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.

**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 real, potential and apparent **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 should be interpreted consistent 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.

**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.

**Process**

**Timing**

**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.

All **Investigators** must complete Form C by January 31 of each year.

Newly hired or affiliated **Investigators** 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 31.

Any **Investigator** 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.

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).

**Other Disclosures.**

**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 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** staff may not
process applications for IRB approval and may not commence continuing review of a 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.

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 health-care related companies or foundations. Further information may be requested by the COI Committee if necessary. 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.

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. Chairs or deans will review and submit the completed Form C 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.

Review by the COI Committee

Timing

Review of Annual Disclosure Forms. As promptly as practicable after the January 31 filing deadline, the COI Committee will review the disclosure forms and reports, determine whether a conflict exists and implement a

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1 As required by law, the term Immediate Family is defined 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. The applicable definition of Immediate Family for all other Investigators can be found in the Definitions section of Part A of this Policy.

2 All Investigators currently conducting research must complete and file an initial Conflicts of Commitment and Interest Disclosure Form, including 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.
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.

**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.

**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.

**PHS-Funded Research.** The COI Committee must review current disclosure forms and reports prior to the expenditure of any funds for PHS-Funded Research.

**Nature of Review**

**Generally.** The COI Committee will review all disclosures to determine whether any disclosed Research Financial Interests or Leadership Roles constitute an actual Conflict of Interest with regard to an Investigator’s research. 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 greater 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.

**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 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 Financial Interest will be considered related to the PHS-Funded Human Subjects Research project.

**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.

Response

Generally. If the COI Committee determines that an actual Conflict of Interest exists, then the COI Committee will endeavor to work with Investigators to manage, reduce or eliminate the Conflict of Interest.

Compelling and Necessary Exceptions. The COI Committee may consider “compelling and necessary” exceptions that would allow an Investigator with an actual Conflict of Interest related to Research Financial Interests or Leadership Roles to conduct research, with appropriate oversight, at the University. This may be allowed to occur, for example, in circumstances where the Investigator has special expertise regarding the particular drug, device or method under investigation that uniquely qualifies that Investigator to conduct the investigation; where the University has special facilities or equipment that are unavailable at most other institutions in the United States that allow or facilitate the proposed research; and/or where 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 that Investigator himself or herself.

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(s) of Interest.

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.

Management or Elimination of Conflicts

Generally. 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.

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. The primary methods of controlling or managing Conflicts of Interest may include:

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;

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

Providing independent monitoring of the subject recruitment and/or informed consent processes;

Requiring independent monitoring and oversight of subject-researcher interactions, data gathering, data analysis, and/or data reporting;

Modifying the research plan;

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;

Eliminating the conflict by divesting or sequestering the conflicting Research Financial Interest or eliminating the Leadership Role;

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;

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

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).

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, who must then comply with the management strategies as modified by the IRB.

**Expedited Action**

If the University identifies a Research Financial Interest of and 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 the disclosed Research Financial Interest is: (1) related to the human subjects research and (2) a Conflict of Interest; and (iii) the COI Committee must implement a management plan if necessary.

If 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.

**Reporting of Conflicts**

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 an initial report on the Conflict of Interest as follows: (i) prior to the expenditure of funds for a PHS-Funded Human Subjects Research project (unless the Conflict of Interest is eliminated before such expenditure); (ii) within 60 days of any such Conflict of Interest arising in an on-going 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) how the Research Financial Interest relates to the PHS-Funded Human Subjects Research project and the basis for the determination that a Conflict of
Interest exists; and (v) 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.

**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 a Conflict of Interest, the University will publicly disclose certain information about the interest prior to the expenditure of any funds for the PHS-Funded Human Subjects Research. The University will make the following information available (either by posting the information on its website or providing in writing within five days in response to a request): (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. Information posted on the University website will remain available for three years and will be updated annually and within 60 days of the receipt of any new information.

**Other Reporting and Corrective Action**

Non-Compliance. If the COI Committee determines that the failure of an Investigator to comply with this policy or management plan appears to have biased the design, conduct or reporting of the 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.

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 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 to previously published presentations of the PHS-Funded Human Subjects Research.

**PHS Subrecipients**

The University shall require any PHS Subrecipient (as defined below) 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 **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 **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.

**Certification**

**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 on-going 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.

**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.

**Appeal of the COI Committee Decision**

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.

**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 real or perceived Conflict of Interest, who must then comply with the management strategies as modified by the IRB.

**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.

**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 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.

**Record Retention**

In the case of disclosures made by Investigators participating or planning to participate in PHS-Funded Human Subjects Research, the Conflict of Interest Administrator 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).
Additional Definitions and Descriptions

**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.

**PHS Financial Conflict of Interest:** A Financial Interest of a PHS Investigator that could directly and significantly affect the design, conduct or reporting of PHS-Funded Research.

**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.

**PHS Subrecipient:** An individual or legal entity that is a subrecipient, subcontractor or consortium member under a PHS-Funded Research project for which the University is the prime recipient or direct contractor.

**Research Financial Interest:**

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;

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

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 any 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.
**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 project director or lead Investigator and the Investigator with the Conflict of Interest; the name of the entity with which the Investigator has the 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.

**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.

**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 Subrecipient.