information disclosed by Investigators pursuant to this policy will be maintained in strict confidence, unless the information must be disclosed under Section IV.G (Reporting of Conflicts). The COI Committee may disclose such information only to other University administrators defined as Designated Officials or personnel within the Office of Sponsored Projects Administration to carry out the purpose of this policy. No other uses or disclosures of the financial and other confidential information of an Investigator will be permitted, unless required by law.
VII. Record Retention

In the case of disclosures made by Investigators participating or planning to participate in PHS-Funded Human Subjects Research, the Office of Sponsored Projects Administration will retain all records related to the disclosure and review of an Investigator’s Research Financial Interests, including any Retrospective Review or other actions taken, for at least three years from the date of submission of the final expenditure report to the Public Health Service or as otherwise required by 45 C.F.R. § 74.53(b) and § 92.42(b).

VIII. Additional Definitions and Descriptions

A. Mitigation Report: Report submitted to the entity funding the PHS-Funded Research after a Retrospective Review. The Mitigation Report will include: the key elements noted in the Retrospective Review, a description of the impact of the bias on the research and a description of the actions taken or planned to mitigate the effect of the bias.

B. PHS Financial Conflict of Interest: A set of circumstances in which a Financial Interest of a PHS Investigator could directly and significantly affect the design, conduct or reporting of related PHS-Funded Research.

C. PHS-Funded Human Subjects Research: Research involving human subjects that is funded by the Public Health Service or by an entity with Public Health Service-delegated authority, including the National Institutes of Health.

D. Research Financial Interest:

(1) Any investments (whether in the form of debt, stock or other equity ownership, options or warrants to purchase stock or other securities or similar instruments) or interest in a Sponsor, research or health care-related organization;

(2) Royalties on any patent or other intellectual property interests, unless paid by the University;

(3) Income, salary or remuneration in cash or in kind, emoluments, benefits, gifts, honoraria, travel expenses, goods or services received from a Sponsor or research or health care-related organization.

A Research Financial Interest does not include holdings in mutual funds or other equity funds in which day-to-day control of investments is held by a person not subject to this policy or any other University conflict of interest policy.

Please note that a Research Financial Interest has no dollar or ownership thresholds; therefore, any interest related to a Sponsor or to the research must be disclosed, however small.
E. **Retrospective Review:** Review of PHS-Funded Research when non-compliance has been found. Documentation of a Retrospective Review will include: the number and title of the research project; the names of the project director or lead Investigator and the Investigator with the Conflict of Interest of a financial nature or PHS Financial Conflict of Interest; the name of the entity with which the Investigator has the Conflict of Interest or PHS Financial Conflict of Interest; the reason for the Retrospective Review; detailed methodology of how the Retrospective Review was conducted; and the findings and conclusions of the Retrospective Review.

F. **Sponsor:** The entity that is sponsoring or funding the research and the entity’s affiliates and subsidiaries, and any entity that monitors research, collects or arranges data for research or otherwise performs any services related to or supporting research, including without limitation assisting in applications or responses to the United States Department of Health and Human Services and/or the United States Food and Drug Administration.

G. **Subrecipient PHS Investigator:** Any person responsible for the design, conduct or reporting of research funded by the Public Health Service and conducted by the University through a PHS Subrecipient.