Tulane University

POLICIES ON CONFLICTS OF COMMITMENT AND INTEREST

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 (whether or 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 other than, with the exception of, researchers involved in certain federally-funded Public Health Service (“PHS”)-funded research.
  - Part A-2 establishes standards applicable to those employees, researchers and research subcontractors who are involved in certain federally-funded 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 Institutional Review Board Members and Research Oversight Officials.** This part of the policy applies only to Research Oversight Officials, for instance, all IRB, IACUC, and IBC members of the University institutional review board and certain other University personnel/staff Faculty and Staff who oversee research. This part, as applied to institutional review board 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 ensure that the academic, administrative and research activities of the University are conducted 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 as well as to the public. 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 and 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 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, Staff, and Staff Investigators of their commitments, financial interests, and outside 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 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, 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, 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 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 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 but also where they know of a Financial Interest held by their Immediate Family (for purposes of Vendor relationships, the definition of Immediate Family also includes parents, parents-in-law, siblings and siblings-in-law). 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 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.

1 For the complete definition of Immediate Family, see p. 7.
screening, or selection of Vendors. 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.

IV.V. General Definitions and Descriptions

A. **Conflict of Interest (“COI”) Committee:** Conflict of Interest: A set of circumstances in which the Professional Interests or duties of an individual, such as professional obligations or judgment owed to the University and its constituencies by a Faculty member, Staff member, or affiliated Investigator, are compromised by, or could reasonably be perceived as being compromised by, his or her Leadership Role(s), Financial Interest(s), Research Leadership Role(s), or Research Financial Interest(s).²

A.B. Conflict of Interest Committee (“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 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.C. Designated Officials: The designated officials of the University for purposes of reviewing, administering, and implementing Conflicts of Commitment and 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

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² See Part C of the Policy for the definition of Research Financial Interest. See Part D of the Policy for the definition of Research Leadership Role.
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, the CEO of TUMG, the Internal Auditor and the Office of the General Counsel. Chairs of the IACUC, IRB and other University administrators or staff may be called upon, as needed, by the Senior Vice Presidents or by the COI Committee for specific purposes.

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

E. Financial Interest: Any Anything of monetary value, whether or not the value is readily ascertainable, consisting of one or more of the following interests of a Faculty or Staff member or an Investigator (and those of the Faculty or Staff member’s or the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities, including any of the following received by an individual in any capacity or for any reason: (note that for this purpose the term “individual” includes the individual and any member of the individual’s Immediate Family):

1. Any payment(s) received from or equity interest(s) 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(s) 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 of more than $5,000 (from any one entity) 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 a 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 and 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 Notwithstanding the foregoing, a Financial Interest does not include the following:

(1) Salary, royalties, or other remuneration paid by the University to an individual if the individual is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights.

(2) Salary, royalties, or other remuneration paid by a Subrecipient to an individual if the individual is currently employed or otherwise appointed by the Subrecipient, including intellectual property rights assigned to the Subrecipient and agreements to share in royalties related to such rights. This exception may not apply to Faculty, Staff or Investigator companies, which will be evaluated on a case-by-case basis.

(3) Any ownership interest in a Subrecipient held by the Investigator, if (a) the entity is a commercial or for-profit organization, and (b) the Investigator is participating in the research as an Investigator only at the Subrecipient level.

(4) 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.

(5) Income from teaching engagements, 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 a research institute affiliated with an institution of higher education.

(6) Income from service on advisory committees or review panels for 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 a 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. Note that for purposes of evaluating Vendor relationships under Part IV above, Immediate Family also includes parents, siblings, parents-in-law, and siblings-in-law.

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 constitute the IRB.

**G.H. 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, or contractor.

**H.I. Leadership Role:** (a) Employment, consulting in any administrative or executive or administrator capacity, (b) consulting in any executive or administrator capacity, or (c) 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. (Note that any such employment, consultancy, or service by an Immediate Family member of an individual subject to this policy constitutes a Leadership Role on the part of such individual.) A Leadership Role may be compensated or non-compensated.

**I.J. 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.

**K. PHS Subrecipient:** An individual or legal entity that is a subrecipient, subcontractor, or consortium member under a PHS-Funded Research project.

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

**M. 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.N. Secondary Commitment:** Activities that are not part of the Primary Commitment, and which impose demands from outside entities, organizations, or projects for the time, energy, fiduciary obligations, or loyalty of Faculty or Staff. These may 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, as well as Leadership Roles and other compensated or non-compensated extramural activities. Secondary Commitments do not include personal activities conducted entirely on holidays, vacations, personal time, which have no conflicting effect on one’s Primary Commitment and weekends which do not reasonably create the appearance of such a conflict.
M. **Staff:** Persons holding non-academic employment with the University. For purposes of this policy, *Staff* shall include administrators who do not have academic appointments with the University.

P. **Subrecipient:** All PHS Subrecipients in addition to any individual or legal entity that is a subrecipient, subcontractor, or consortium member under a non-PHS Funded Research project.

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.
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 Staff other than those Investigators who are 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 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 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 if necessary 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 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, 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 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 the 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 the Faculty or Staff member 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, 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 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 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 if necessary, 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 in academic units 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 to Office of Sponsored Projects Administration through the University’s electronic online process. Supervisors, chairs, or deans and the Office of Sponsored Projects Administration will review and submit, 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 the disclosure forms, 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—or, Conflict of Interest, or PHS Financial Conflict of Interest—exists and implement a management plan, if necessary.

(c) PHS-Funded Research. The COI Committee must review current disclosure forms 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.

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3 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.
(3) **Response**

(a) **Generally.** If the **COI Committee** determines that an actual 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**.

(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**, **Conflict of Interest** or **Conflicts of PHS Financial Conflict 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(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 publicly disclose certain information about the interest, prior to the University’s expenditure of any funds for the under a PHS-Funded Research. The University will make the following information available (either by posting the information on its website or –funded research project, ensure public accessibility as provided herein to certain information about such conflicts of interest, by providing in writing, within five days in response to of a valid 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. 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 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 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**

J.**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 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.

K.**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-
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.

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).

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 set of circumstances in which 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 the 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 PHS Subrecipient.
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 Policies 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” “physician self-referral 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 other health care providers in lieu of the definition included in the policy to which this Part B is attached:

“E.F. Immediately 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.”
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 **real, potential and apparent Conflicts of Interest** may occur during research, this policy is intended to assist **Investigators** in determining when they have **Conflicts of Interest** in research, and to guide them in disclosing all potential conflicts and in cooperating with the management or elimination of the conflicts, where necessary. The guidelines and mechanisms, as applied to **Investigators** and **Subrecipient PHS Investigators** (as defined below) participating in **PHS-Funded Research**, are intended to comply with the **PHS-Funded Research** conflict of interest regulations outlined at 42 C.F.R. Part 50 Subpart F and **at 45 C.F.R. Part 94 and** should be interpreted **consistently** with those regulatory requirements and any implementing guidance.

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

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

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

IV. Process

A. Timing

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

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

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

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

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

(2) Other Disclosures.

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

B. Information Required

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

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4 As required by 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 is defined differently for members of the Tulane University Medical Group and other health care providers. Such members and health care providers must refer to the definition of Immediate Family that can be found in Part B of this Policy regarding such definition. The applicable definition Note that for purposes of evaluating Vendor relationships, Immediate Family for all other Investigators can be found also includes parents, siblings, parents-in-law, and siblings-in-law.

5 All Investigators currently conducting research must complete and file an initial Conflicts of Commitment and Interest Disclosure Form, including Form C, in the case of 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.

6 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. Chairs, supervisors, chairs or deans will review and submit, 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 the disclosure forms 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 disclosure forms 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 an actual 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 greater or 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 an actual 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) Compelling and Necessary Exceptions. The COI Committee may consider “compelling and necessary” exceptions that would allow an Investigator with an actual Conflict of Interest related to Research Financial Interests or Leadership Roles to conduct research, with appropriate oversight, at the University. This may be allowed to occur, for example, in circumstances where the Investigator has special expertise regarding the particular drug, device. 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.

(b)(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; where that the University has special facilities or equipment that are needed for the research and unavailable at most other institutions in the United States— that allow; or facilitate the proposed research; and/or where 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 that the Investigator himself or herself.

(e)(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(s) 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. The 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. The primary methods of controlling or managing Conflicts of Interest may 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 eliminating 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—where 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 disclosed 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 (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 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 the 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 of Interest is eliminated before such expenditure); (ii) within 60 days of any such Conflict of Interest 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 publicly disclose certain information about the interest prior to the University’s expenditure of any funds for the PHS-Funded Human Subjects Research. The University will make the following information available (either by posting the information on its website or 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 in response to a valid request; (http://tulane.edu/counsel/upload/Request-for-Report-of-Financial-Conflict-of-Interest-2.pdf): (i) the name, title and role of the individual with the Research Financial Interest; (ii) the entity with which the Research Financial Interest is held; and (iii) the nature and approximate value of the Research Financial Interest. Information posted on the University website will remain available for three years. 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 the PHS-Funded Human Subjects Research, the Office of Sponsored Projects Administration will promptly notify the Public Health Service entity funding the research of the corrective action taken or to be taken. The COI Committee will ensure compliance with any additional corrective actions imposed by the Public Health Service entity funding the research.

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

V. Audit and Sanctions for Non-Compliance

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

VI. Confidentiality

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

VII. Record Retention

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

VIII. Additional Definitions and Descriptions

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

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

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

D. 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.
D. Research Financial Interest:

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

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

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

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

Please note that a Research Financial Interest has no dollar or ownership thresholds; therefore, any interest related to a Sponsor or to the research must be disclosed, however small.

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

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

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

This policy applies to Research Oversight Officials (as defined below), which includes, but is not limited to, Institutional Review Board (“IRB”) Members and members of other institutional bodies) responsible for research oversight at Tulane University. This policy defines Research Oversight Officials to include all personnel Faculty and staff 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 requires and accrediting agencies require that IRB Members 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 human 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 IRB Members 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 human subjects research, Tulane University seeks to ensure that its Research Oversight Officials can carry out their responsibilities to protect the rights and welfare of human subjects participating in research projects at the University. Since the University recognizes that real, potential and apparent Conflicts of Interest may occur during research, this policy is intended to assist IRB Members as well as other 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 IRB Members and other 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 human 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’s Research Financial Interests. In particular, IRB Members and Research Oversight Officials may not have whose Research Financial Interests in any research sponsor or health-care related organization, nor any Research Leadership Roles in any research sponsor or research-related organization that could affect or reasonably be perceived to affect their review of research. 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 IRB Members and Research Oversight Officials must complete Form D of the Conflicts of Commitment and Interest Disclosure Form. 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 IRB Member or Research Oversight Official continues to supervise research at the University. IRB Members and 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. IRB Members and Research Oversight Officials must indicate upon the form disclose any and all Research Financial Interests and/or Research Leadership Roles they or their Immediate Family may have in any research or health care-related organization, including any not-for-profit or tax exempt health care-related companies or foundations. IRB Members and 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 an IRB Member or a Research Oversight Official or their Immediate Family in any research or health care-related organization changes in any material

7 As required by 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 is defined differently for members of the Tulane University Medical Group and other health care providers. Such members and health care providers must refer to the definition of Immediate Family that can be found in the addendum to the University’s Policy on Conflicts Part B of Commitment and Interest Disclosure Form regarding such definition. The applicable definition Note that for purposes of evaluating Vendor relationships, Immediate Family for all other Faculty and Staff members can be found in the Definitions section of that Policy also includes parents, siblings, parents-in-law, and siblings-in-law.

8 IRB Members and other 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 member of the University’s Research Oversight personnel official. Please see Tulane’s Conflicts Part C of Interest Policy for Investigators in Human Subjects Research.
way, the IRB Member or 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 Paragraph 1 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 financial and other confidential information of a Faculty and/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 IRB Member or Research Oversight Official to make certain that the IRB Member or Research Oversight Official does not possess, or a member of his or her Immediate Family, possesses any research or health care-related Research Financial Interests, or any Research Leadership Roles that could reasonably affect the Member’s or Official’s review of research. If the COI Committee concludes that the IRB Member or Research Oversight Official is devoid of any such Research Financial Interests and that the Member or Official does not possess any Research Leadership Roles that could reasonably affect the Member’s or Official’s review of research, then the matter will go no further. If, however, the COI Committee concludes that the IRB Member or Research Oversight Official possesses one or more Research Financial Interests, and/or that the Member or Official holds one or more Research Leadership Roles that could affect the Member’s or Official’s review of research, then the COI Committee will promptly inform the Member or Official in writing of its determination and of the remedies that must be taken by the Member or Official to fall into compliance. A Conflict of Interest will be deemed to exist per se if the IRB Member or Research Oversight Official is an inventor or co-inventor of a product or method in a study undergoing review or continuing review by that Member or Official, and/or where the IRB Member or 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 an IRB Member or Research Oversight Official is out of compliance with this policy due to has one or more Research Financial Interests, the COI Committee will require that the Member or Official reduce every such Research Financial Interest in any research Sponsor (as defined below) or health care-related organization to a de minimis level. The IRB Member or 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 an IRB Member or Research Oversight Official is out of compliance with this policy due to has one or more Research Leadership Roles that could affect his or her review of research, the COI Committee will require that the
 MEMBER or Official either terminate their Research Leadership Role(s) or recuse himself or herself from the review of any research protocol that could be affected by that role. While any IRB Member or 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 IRB Member’s or 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 Member or Official, or is deemed to exist based on the IRB Member’s or 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

IRB Members and Research Oversight Officials must recuse themselves from reviewing a research protocol whenever they self-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 IRB Member or Research Oversight Official has a Conflict of Interest. Nevertheless, the IRB Member or 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

An IRB Member or 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 not contest the terms and conditions of this policy (e.g., they may not contest the prohibition on Research Financial Interests, nor the remedy for such interests). 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 IRB Member or 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 IRB Member or Research Oversight Official to comply with this policy. Upon receipt of the applicable Senior Vice President’s written report, the IRB Member or 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, an IRB Member or Research Oversight Official may be audited for the purpose of verifying whether the IRB Member or 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 IRB Member or 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). An IRB Member or 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 IRB or other institutional research oversight body, and/or any other research oversight roles and responsibilities; non-renewal of appointment; and/or dismissal.

V. Additional Definitions

A. Research Leadership Role: (a) Employment—consulting in any administrative or executive or administrator capacity, or (b) consulting in any executive or administrator capacity, or (c) serving as (i) a member of a board of trustees or board of directors or administrators, (ii) an officer, or (iii) a member of an advisory committee, advisory board or subcommittee of a board of trustees or a board of, directors or administrators, whether remunerated or non-remunerated, in a research Sponsor or research-related organization. A Research Leadership Role may be compensated or non-compensated.

B. 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 any University conflict of interest policy.

Please note that a Research Financial Interest has no dollar or ownership thresholds; therefore, any interest related to a Sponsor or to the research must be disclosed, however small.
C. **Research Oversight Official:** Personnel (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. All **Designated Officials** in the policy of Tulane University **Policies** on Conflicts of Commitment and Interest are also **Research Oversight Officials**. An **Investigator** is not a **Research Oversight Official** simply because the he or she is an investigator is an **Investigator**.

D. **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.