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 and to act and 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, 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 potential, actual or perceived Conflicts of Interest and Conflicts of Commitment to ensure that the University, **Faculty**, **Staff**, and certain other **Investigators** conduct research, academic and administrative activities in a fair and unbiased manner. An integral part of this policy is therefore disclosure by **Faculty** and **Staff** of their commitments, financial interests and activities. The guidelines and mechanisms, as applied to **Faculty**, **Staff**, and certain other **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 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 be perceived as being compromised by, his or her Leadership Roles, Secondary Commitments 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 depends on the situation and not on the character of the individual. For example, Faculty or Staff who make decisions about purchasing or contracting for goods or services received by the University should not have relationships with, or Financial Interests in, outside Vendors or suppliers that conflict with, or appear to conflict with, their duty to act in the University’s best interests when purchasing or contracting on behalf of the University.

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, 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 one or more other Faculty members, the University or one or more University officials.

IV. General Definitions and Descriptions

A. Conflict of Interest ("COI") Committee: The COI Committee will be composed of at least nine members with five members constituting a quorum. The COI Committee members collectively should have knowledge in financial investments, legal issues, ethics and human subjects research. These members may be drawn from within and outside of the University. All members of the COI Committee must undergo training in the assessment and management of Conflicts of Interest and Conflicts of Commitment. COI Committee members will be nominated by the Committee on Research and appointed by the President. The President shall appoint the Chair of the COI Committee.

The COI Committee shall meet monthly, unless the Chair of the COI Committee determines there is no issue to be considered. The COI Committee members may participate in a meeting of the COI Committee by means of conference telephone or similar communications equipment if all persons participating in the meeting can hear each other at the same time. Such participation shall constitute presence in person at the meeting for purposes of a constituting a quorum and taking any action.

Appointment to the COI Committee is for a period of three years and may be renewed indefinitely at the discretion of the President. A COI Committee member may be removed by a Senior Vice President of the University only for good cause, which must be
fully documented for audit and grievance purposes. If a COI Committee member has or may have a Conflict of Interest with respect to any of his or her duties on the COI Committee, the COI Committee member will disclose such conflict and recuse himself or herself from such duty.

B. Designated Officials: The designated officials of the University for purposes of reviewing, administering and implementing Conflicts of Interest determinations shall be the President, the Senior Vice President for Academic Affairs and Provost, the Senior Vice President and Dean of the School of Medicine, the Deans and the Vice Deans of the Schools of Medicine, Public Health and Tropical Medicine, Architecture, Business, Science and Engineering, Newcomb-Tulane College, Law, Liberal Arts, Social Work, and Continuing Studies, the Director of the Tulane National Primate Research Center, the Vice President for Research, the Senior Vice President for Operations and Chief Financial Officer, the Executive Vice President for University Relations, the Chief of Staff and Vice President for Administrative Services and the General Counsel. Chairs of the IACUC, IRB and other University administrators may be called upon, as needed, by the Senior Vice Presidents or by the COI Committee for specific purposes.

C. Faculty: Persons holding academic positions of employment with the University.

D. Financial Interest: Any of the following received by an individual in any capacity or for any reason:

1. Any payment received from or equity interest held in a publicly traded entity during the 12-month period prior to the disclosure with a value that, in the aggregate, exceeds $5,000;

2. Any payment received from a non-publicly traded entity during the 12-month period prior to the disclosure with a value that, in the aggregate, exceeds $5,000;

3. Any equity interest in a non-publicly traded entity;

4. Income generated from intellectual property rights and interests, unless paid by the University to an individual employed or appointed by the University;

5. Reimbursed or sponsored travel with a value that exceeds $5,000, unless reimbursed or sponsored by the University or a federal, state or local government agency, an institution of higher education as defined in 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center or research institute affiliated with an institution of higher education. There is no dollar threshold for reimbursed or sponsored travel for Faculty and Staff who are Investigators for PHS-Funded Research, Affiliated PHS Investigators (as defined below in Part A-2) or Subrecipient PHS Investigators (as defined below in Part A-2).

A Financial Interest must be disclosed by Faculty, Staff or certain Investigators if it is related to that individual’s professional responsibilities on behalf of the University. These responsibilities may include, for example, activities such as research and research
consultation, teaching, professional practice, institutional committee memberships, and service on IRBs or safety monitoring boards.

A Financial Interest does not include: income from investments in which the day-to-day control of investments is held by a person not subject to this policy or any other University conflict of interest policy; remuneration paid by the University to the individual if the individual is employed or appointed by the University; or income from teaching, seminars or lectures paid by a federal, state or local government agency, an institution of higher education as defined in 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center or research institute affiliated with an institution of higher education.

E. **Immediate Family:** Spouse or domestic partner, children (including adoptees) and other dependents. Because of strict conflict of interest rules required by federal and state law, the definition of **Immediate Family** for a member of the Tulane University Medical Group and for other health care providers is broader than the definition for other **Faculty** and **Staff** members. **Members of the Tulane University Medical Group or other health care providers must refer to Part B of this policy for the definition of Immediate Family.**

F. **Institutional Review Board ("IRB"):** Any board, committee or other group formally designated by the University to review human subjects research, and which was established and which functions and operates in conformity with Part 46 of Title 45 and Part 56 of Title 21 of the Code of Federal Regulations. **IRB Members** are those persons who comprise the **IRB.**

G. **Investigator:** Any **Faculty**, **Staff** or affiliated person who serves as a project director or principal investigator or who, regardless of title or position, is responsible for the design, conduct or reporting of research. **Investigator** may include, for example, a collaborator or consultant.

H. **Leadership Role:** Employment, consulting in any administrative or executive capacity, or serving as (i) a member of a board of trustees, directors or administrators, (ii) an officer or (iii) a member of an advisory committee, advisory board or subcommittee of a board of trustees, directors or administrators, whether compensated or non-compensated.

I. **PHS-Funded Research:** Research funded by the Public Health Service or by an entity with Public Health Service-delegated authority, including the National Institutes of Health.

J. **Professional Interests:** Academic, research, personal, professional and/or institutional integrity, patient safety and welfare, or any other interest that may be added to this policy from time to time.

K. **Primary Commitment:** The time, energy and loyalty that any **Faculty** or **Staff** is required to dedicate to the University.

L. **Secondary Commitment:** Activities that are not part of the **Primary Commitment**, which include but are not limited to employment, consulting or participation in outside
businesses or organizations. The time, energy and loyalty that any Faculty or Staff dedicates to outside Leadership Roles and other compensated or non-compensated extramural activities. Secondary Commitments do not include personal activities conducted on holidays, vacations and weekends.

M. **Staff:** Persons holding non-academic employment with the University.

N. **Vendor:** Any individual, business, partnership, corporation or other entity that sells or conveys goods or services to the University, or that arranges for the purchase or sale of goods or services to, for or by the University.
I. Scope

These standards apply to Faculty and Staff other than those Investigators who are 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 31 of each year.

(2) Newly hired or affiliated 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 31.

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 if necessary.

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 in 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, and deans will review and submit the completed Form A 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 31 filing deadline, the COI Committee will review the disclosure forms, 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 COI Committee.

(3) Response

(a) Generally. If the COI Committee determines that an actual Conflict of Commitment or Conflict of Interest exists, then the COI Committee will endeavor to work with Faculty or Staff members to manage, reduce or eliminate the Conflict of Commitment or Conflict of Interest.

(b) Compelling and Necessary Exceptions. The COI Committee may consider “compelling and necessary” exceptions that would allow Faculty
or Staff members for whom an actual Conflict of Commitment or Conflict of Interest has been determined to exist to maintain their Leadership Role, Secondary Commitment or Financial Interest with appropriate oversight and controls to safeguard the reputations and integrity of the University and its Faculty and Staff.

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. The primary methods of controlling or managing conflicts shall include:

(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

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 31 of each year.

(2) Newly hired or 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 31.

(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 if necessary.

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 in 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 disclosure forms to Office of Sponsored Projects Administration. Supervisors, chairs, and deans will review and submit the completed Form A 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 31 filing deadline, the COI Committee will review the disclosure forms, 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.
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 or Conflict of Interest exists and implement a management plan if necessary.

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

Nature of Review

(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.

Response

(a) Generally. If the COI Committee determines that an actual Conflict of Commitment or 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.

(b) Compelling and Necessary Exceptions. The COI Committee may consider “compelling and necessary” exceptions that would allow Faculty or Staff members or Affiliated PHS Investigators for whom an actual Conflict of Commitment or Conflict of Interest has been determined to exist to maintain their Leadership Role, Secondary Commitment or Financial Interest with appropriate oversight and controls to safeguard the reputations and integrity of the University and its Faculty, Staff and Affiliated PHS Investigators.
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, Staff or Affiliated PHS Investigator in developing the management plan, the COI Committee may require, if necessary, that Faculty, Staff or Affiliated PHS Investigator to 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 or 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 (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 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 COI Committee.

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 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 on-going 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) 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 (v) a description of the management plan in place to address the 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 PHS Financial Conflict of Interest and any changes to the management plan.

(2) Public Disclosure. If Faculty, Staff 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 a PHS Financial Conflict of Interest, the University will
publicly disclose certain information about the interest prior to the expenditure of any funds for the PHS-Funded Research. The University will make the following information available (either by posting the information on its website or providing in writing within five days in response to a request): (i) the name, title and role of the individual with the Financial Interest; (ii) the entity with which the Financial Interest is held; and (iii) the nature and approximate value of the Financial Interest. Information posted on the University website will remain available for three years and will be updated annually and within 60 days of the receipt of any new information.

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 management plan appears to have biased the design, conduct or reporting of the 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 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 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 to previously published presentations of the PHS-Funded Research.

I. PHS Subrecipients

The University shall require any PHS Subrecipient (as defined below) by contract to either comply with this policy or to comply with its own financial conflicts of interest policy if such policy is compliant with the PHS-Funded Research conflict of interest regulations. If 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 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 on-going 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 Conflicts of Interest Administrator 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).

VII. Additional Definitions

A. Affiliated PHS Investigator: Any other person other than a Faculty or Staff member, who serves as project director or principal investigator or who, regardless of title or position, is responsible for the design, conduct or reporting of research funded by the Public Health Service and conducted by the University. Affiliated PHS Investigator may include, for example, a collaborator or consultant.

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

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

D. Retrospective Review: Review of PHS-Funded Research when non-compliance has been found. Documentation of a Retrospective Review will include: the number and title of the research project; the names of project director or lead PHS Investigator and the PHS Investigator with the Conflict of Interest; the name of the entity with which the PHS Investigator has the Conflict of Interest; the reason for the Retrospective Review; detailed methodology of how the Retrospective Review was conducted; and the findings and conclusions of the Retrospective Review.

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

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

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

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 policy of Tulane University on Conflicts of Commitment and Interest incorporates 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 the “Stark” laws). As required by such laws, the definition of Immediate Family in this Addendum shall apply to members of the Tulane University Medical Group and health care providers in lieu of the definition included in the policy to which this Part B is attached:

“E. 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.”