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## Policy of Tulane University on Conflicts of Commitment and Interest Part A

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All terms in **Bold** are defined at the end of this Part A of the Policy.

### Principles

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

This policy provides guidelines and mechanisms for dealing with potential, actual or perceived conflicts of commitment and interest to ensure that the University and Faculty and Staff members conduct academic and administrative activities in a fair and unbiased manner. Thus, an integral part of this policy is disclosure by Faculty and Staff members of their commitments, financial interests and activities.

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

### Conflict of Commitment

Faculty and Staff members owe their **Primary Commitment** to University activities and responsibilities, must act in the institution's best interests, and must not permit any **Secondary Commitments** to an outside organization, entity or project jeopardize this **Primary Commitment**. A Conflict of Commitment occurs when these efforts for the University are compromised by one or more **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 were not to the University.

## Conflict of Interest

A Conflict of Interest arises whenever the Faculty or Staff member's **Professional Interests**, such as professional obligations or judgment owed to the University and its constituencies are compromised by, or could be perceived as being compromised by, his or her **Leadership Roles, Secondary Commitments or Financial Interests**. 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 of a Faculty Member could affect a **Financial Interest** of the University, or of a Faculty or Staff member. Academic integrity is compromised when the Faculty member modifies his work to augment or shield that **Financial Interest**, such that the work product does not accurately reflect the Faculty member's research, beliefs and opinions. For example, academic integrity may be compromised when a Faculty member prepares the content of a book, article, audit or other report, with knowledge that such content could reasonably be expected to affect a **Financial Interest** of that Faculty member, one or more other Faculty members, the University, or one or more University officials.

## Process

- 1) Disclosure: All Faculty and Staff must complete on an annual basis (by January 31 of each year) a Conflict of Interest and Conflict of Commitment Disclosure Form A. This Form A requires the individual to report any and all **Leadership Roles, Secondary Commitments and Financial Interests**. 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 could reasonably be expected to affect, or appear to affect, the professional judgment of a Faculty or Staff member. Faculty and Staff in academic units must submit completed disclosure forms to their department chair or the dean if the unit does not have a departmental chair structure. Staff in non-academic units must submit disclosure forms to their direct supervisor. Deans (in consultation with their department chairs where appropriate) and direct supervisors will review and forward (i) the completed Conflict of Interest and Conflict of Commitment Disclosure Form, (ii) a report that includes recommendations concerning the management of any disclosed conflicts, and (iii) a list of the names of individuals who fail to provide a disclosure form to the University's **Conflict of Interest Committee** (the "**COI Committee**"). Deans and direct supervisors will also forward a copy of the report, and a copy of the list of names of individuals who have not provided the required Conflict of Interest and Conflict of Commitment Disclosure Form, to the Senior Vice President responsible for their unit. Newly hired or affiliated Faculty and Staff must submit a Conflict of Interest and Conflict of Commitment Disclosure Form within the first three months of employment or affiliation, and must thereafter comply with the annual filing deadline of January 31.

- 2) Updating: If at any time over the course of the year one or more **Leadership Roles, Secondary Commitments** or **Financial Interests** of a Faculty or Staff member changes in any material way, the Faculty or Staff member must promptly provide an updated Conflict of Interest and Conflict of Commitment Disclosure Form in accordance with the procedures described in Paragraph (1).
- 3) Confidentiality: All financial and other confidential information disclosed by Faculty and Staff to the individuals described in Paragraph (1) will be maintained in strict confidence. The **COI Committee** may disclose such information only to other University administrators defined as **Designated Officials** to carry out the purpose of this Policy. No other uses or disclosures of the financial and other confidential information of a Faculty or Staff member will be permitted, unless required by law.
- 4) Review by the COI Committee: As promptly as practicable after the January 31 filing deadline, the **COI Committee** will review the disclosure forms and reports. The **COI Committee** may ask that a 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**. The **COI Committee** will endeavor to work with the Faculty or Staff member to manage, reduce or eliminate any identified conflicts. When necessary, the **COI Committee** will require that a Faculty or Staff member comply with a particular strategy for managing a conflict.
- 5) 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 members.
- 6) Management or Elimination of Conflicts of Commitment and Conflicts of Interest: The **COI Committee**’s management strategy 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 of Interest shall include:
  - (i) Modifying the University employment responsibilities of the conflicted Faculty or Staff member;
  - (ii) 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;
  - (iii) 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 Commitment**);

- (iv) 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 Commitment**).
- 7) Appeal of COI Committee Decision: A 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.

#### Audit and Sanctions for Non-Compliance

At the request of a Senior Officer 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 the annual Conflict of Interest and Conflict of Commitment Disclosure Form (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). A Faculty or Staff member who fails to file a completed Conflict of Interest and Conflict of Commitment Disclosure Form 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, 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.

## Definitions & Descriptions Part A

- a. **Conflict of Interest Committee.** The **COI Committee** will be composed of at least nine (9) members with five (5) members constituting a quorum. The Committee members collectively should have knowledge in financial investments, legal issues, ethics, and human subjects research. These members may be drawn from within and outside of the University. All members of the **COI Committee** must undergo training in the assessment and management of Conflicts of Interest and Conflicts of Commitment. **COI Committee** members will be nominated by the Committee on Research and appointed by the President. The President shall appoint the Chair of the **COI Committee**.

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

Appointment to the **COI Committee** is for a period of three (3) years and may be renewed indefinitely at the discretion of the President. A **COI Committee** member may be removed by a Senior Vice President of the University only for good cause, which must be fully documented for audit and grievance purposes. If a **COI Committee** member has or may have a Conflict of Interest with respect to any of his or her duties on the **COI Committee**, the **COI Committee** member will disclose such conflict and recuse himself or herself from such duty.

- b. **Designated Officials:** The designated officials of the University for purposes of reviewing, administering and implementing Conflicts of Interest determinations shall be the President, the Senior Vice President for Academic Affairs and Provost, the Senior Vice President for the Health Sciences, the Deans of the Schools of Medicine, Public Health and Tropical Medicine, Architecture, Business, Engineering, Graduate School, Law, Liberal Arts and Sciences, Newcomb College, Social Work, Tulane College and University College, the Director of the Tulane National Primate Research Center, the Senior Vice President for Operations and Chief Financial Officer, the Senior Vice President for External Affairs and the General Counsel. Chairs of the IRB and other University administrators may be called upon, as needed, by the Senior Vice Presidents or by the **COI Committee** for specific purposes.
- c. **Financial Interest:** Aggregate investments (whether in the form of debt, stock or other equity ownership, options or warrants to purchase stock or other securities or similar instruments) with a value exceeding \$10,000 or representing a five (5%) percent or greater interest in any entity, enterprise or trust; royalties on any patent or other intellectual property interests with a value exceeding \$10,000, unless paid by Tulane; or income, salary or remuneration in cash or in kind, emoluments, benefits, gifts, honoraria, travel expenses, goods or services with a value exceeding \$10,000. **Financial Interest** does not include holdings in mutual funds or other equity funds in which the day-to-day

control of investments is held by a person not subject to any Tulane University Conflict of Interest policy.

- d. **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 healthcare 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**.
- e. **Leadership Role**: Employment, consulting in any administrative or executive capacity, or serving as (i) a member of a board of trustees, directors or administrators, (ii) an officer or (iii) a member of an advisory committee, advisory board or subcommittee of a board of trustees, directors or administrators, whether compensated or non-compensated.
- f. **Professional Interests**: Academic, 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.
- g. **Primary Commitment**. The time, energy and loyalty that Faculty and Staff members are required to dedicate to the University.
- h. **Secondary Commitment**. Activities that are not part of the **Primary Commitment**, which include but are not limited to employment, consulting or participation in outside businesses or organizations. The time, energy and loyalty that Faculty and Staff members dedicate to outside **Leadership Roles** and other compensated or non-compensated extramural activities. **Secondary Commitments** do not include personal activities conducted on holidays, vacations and weekends.
- i. **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

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Part B of the  
Policy of Tulane University on  
Conflicts of Commitment and Interest  
For Members of the Tulane University Medical Group and Health Care Providers

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

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

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

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## Part C of the Policy of Tulane University on Conflicts of Commitment and Interest

### For Investigators in Human Subjects Research

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All terms in **Bold** are defined either at the end of the Tulane University Conflict of Commitment and Interest Policy or this Part C

#### Applicability

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

#### Principles

Federal law and policy require that for federally financed research studies, the university hosting the research gather information related to each **Investigator's Research Financial Interests**, as well as **Financial Interests** that may be affected by the research itself. Although these requirements originated in a concern for assuring the integrity of federally financed research data, Tulane 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, Tulane 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. While this policy governs the Conflicts of Interest of **Investigators**, it 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.

#### Process

- 1) Disclosure: All **Investigators** must complete Form C: Annual Research-Related Financial and Leadership Disclosures (hereinafter "Form C") of the Conflict of Interest and Conflict of Commitment Disclosure Form. This form must be submitted to the

**Investigator**'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 31 of each year) for as long as the **Investigator** continues to conduct any research at the University. **Investigators** who are newly hired by or affiliated with the University or who have not previously conducted research at the University may submit Form C of the Conflict of Interest and Conflict of Commitment Disclosure Form at any time during the year, provided that such **Investigators** may submit the form directly to the **COI Committee** in order to provide it at least three (3) weeks prior to the scheduled meeting date of the University's **Institutional Review Board** ("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**. Thereafter, such **Investigators** must comply with the January 31 filing deadline.

**Investigators** must indicate in Form C any and all **Research Financial Interests** and/or **Leadership Roles** they or their **Immediate Family**<sup>1</sup> may have in any research or health care-related organization, including any not-for-profit or tax-exempt health care-related companies or foundations.<sup>2</sup> **Investigators** must append to the Disclosure Form a copy of every report of their **Research Financial Interests** that they are required to submit to any **Sponsor** of research.<sup>3</sup> Any report of **Research Financial Interests** that is sent to a **Sponsor** of research anytime after the January 31 filing deadline must also be sent without delay to the **COI Committee**.

- 2) Updating: If at any time over the course of the year one or more **Research Financial Interests** or **Leadership Roles** of an **Investigator** or an **Investigator's Immediate Family** in any research or health care-related organization changes in any material way, the **Investigator** must promptly notify the **COI Committee** of that change by submitting a written statement detailing such change(s).

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<sup>1</sup> As required by law, the term **Immediate Family** is defined differently for members of the Tulane University Medical Group and other health care providers. Such members and health care providers must refer to the definition of **Immediate Family** that can be found in Part B of the University's Policy on Conflicts of Commitment and Conflicts of Interest regarding such definition. The applicable definition of Immediate Family for all other Faculty and Staff members can be found in the Definitions section of that Policy.

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

<sup>3</sup> This includes, but is not limited to, reports that must be made to **Sponsors** pursuant to regulations of the United States Food and Drug Administration.

**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** of research.

- 3) Confidentiality: All financial and other confidential information disclosed by Investigators as described in Paragraph 1 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 an Investigator will be permitted, unless required by law.
- 4) IRB Application and Continuing Review Forms: In the application for **IRB** approval of the 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 Conflict of Commitment and Conflict of 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** staff may not process applications for **IRB** approval and may not commence continuing review of a protocol until each **Investigator** has provided this required information. 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 information has been provided.
- 5) Review by the COI Committee: The **COI Committee** shall meet to consider whether any disclosed **Research Financial Interests** or **Leadership Roles** constitute an actual Conflict of Interest in regard to an **Investigator's** research. For this purpose, the **COI Committee** may ask that the **Investigator** provide additional information or discuss the matter with the **COI Committee** in person. 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 in regard to research integrity and the safety and welfare of human subjects. The greater the **Research Financial Interest** or **Leadership Role** of the **Investigator** in the research being conducted by that **Investigator**, the greater the potential risk that the conflicts may inappropriately influence research outcomes and/or subject safety and welfare. Whenever an **Investigator** indicates in an **IRB** or continuing review application that the research may be affected by one or more **Research Financial Interests** or **Leadership Roles** held by the **Investigator** and the **Investigator** has not disclosed the information to the **COI Committee**, the **IRB** will forward the **Investigator's** response to the **COI Committee** for review and resolution.
- 6) Compelling and Necessary Exceptions: The **COI Committee** may consider "compelling and necessary" exceptions that would allow an **Investigator** with an actual Conflict of Interest related to **Research Financial Interests** or **Leadership Roles** to conduct research, with appropriate oversight, at the University. This may be allowed to occur, for example, in circumstances where the **Investigator** has special expertise regarding the

particular drug, device or method under investigation that uniquely qualifies that **Investigator** to conduct the investigation; where the University has special facilities or equipment that are unavailable at most other institutions in the United States that allow or facilitate the proposed research; and/or where the **Investigator** or the University is particularly well situated to enroll study subjects because of the patient population of University-affiliated health care providers or of that **Investigator** himself or herself.

- 7) Management or Elimination of Conflicts of Interest: 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 shall include:
- (i) Eliminating the conflict by referring the study to non-conflicted **Investigators** at the University, by divesting or sequestering the conflicting **Research Financial Interest** or eliminating the **Leadership Role**, or by referring the study to another site at which **Investigators** are not conflicted;
  - (ii) 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**;
  - (iii) Disclosing the conflicting **Research Financial Interest** or **Leadership Role** to **Sponsors**, research subjects (i.e., during the informed consent process) and/or journals and other publications;
  - (iv) Providing independent monitoring of the subject recruitment and/or informed consent processes;
  - (v) Requiring independent monitoring and oversight of subject-researcher interactions, data gathering, data analysis, and/or data reporting;
  - (vi) 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
  - (vii) 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.
- 8) Appeal of COI Decision: The **COI Committee** shall promptly notify the **Investigator** and the **IRB** of its finding(s) regarding whether the **Research Financial Interest(s)** and/or **Leadership Role(s)** of the **Investigator** constitutes a Conflict of Interest, and if

so, regarding the method(s) it recommends for managing any such Conflict(s) of Interest. **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.

- 9) IRB Review of the COI Committee's and/or Senior Vice President's Findings and Management Strategy: The **IRB** shall review the findings and management strategies of the **COI Committee**, and of the applicable Senior Vice President when there has been an appeal. The **IRB** may accept the management strategies, or may strengthen them. If the **IRB** elects to strengthen the management strategies, it must document its reasons for doing so and submit a copy of its written report to the **COI committee** and to the applicable Senior Vice President. The **IRB** must promptly notify the **Investigator** in writing of its determination regarding the Investigator's real or perceived Conflict of Interest, who must comply with the management strategies as modified by the **IRB**.
- 10) 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**.

### Audits 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, Financial Interests, including Research Financial Interests** in the Annual Conflict of Commitment and Conflicts of Interest Disclosure Form, including Forms B and 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 of the Conflict of Interest and Conflict of Commitment Disclosure Form 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; and/or dismissal.

## Additional Definitions & Descriptions Part C

- j. **Investigator**: Any professional research staff member involved in exercising independent judgment in research design, enrollment, data collection and gathering, data analysis and/or preparation for publication that requires **IRB** approval.
- k. **IRB or Institutional Review Board**: 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 who comprise the IRB.
- l. **Research Financial Interest**: Any investments (whether in the form of debt, stock or other equity ownership, options or warrants to purchase stock or other securities or similar instruments) or interest in a **Sponsor**, research or healthcare related organization; royalties on any patent or other intellectual property interests, unless paid by Tulane; or 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 healthcare related organization. **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 covered by any Tulane University Conflict of Interest policy. Please note that 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.
- m. **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.