



ADMINISTRATIVE POLICY TEMPLATE

Policy Title	Tulane University Policies on Conflicts of Commitment and Interest (“COI Policy”)
Policy Subtitle/Subject	COI Policy
Responsible Executive(s) (RE)	General Counsel
Responsible Office(s) (RO)	Office of the General Counsel
Primary Point of Contact from RO	Assistant Director of Compliance
Contact Information (email and phone)	coi@tulane.edu and 504-247-1286
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Effective Date	10/21/2024

☒ Permanent

☐ Temporary

1.0 POLICY STATEMENT

Tulane University is committed to compliance with legal and ethical standards addressing conflicts of interest in the academic, administrative and research activities of the University.

2.0 PURPOSE AND SCOPE

The Tulane University Policies on Conflicts of Commitment and Interest (“COI Policy”) are collectively intended to promote conducting academic, administrative and research activities of the University in a fair and objective manner in accordance with the law and the best interests of the University.

3.0 APPLICABILITY OF THIS POLICY

The COI Policy applies to all employees of the University, certain researchers who are not University employees, and certain University subcontractors involved in research. Part D applies to members of any institutional office or body at the University who

perform research oversight functions in which they exercise professional or administrative-level discretion (for instance, all IRB, IACUC, and IBC members).

4.0 WEBSITE ADDRESS FOR THIS POLICY

Enterprise Risk Services will add the web address of the policy after it is added to the policy library.

5.0 CONTACTS

Subject	Contact	Telephone	E-mail/Web Address
Conflicts of Commitment and Conflicts of Interest	Assistant Director of Compliance	504-247-1286	coi@tulane.edu

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7.0 DEFINITIONS

All terms in **Bold** in section 8.0 Policy and Procedures are defined in various parts of the policy.

8.0 POLICY AND PROCEDURES

Tulane University is committed to compliance with legal and ethical standards addressing conflicts of interest in the academic, administrative and research activities of the University. The University has therefore implemented a policy addressing conflicts of commitment and interest in the following four parts:

- **Part A – Policy of Tulane University on Conflicts of Commitment and Interest.** This part of the policy applies to all employees of the University, certain researchers who are not University employees, and certain University subcontractors involved in research. This part establishes standards for identifying and responding to conflicts of commitment and interest.
 - **Part A-1** establishes basic standards applicable to all employees, with the exception of researchers involved in Public Health Service (“PHS”)-funded research.
 - **Part A-2** establishes standards applicable to those employees, researchers and research subcontractors who are involved in PHS-funded research. These standards include additional requirements to comply with the Public Health Service conflict of interest regulations.
- **Part B – Policy of Tulane University on Conflicts of Commitment and Interest for Members of the Tulane University Medical Group and Health Care Providers.** This part of the policy applies only to members of the Tulane University Medical Group and

certain other health care providers. This part incorporates federal and state laws addressing fraud and abuse.

- **Part C – Conflicts of Interest for Investigators in Human Subjects Research.** This part of the policy applies only to certain researchers that are involved in human subjects research. This part establishes enhanced disclosure requirements for such researchers. The standards, as applied to certain researchers and research subcontractors involved in federally-funded research, include additional requirements to comply with the Public Health Service conflict of interest regulations.
- **Part D – Policy for Conflicts of Interest of Research Oversight Officials.** This part of the policy applies only to **Research Oversight Officials**, for instance, all **IRB**, **IACUC**, and **IBC** members and certain other University **Faculty** and **Staff** who oversee research. This part, as applied to Institutional Review Board members, assists the University in complying with federal laws precluding such members from participating in the review of research in which the member has a conflicting interest.

These parts of the policy are collectively intended to promote conducting academic, administrative and research activities of the University in a fair and objective manner in accordance with the law and the best interests of the University.

A copy of this policy will be posted on the University website on a page accessible to the general public, all employees of the University, certain researchers (whether or not University employees), and certain University subcontractors involved in research. A revised copy will be posted within 30 days if and when the policy is amended.

PART A

POLICY OF TULANE UNIVERSITY ON CONFLICTS OF COMMITMENT AND INTEREST

[All terms in **Bold** are defined in this Part A of the policy.]

I. Principles

Tulane University's mission is to create, communicate and conserve knowledge in order to enrich the capacity of individuals, organizations and communities to think, to learn, to act and to lead with integrity and wisdom. Accordingly, the University recognizes that its **Faculty** and **Staff** participate in **Leadership Roles**, such as consulting, serving on boards of companies, whether for-profit or non-profit, and other **Secondary Commitments** that benefit the participant and the University, its students and patients, and the public at large. The University, **Faculty**, and **Staff** have a shared interest in assuring the institutional integrity of the University as well as the personal and professional integrity of the **Faculty** and **Staff**. The University is committed to maintaining the highest standards of excellence in teaching, research, patient care, and welfare.

This policy provides guidelines and mechanisms for identifying and addressing **Conflicts of Interest** and **Conflicts of Commitment** that pertain to conducting research, academic, and administrative activities in a fair and unbiased manner. An integral part of this policy is therefore disclosure by **Faculty**, **Staff**, and **Investigators** of their commitments, financial interests, and outside activities. The guidelines and

mechanisms, as applied to **Faculty**, **Staff**, and **Investigators** 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 45 C.F.R. Part 94 and should be interpreted consistent with those regulatory requirements and any implementing guidance.

While this policy governs **Conflicts of Interest** and Conflicts of Commitment, the policy does not regulate disputes between two or more **Faculty** or **Staff**, or disputes between one or more **Faculty** or **Staff** and the University. Such disputes are to be resolved according to the University's established dispute resolution procedures.

II. Conflict of Commitment

Faculty and **Staff** owe their **Primary Commitment** to University activities and responsibilities, must act in the University's best interests in fulfilling their obligations to the University, and must not permit any **Leadership Roles** or **Secondary Commitments** to an outside organization, entity or project to jeopardize this **Primary Commitment**. A Conflict of Commitment occurs when these efforts for the University are compromised by one or more **Leadership Roles** or **Secondary Commitments**. For example, a Conflict of Commitment would occur if a **Faculty** member exceeded permitted time limits on outside consulting, or if, as a result of a **Leadership Role** in an outside organization, entity or project, an individual's primary professional loyalty was not to the University.

III. Conflict of Interest

A **Conflict of Interest** arises whenever **Faculty**, **Staff**, or an affiliated **Investigator's Professional Interests**, such as professional obligations or judgment owed to the University and its constituencies, are compromised by, or could reasonably be perceived as being compromised by, his or her **Leadership Roles** or **Financial Interests**. In the case of **PHS-Funded Research**, a **PHS Financial Conflict of Interest** arises when the **Financial Interests** of an **Investigator** could directly and significantly affect the design, conduct, or reporting of **PHS-Funded Research**.

A **Conflict of Interest** is based on the situation and not on the character of the individual.

A **Conflict of Interest** can also occur when the academic work or research activities of a **Faculty** member could affect a **Financial Interest** of the University or of a **Faculty** or **Staff** member. Academic integrity is compromised when a **Faculty** member modifies his or her work to augment or shield that **Financial Interest**, such that the work product does not accurately reflect the **Faculty** member's research, beliefs, and opinions. For example, depending on the circumstances, academic integrity may be compromised when a **Faculty** member prepares the content of a book, article, audit or other report or conducts research with knowledge that such content or research results could reasonably be expected to affect a **Financial Interest** of that **Faculty** member, or of one or more other **Faculty** members, the University, or one or more University officials.

IV. Special Concerns about Vendor Relationships

Relationships with **Vendors/Contractors** to the University can also give rise to **Conflicts of Interest**. As a rule, **Faculty** and **Staff** should not be involved in decisions about purchasing or contracting for goods or services received by the University if their interests in or relationships

with the involved **Vendor/Contractor** conflict with, or reasonably appear to conflict with, their duty to act in the University's best interests. This applies not only where **Faculty** or **Staff** themselves have a **Financial Interest** in a **Vendor/Contractor** but also where they know of a **Financial Interest** held by their **Immediate Family** (for purposes of **Vendor/Contractor** relationships, the definition of **Immediate Family** also includes parents, parents-in-law, siblings and siblings-in-law)¹. Where **Immediate Family** holds the interest, note that the potential **Conflict of Interest** for the **Faculty** or **Staff** member might be of a financial or non-financial nature, or both.

In some instances, a **Conflict of Interest** arising from a **Vendor/Contractor** relationship can be sufficiently averted by voluntary self-recusal or by an externally imposed requirement (for example, through a COI management plan) that the individual abstain from participating in the nomination, screening, or selection of **Vendors/Contractors**. In other instances, however, the nature of the relationship and resulting risk may be so pervasive that recusal or exclusion from discrete transactional decisions may not be adequate.

PART A-1

STANDARDS APPLICABLE TO FACULTY AND STAFF OTHER THAN INVESTIGATORS INVOLVED IN PHS-FUNDED RESEARCH

[All terms in **Bold** are defined either in Part A or this Part A-1.]

I. Scope

These standards apply to **Faculty**, **Staff**, and **Investigators** not involved in **PHS-Funded Research**.

II. Process

A. *Timing*

A Conflicts of Commitment and Interest Disclosure Form A ("Form A") must be submitted on an annual basis and in response to certain events.

- (1) All **Faculty** and **Staff** must complete Form A by January 31st of each year.
- (2) Newly hired **Faculty** and **Staff** must submit Form A within 60 days of employment or association, and must thereafter comply with the annual filing deadline of January 31st.
- (3) Any **Faculty** or **Staff** must promptly, but no later than 30 days, after the acquisition or discovery of any new **Leadership Role**, **Secondary Commitment** or **Financial Interest** or the material modification of any **Leadership Role**, **Secondary Commitment** or **Financial Interest** provide an updated Form A.

B. *Information Required*

Form A requires the individual to report any and all **Leadership Roles**, **Secondary Commitments** and **Financial Interests** that reasonably appear to be related to the individual's professional responsibilities on behalf of the University, such as research and research consultation, teaching, professional practice, institutional committee memberships, and service on **IRBs** or safety monitoring boards. In addition, this form requires the individual to report any and all **Leadership Roles**, **Secondary Commitments** and **Financial Interests** that the individual's **Immediate Family** may have that reasonably appear to be related to the individual's professional responsibilities on behalf of the University, such as research and research consultation, teaching, professional practice, institutional committee memberships, and service on **IRBs** or safety monitoring boards. Further information may be requested by the **COI Committee** as appropriate.

Form A requires the individual to report the following information concerning reimbursed or sponsored travel: sponsor/organizer, purpose, duration and destination. The **COI Committee** may also request further information such as the value of the reimbursed or sponsored travel.

Individuals should retain documentation of such travel for reporting purposes and requests for further information by the **COI Committee**. Individuals should seek to obtain documentation of reimbursed or sponsored travel from the sponsor/organizer if documentation is not readily provided.

C. ***Submission of Forms***

Faculty and **Staff** must submit completed disclosure forms through an electronic online process. The online submissions for **Faculty** and **Staff** in academic units are forwarded to their department supervisor, chair or the dean if the unit does not have a departmental chair structure. The online submissions for **Staff** in non-academic units are forwarded to their direct supervisor. Supervisors, chairs, or deans, as applicable, are responsible for reviewing the completed Form A prior to its submission to the University's **COI Committee**. A list of names of individuals who have not provided the required Form A 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, determine whether a conflict exists, and implement a management plan if necessary. The **COI Committee** may ask that an **Investigator** or **Faculty** or **Staff** member who has a potential conflict provide additional information or discuss the matter with the **COI Committee** in person. The **COI Committee** will examine disclosed conflicts to assess the degree of risk they carry to **Primary Commitments** and **Professional Interests**.
- (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 **Faculty** or **Staff** member, the **COI Committee** will complete its review and determination as to whether a Conflict of Commitment or **Conflict of Interest** exists and implement a management plan, if necessary.

(2) Nature of Review

- (a) Generally. The **COI Committee** will review all disclosures to determine whether a Conflict of Commitment or a **Conflict of Interest** exists.
- (b) Guidelines. The University will maintain guidelines for the **COI Committee** to assist the committee in assessing whether any Conflict of Commitment or **Conflict of Interest** exists. The guidelines will be developed and updated by the **COI Committee**.

(3) Response

If the **COI Committee** determines that a Conflict of Commitment or **Conflict of Interest** exists, then the **COI Committee** will endeavor to work with the **Faculty** or **Staff** member to manage, reduce, or eliminate the Conflict of Commitment or **Conflict of Interest**.

E. *Management or Elimination of Conflicts*

- (1) Generally. The **COI Committee** will develop and implement a management plan to manage, reduce or eliminate any identified Conflicts of Commitment or **Conflicts of Interest**. While the **COI Committee** will endeavor to work with the **Faculty** or **Staff** member in developing the management plan, the **COI Committee** may require, if necessary, that the **Faculty** or **Staff** member comply with a particular management plan for managing a conflict.
- (2) Management Plan. The management plan developed by the **COI Committee** will be based upon an assessment of the nature, scope and severity of the Conflict of Commitment or **Conflict of Interest**. Methods of controlling or managing conflicts include, but are not limited to, the following:
 - (a) Modifying the University employment or research responsibilities of the conflicted **Faculty** or **Staff** member;
 - (b) Disclosing the conflicting **Leadership Role, Secondary Commitment** or **Financial Interest** to the public, for example, during conference presentations and/or in journals and other publications;
 - (c) Reducing the conflict by reducing or altering the **Leadership Role, Secondary Commitment** or **Financial Interest** (*e.g.*, partial divestiture or sequestration of one or more **Financial Interests**, reduction of time spent in furtherance of one or more **Leadership Roles** or **Secondary Commitments**);
 - (d) Eliminating the conflict by eliminating the **Leadership Role, Secondary Commitment** or **Financial Interest** (*e.g.*, total divestiture or sequestration of one or more **Financial Interests**, resignation from one or more **Leadership Roles** or **Secondary Commitments**).

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 Commitment or **Conflict of Interest**.

F. *Certification*

In the case of applications for National Science Foundation funding awards, 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.

G. *Appeal of the COI Committee Decision*

Any **Faculty** or **Staff** member who disagrees with the **COI Committee**'s findings or required management strategies may appeal in writing to the Senior Vice President responsible for that **Faculty** or **Staff** member's unit. A copy of the appeal must be sent to the **COI Committee**. 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. The applicable Senior Vice President shall promptly notify the **Faculty** or **Staff** member and the **COI Committee** in writing of the conclusions of his or her review, including the actions that must be taken by the **Faculty** or **Staff** member to comply with this policy. Upon receipt of the applicable Senior Vice President's written report, the **Faculty** or **Staff** member must promptly comply with the actions specified in that report.

III. **Audit and Sanctions for Non-Compliance**

At the request of a **Designated Official** of the University, a **Faculty** or **Staff** member may be audited for the purpose of verifying whether the individual truthfully and accurately disclosed his or her **Leadership Roles, Secondary Commitments and Financial Interests** in Form A (and in any updates thereto), and for the purpose of verifying whether the individual is complying with the actions, if any, that were specified in the written report of the **COI Committee** (or the applicable Senior Vice President where there has been an appeal). Any **Faculty** or **Staff** member who fails to file a completed Form A by the annual deadline, or who fails to comply with any other action specified by this policy, the **COI Committee** or applicable Senior Vice President (as relates to this policy), will be subject to potential sanctions in accordance with applicable University policy and procedures. These sanctions may include: formal admonition or censure; suspension; non-renewal of appointment; and/or dismissal.

IV. **Confidentiality**

All financial and other confidential information disclosed by a **Faculty** or **Staff** member pursuant to this policy will be maintained in strict confidence. 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 any **Faculty** or **Staff** member will be permitted, unless required by law.

PART A-2

STANDARDS APPLICABLE TO INVESTIGATORS INVOLVED IN PHS-FUNDED RESEARCH

[All terms in **Bold** are defined either in Part A or this Part A-2.]

I. Scope

These standards apply to **Faculty** and **Staff** who are **Investigators** for **PHS-Funded Research**, **Affiliated PHS Investigators** (as defined below), and **Subrecipient PHS Investigators** (as defined below). Any references to **Faculty** and **Staff** in this Part A-2 shall include *only* **Faculty** and **Staff** who are **Investigators** for **PHS-Funded Research**.

II. Communication and Training

Faculty, **Staff** and **Affiliated PHS Investigators** who may or will participate in **PHS-Funded Research** as **Investigators** will receive a copy of this policy; specific information about their obligations to disclose **Financial Interests**; and the **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 a **Faculty**, **Staff** or **Affiliated PHS Investigator** is non-compliant with this policy or with a management plan implemented to address a **PHS Financial Conflict of Interest** (as defined below).

III. Process

A. *Timing*

A Conflicts of Commitment and Interest Disclosure Form A (“Form A”) must be submitted on an annual basis and in response to certain events.

- (1) All **Faculty**, **Staff** and **Affiliated PHS Investigators** must complete Form A by January 31st of each year.
- (2) Newly hired **Faculty**, **Staff** and **Affiliated PHS Investigators** must submit Form A within 60 days of employment or association, and must thereafter comply with the annual filing deadline of January 31st.
- (3) Any **Faculty**, **Staff** or **Affiliated PHS Investigators** must promptly, but no later than 30 days, after the acquisition or discovery of any new **Leadership Role**, **Secondary Commitment** or **Financial Interest** or the material modification of any **Leadership Role**, **Secondary Commitment** or **Financial Interest** provide an updated Form A.
- (4) **Faculty**, **Staff** or an **Affiliated PHS Investigator** planning to participate in **PHS-Funded Research** must have submitted an up-to-date Form A prior to the submission of an application for **PHS-Funded Research**.

B. *Information Required*

Form A requires the individual to report any and all **Leadership Roles**, **Secondary Commitments** and **Financial Interests** that reasonably appear to be related to the individual’s professional

responsibilities on behalf of the University, such as research and research consultation, teaching, professional practice, institutional committee memberships, and service on **IRBs** or safety monitoring boards. In addition, this form requires the individual to report any and all **Leadership Roles, Secondary Commitments** and **Financial Interests** that the individual's **Immediate Family** may have that reasonably appear to be related to the individual's professional responsibilities on behalf of the University, such as research and research consultation, teaching, professional practice, institutional committee memberships, and service on **IRBs** or safety monitoring boards. Further information may be requested by the **COI Committee** as appropriate.

Form A requires the individual to report the following information concerning reimbursed or sponsored travel: sponsor/organization, purpose, duration and destination. The **COI Committee** may also request further information such as the value of the reimbursed or sponsored travel. Individuals should retain documentation of such travel for reporting purposes and requests for further information by the **COI Committee**. Individuals should seek to obtain documentation of reimbursed or sponsored travel from the sponsor/organizer if documentation is not readily provided.

C. *Submission of Forms*

Faculty and **Staff** must submit completed disclosure forms through an electronic online process. The online submissions for **Faculty** and **Staff** in academic units are forwarded to their department supervisor, chair or the dean if the unit does not have a departmental chair structure. The online submissions for **Staff** in non-academic units are forwarded to their direct supervisor. **Affiliated PHS Investigators** must submit their completed disclosure forms through the University's electronic online process. Supervisors, chairs, or deans, as applicable, are responsible for reviewing the completed Form A prior to its submission to the University's **COI Committee**. A list of names of individuals who have not provided the required Form A 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, determine whether a conflict exists and implement a management plan, if necessary. The **COI Committee** may ask that the **Faculty** or **Staff** member or **Affiliated PHS Investigator** who has a potential conflict provide additional information or discuss the matter with the **COI Committee** in person. The **COI Committee** will examine disclosed conflicts to assess the degree of risk they carry to **Primary Commitments** and **Professional Interests**.
- (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 **Faculty** or **Staff** member or **Affiliated PHS Investigator**, the **COI Committee** will complete its review and determination as to whether a

Conflict of Commitment, **Conflict of Interest**, or **PHS Financial Conflict of Interest**² exists and implement a management plan, if necessary.

- (c) 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 a Conflict of Commitment or a **Conflict of Interest** exists.
- (b) PHS-Funded Research. The **COI Committee** will additionally review the disclosures of **Faculty**, **Staff** and **Affiliated PHS Investigators** to determine whether any **Financial Interest** is: (i) related to **PHS-Funded Research**; and (ii) a **PHS Financial Conflict of Interest**. If the **Financial Interest** could be affected by the **PHS-Funded Research** project or is held in an entity whose financial interest could be affected by the **PHS-Funded Research** project, the **Financial Interest** will be considered related to the **PHS-Funded 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 Research** and whether any **PHS Financial Conflict of Interest** exists. The guidelines will be developed and updated by **COI Committee**.

(3) Response

- (a) If the **COI Committee** determines that a Conflict of Commitment, **Conflict of Interest** or **PHS Financial Conflict of Interest** exists, then the **COI Committee** will endeavor to work with **Faculty** or **Staff** members or **Affiliated PHS Investigators** to manage, reduce or eliminate the Conflict of Commitment or **Conflict of Interest** or **PHS Financial Conflict of Interest**.

E. *Management or Elimination of Conflicts*

- (1) Generally. The **COI Committee** will develop and implement a management plan to manage, reduce or eliminate any identified Conflict of Commitment, **Conflict of Interest** or **PHS Financial Conflict of Interest**. While the **COI Committee** will

² The differentiation, made here and in subsequent paragraphs, between **Conflict of Interest** and **PHS Financial Conflict of Interest** mirrors the definition of conflict of interest in this policy and the conflict of interest definitions in the PHS rules. This policy defines a conflict of interest essentially as an interest or leadership role that could compromise the integrity of one's professional activities. The PHS rules point to whether a financial interest is related to PHS-funded research and could directly and significantly affect the design, conduct, reporting, or review of the research.

endeavor to work with the **Faculty, Staff or Affiliated PHS Investigator** in developing the management plan, the **COI Committee** may require, if necessary, that **Faculty, Staff or Affiliated PHS Investigator(s)** comply with a particular management plan for managing a conflict. The management plan must be implemented before the expenditure of any funds under a **PHS-Funded Research** project.

- (2) Management Plan. The management plan developed by the **COI Committee** will be based upon an assessment of the nature, scope and severity of the Conflict of Commitment, **Conflict of Interest** or **PHS Financial Conflict of Interest**. The primary methods of controlling or managing conflicts shall include:
- (a) Modifying the University employment or research responsibilities of the conflicted **Faculty, Staff or Affiliated PHS Investigator**;
 - (b) Disclosing the conflicting **Leadership Role, Secondary Commitment or Financial Interest** to the public, for example, during conference presentations and/or in journals and other publications;
 - (c) Reducing the conflict by reducing or altering the **Leadership Role, Secondary Commitment or Financial Interest** (e.g., partial divestiture or sequestration of one or more **Financial Interests**, reduction of time spent in furtherance of one or more **Leadership Roles or Secondary Commitments**);
 - (d) Eliminating the conflict by eliminating the **Leadership Role, Secondary Commitment or Financial Interest** (e.g., total divestiture or sequestration of one or more **Financial Interests**, resignation from one or more **Leadership Roles or Secondary Commitments**).

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 Commitment or **Conflict of Interest** or **PHS Financial Conflict of Interest** (e.g., the completion of the **PHS-Funded Research** project).

F. *Expedited Action*

If the University identifies a **Financial Interest** of **Faculty, Staff** or an **Affiliated PHS Investigator** that was not timely disclosed or reviewed in accordance with this policy, the following actions must occur within 60 days: (i) the **Faculty, Staff or Affiliated PHS Investigator** must fully disclose the **Financial Interest** to the **COI Committee** through the submission of an updated Form A; (ii) the **COI Committee** must review the **Financial Interest** and determine whether the disclosed **Financial Interest** is: (1) related to **PHS-Funded Research** and (2) a **PHS Financial Conflict of Interest**; and (iii) 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 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 III.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 Research. The Office of Sponsored Projects Administration will provide to the Public Health Service entity funding any **PHS-Funded Research** project an initial report on any **Conflict of Interest** of a financial nature and on any **PHS Financial Conflict of Interest** as follows: (i) prior to the expenditure of funds for a **PHS-Funded 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 ongoing **PHS-Funded Research** project; and (iii) as required under Section III.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 Research** project.

The initial report will identify: (i) the **PHS-Funded Research** project and the **Faculty, Staff** or **Affiliated PHS Investigator**; (ii) the entity with which the **Financial Interest** is held; (iii) the nature and value of the **Financial Interest**; (iv) in the case of a **Conflict of Interest** under Part A of the policy, how the **Financial Interest** could compromise, or appear to compromise, the **Professional Interests** of the **Investigator**; (v) in the case of a **PHS Financial Conflict of Interest**, how the **Financial Interest** relates to the **PHS-Funded 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** or **PHS Financial Conflict of Interest**.

Information to be reported concerning the management plan will include: (i) the role and duties of the **Faculty, Staff** or **Affiliated PHS 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 **Faculty, Staff** or **Affiliated PHS 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** or **PHS Financial Conflict of Interest**, as applicable, and any changes to the management plan.

- (2) Public Disclosure. If a **Faculty** or **Staff** member or **Affiliated PHS Investigator** of a **PHS-Funded 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 for [Report of Financial Conflict of Interest Form](#): (i) the name, title and role of the individual with the **Financial Interest**; (ii) the entity with which the **Financial Interest** is held; and (iii) the nature and approximate value of the **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 the **Faculty, Staff or Affiliated PHS Investigator** to comply with this policy or a management plan appears to have biased the design, conduct or reporting of **PHS-Funded 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 exercise oversight regarding 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 Research** to evaluate the safety and effectiveness of a drug, medical device or treatment, the **COI Committee** will require the **Faculty, Staff or Affiliated PHS Investigator** to disclose the Conflict of Interest in each public presentation of the **PHS-Funded Research** and to request addenda adding the disclosure of the Conflict of Interest to previously published presentations of the **PHS-Funded 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 **Affiliated PHS Investigators** for purposes of Section III (Process). **Subrecipient PHS Investigators**, however, will not have to provide information regarding **Leadership Roles** or **Secondary Commitments** on Form A. If the **PHS Subrecipient** will comply with its own conflicts of interest policy, the University will report any financial conflicts of interest 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 III.G (Reporting of Conflicts). Additional information on implementation of these provisions is set forth in the University Subrecipient Monitoring Policy.

J. *Certification*

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 **Faculty, Staff or Affiliated PHS Investigator** compliance and manages **Conflicts of Interest**; (iii) provides ongoing reports to the Public Health Service; (iv) agrees to make information concerning **Faculty, Staff or Affiliated PHS Investigator** disclosures 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.

K. *Appeal of the COI Committee Decision*

Any **Faculty, Staff or Affiliated PHS Investigator** who disagrees with the **COI Committee's** findings or required management strategies may appeal in writing to the Senior Vice President responsible for that **Faculty, Staff or Affiliated PHS Investigator's** unit. A copy of the appeal must be sent to the **COI Committee**. 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. The applicable Senior Vice President shall promptly notify the **Faculty, Staff or Affiliated PHS Investigator** and the **COI Committee** in writing of the conclusions of his or her review, including the actions that must be taken by the **Faculty, Staff or Affiliated PHS Investigator** to comply with this policy. Upon receipt of the applicable Senior Vice President's written report, the **Faculty, Staff or Affiliated PHS Investigator** must promptly comply with the actions specified in that report.

IV. *Audit and Sanctions for Non-Compliance*

At the request of a **Designated Official** of the University, a **Faculty, Staff or Affiliated PHS Investigator** may be audited for the purpose of verifying whether the individual truthfully and accurately disclosed his or her **Leadership Roles, Secondary Commitments and Financial Interests** in Form A (and in any updates thereto), and for the purpose of verifying whether the individual is complying with the actions, if any, that were specified in the written report of the **COI Committee** (or the applicable Senior Vice President where there has been an appeal). Any **Faculty, Staff or Affiliated PHS Investigator** who fails to file a completed Form A by the annual deadline, or who fails to comply with any other action specified by this policy, the **COI Committee** or applicable Senior Vice President (as relates to this policy), will be subject to potential sanctions in accordance with applicable University policy and procedures. These

sanctions may include: formal admonition or censure; suspension; non-renewal of appointment; prohibition on expending PHS funds; and/or dismissal.

V. Confidentiality

All financial and other confidential information disclosed by **Faculty, Staff, and Affiliated PHS Investigators** pursuant to this policy will be maintained in strict confidence, unless the information must be disclosed under Section III.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 any **Faculty, Staff and Affiliated PHS Investigators** will be permitted, unless required by law.

VI. Record Retention

In the case of disclosures made by **Faculty, Staff or Affiliated PHS Investigators** participating or planning to participate in **PHS-Funded Research**, the Office of Sponsored Projects Administration will retain all records related to the disclosure and review of such **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).

PART B

POLICY OF TULANE UNIVERSITY ON CONFLICTS OF COMMITMENT AND INTEREST MEMBERS OF THE TULANE UNIVERSITY MEDICAL GROUP AND HEALTH CARE PROVIDERS

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

This Addendum shall apply ONLY to members of the Tulane University Medical Group and other health care providers. For the purposes of this Addendum, a health care provider is a physician or other health care professional or **Staff** member who orders medical items, supplies (including for example pharmaceuticals) or services for patients or who refers patients to other health care providers or suppliers of medical items, supplies or services. A physician or other **Staff** member who performs no patient care services, directly or indirectly, and whose duties encompass no direct or indirect patient care is NOT covered by this Addendum.

By this Addendum, the Tulane University Policies on Conflicts of Commitment and Interest incorporate federal and state laws requiring that persons making purchasing and/or patient referral decisions not receive any remuneration or payment for making such decisions (often referred to as “anti-kickback” laws) and other laws that prohibit physicians from referring patients to services and facilities in which those physicians and their families hold **Financial Interests** (often referred to as “physician self-referral laws”). Considering such laws, the definition of **Immediate Family** in this Addendum shall apply to members of the Tulane University Medical Group and other health care providers in lieu of the definition included in the policy to which this Part B is attached:

- F Immediate Family.** Spouse or domestic partner, children and other dependents, natural or adoptive parents, siblings, stepparent, stepchild, stepbrother or sister, father-in-law, mother-in-law, daughter-in-law, son-in-law, brother-in-law, sister-in-law, grandparent, grandchild, and spouse of grandparent or grandchild.
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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.

- (b) 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**³ may have in any research or health care-related organization, including any not-for-profit or tax-exempt health-care related companies or foundations.⁴ 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.⁵

³ 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/Contractor** relationships, **Immediate Family** also includes parents, siblings, parents-in-law, and siblings-in-law.

⁴ 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**.

⁵ 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, chairs 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 for [Report of Financial Conflict of Interest Form](#): (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).

A. ***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.

- B. ***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**.
- C. ***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.
- D. ***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**.

PART D

POLICY FOR CONFLICTS OF INTEREST OF RESEARCH OVERSIGHT OFFICIALS

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

I. Applicability

This policy applies to **Research Oversight Officials** (as defined below) responsible for research oversight at Tulane University. This policy defines Research Oversight Officials to include all **Faculty** and **Staff** of any institutional office or body (for instance, all **IRB**, IACUC, and IBC members) at the University who perform research oversight functions in which they exercise professional or administrative-level discretion.

II. Principles

Federal law and accrediting agencies require that **IRB** and IACUC members not have any conflicting interests in the research that they review. The University is concerned, as are various professional organizations, with the possible influence of such **Research Financial Interests** (as defined below) on research integrity and on the safety and welfare of subjects involved in research protocols regardless of the source of research funding. The University is also concerned with any **Research Leadership Roles** (as defined below) that may be held by **Research Oversight Officials** in any entities that sponsor research, or that perform support, marketing, recruitment, data analysis, or FDA liaison activities for research. The University's policies therefore incorporate those concerns as well.

Consistent with federal laws and the ethical principles of research, Tulane University seeks to ensure that its **Research Oversight Officials** can carry out their responsibilities to protect the rights and welfare of 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 **Research Oversight Officials** in determining when they have **Conflicts of Interest** in research and to guide them in disclosing all potential conflicts and then, as appropriate, cooperating in the management or elimination of the conflicts. While this policy governs the **Conflicts of Interest of Research Oversight Officials** at the University, it does not regulate disputes between two or more individuals, nor does it regulate disputes between one or more individuals and the University. Such disputes are to be resolved according to the University's established dispute resolution procedures.

Because **IRB Members** and other **Research Oversight Officials** have primary responsibility for protecting the safety and welfare of subjects participating in research at the University, it is the policy of the University that **IRB Members** and **Research Oversight Officials**, may not review any research protocol in which a decision to approve or disapprove the protocol could affect or reasonably be perceived to affect the **IRB Member's** or **Research Oversight Official's** or their

Immediate Family's⁶ Research Financial Interests. **Research Oversight Officials** whose **Research Financial Interests** or **Research Leadership Roles** could affect or reasonably be perceived to affect their review of a research protocol must reduce such interests, eliminate such roles, and/or recuse themselves from reviewing the protocol in accordance with Sections III.E and F below.

III. Process

A. Disclosure

All **Research Oversight Officials** must complete Form D of the Conflicts of Commitment and Interest Disclosure Form.⁷ This form must be submitted to the member or official's department chair or dean in accordance with the process described in the Tulane University Policy on Conflicts of Commitment and Interest and must be updated on an annual basis (by January 31st of each year) for as long as the **Research Oversight Official** continues to supervise research at the University. **Research Oversight Officials** who are newly hired by or affiliated with the University must submit Form D of the Disclosure Form prior to beginning their research oversight duties, and must thereafter comply with the January 31st filing deadline. **Research Oversight Officials** must disclose any and all **Research Financial Interests** and/or **Research Leadership Roles** they or their **Immediate Family** may have. **Research Oversight Officials** must also indicate whether any of their **Research Leadership Roles** could affect, or appear to affect, their review of any particular research projects.

B. Updating

If at any time over the course of the year one or more **Research Financial Interests** or **Research Leadership Roles** of a **Research Oversight Official** or their **Immediate Family** changes in any material way, the **Research Oversight Official** must promptly notify the **COI Committee** of that change by submitting a written statement detailing such change(s).

C. Confidentiality

All financial and other confidential information disclosed by **Faculty** and **Staff** to the individuals described in Section III.A above will be maintained in strict confidence. The **COI Committee** may need to disclose information to other University administrators defined as **Designated Officials** in this policy to carry out the purpose of this policy. No other uses or disclosures of the

⁶ 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/Contractor** relationships, **Immediate Family** also includes parents, siblings, parents-in-law, and siblings-in-law.

⁷ **Research Oversight Officials** who are also **Investigators** must complete Form C of the Annual Conflicts of Commitment and Interest Disclosure Form in their capacity as **Investigator**, and Form D in their capacity as a University research official. Please see Part C of the Policy.

financial and other confidential information of a **Faculty** or **Staff** member will be permitted, unless required by law.

D. *Review by the COI Committee*

As promptly as practicable after the January 31st filing deadline, the **COI Committee** will review Form D of the Disclosure Form of the **Research Oversight Official** to determine whether the **Research Oversight Official**, or a member of his or her **Immediate Family**, possesses any **Research Financial Interests** or any **Research Leadership Roles** that could reasonably affect the Official's review of research. If the **COI Committee** concludes that the **Research Oversight Official** has no such **Research Financial Interests** and that the Official does not possess any **Research Leadership Roles** that could reasonably affect the Official's review of research, then the matter will go no further. If, however, the **COI Committee** concludes that the **Research Oversight Official** possesses one or more **Research Financial Interests**, and/or that the Official holds one or more **Research Leadership Roles** that could affect the Official's review of research, then the **COI Committee** will promptly inform the Official in writing of its determination and of the remedies that must be taken by the Official. A **Conflict of Interest** will be deemed to exist *per se* if the **Research Oversight Official** is an inventor or co-inventor of a product or method in a study undergoing review or continuing review by that Official, and/or where the **Research Oversight Official** is, or expects to be, included as an author on any publication relating to the study under review.

E. *Management or Elimination of Conflicts of Interests*

Where a **Research Oversight Official** has one or more **Research Financial Interests**, the **COI Committee** will require that the Official reduce every such **Research Financial Interest** to a *de minimis* level. The **Research Oversight Official** has the discretion of selecting how to accomplish this obligation (*e.g.*, partial divestiture of the official's **Research Financial Interests**, and/or partial divestiture of the **Research Financial Interests** of the official's spouse or dependent children), but the time-frame in which divestiture must occur will be stipulated by the **COI Committee** and ordinarily shall not be more than four weeks. Where a **Research Oversight Official** has one or more **Research Leadership Roles** that could affect his or her review of research, the **COI Committee** will require that the Official either terminate the **Research Leadership Role(s)** or recuse himself or herself from the review of any research protocol that could be affected by that role. While a **Research Oversight Official** may not review a study that is being funded by a **Sponsor** (as defined below) in which he or she holds a **Research Leadership Role**, **Research Leadership Roles** in other research-related organizations will be assessed on a case-by-case basis by the **COI Committee**. If a **Conflict of Interest** is deemed to exist based on the **Research Oversight Official's** status as an inventor or co-inventor of a product or method in a study undergoing review or continuing review by that Official, or is deemed to exist based on the **Research Oversight Official's** existing or expected status as an author on any publication relating to the study under review, the remedy will be recusal.

F. *Recusal*

Research Oversight Officials must recuse themselves from reviewing a research protocol whenever they identify themselves as possessing a **Conflict of Interest** in relation to that protocol,

and whenever they have been directed to do so by the **COI Committee** (or the Senior Vice President in the case of an appeal). In all cases, recusal must occur before the discussion of, and vote on, the research protocol in relation to which the **Research Oversight Official** has a **Conflict of Interest**. Nevertheless, the **Research Oversight Official** may remain in the room prior to the discussion or vote in order to provide information relating to the protocol, and may, if he or she is an inventor and/or serves as an **Investigator** on that protocol, present or assist in presenting the protocol to the **IRB Members**.

G. Appeal of COI Decision

A **Research Oversight Official** who disagrees with the **COI Committee's** findings and/or management strategy may appeal in writing to the Senior Vice President responsible for the research. A copy of the appeal must be sent to the **COI Committee**. An appeal may exist with regard to whether the **Research Oversight Official's Research Leadership Role** is likely to affect his or her review of research, but **Research Oversight Officials** may not contest the terms and conditions of this policy. The applicable Senior Vice President may agree with the **COI Committee's** findings and/or management strategy, or may amend such findings and/or management strategy by, for example, strengthening or weakening the management strategy. The applicable Senior Vice President shall promptly notify the **Research Oversight Official** and the **COI Committee** in writing of the conclusions of his or her review, including the actions that must be taken by the **Research Oversight Official** to comply with this policy. Upon receipt of the applicable Senior Vice President's written report, the **Research Oversight Official** must promptly comply with the actions specified in that report.

IV. Audits and Sanctions for Non-Compliance

If required by a Senior Vice President of the University, a **Research Oversight Official** may be audited for the purpose of verifying whether the **Research Oversight Official** truthfully and accurately disclosed his or her **Research Leadership Roles, Secondary Commitments** and **Financial Interests**, including **Research Financial Interests** in the Annual Research-Related Financial and Leadership Disclosure form (and in any updates thereto), and for the purpose of verifying whether the **Research Oversight Official** is complying with the actions, if any, that were specified in the written report of the **COI Committee** (or the Senior Vice President where there has been an appeal). A **Research Oversight Official** who does not comply with the actions specified by the **COI Committee** or the Senior Vice President will be subject to potential sanctions in accordance with University policy and procedures. These sanctions may include: formal admonition or censure; suspension or removal from the institutional research oversight body, and/or any other research oversight roles and responsibilities; non-renewal of appointment; and/or dismissal.

9.0 CONSEQUENCE OF VIOLATING THE POLICY

Any Faculty or Staff member who fails to comply with any action specified by this policy, the **COI Committee**, or applicable Senior Vice President (as relates to this policy), will be subject to potential sanctions in accordance with applicable University policy and procedures. These sanctions may include: formal admonition or censure; suspension; non-renewal of appointment; and/or dismissal.

Appendix A.

General Definitions and Descriptions