

Policy for Conflicts of Interest of Institutional Review Board Members and Research Oversight Officials

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

Applicability

This policy applies to **Research Oversight Officials**, 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 and staff of any institutional office or body at the University who perform research oversight functions in which they exercise professional or administrative-level discretion

Principles

Federal law requires that **IRB 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** 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 **Leadership Roles** that may be held by **IRB Members** 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 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 the **IRB Member's** or **Research Oversight Official's** or their **Immediate Family's**¹ **Research Financial Interests**. In particular, **IRB Members** and **Research Oversight Officials** may not have **Research Financial Interests** in any research sponsor or health-care related organization, nor any **Leadership Roles** in any research sponsor or research-related organization that could affect their review of research.

Process

- 1) Disclosure: All **IRB Members** and **Research Oversight Officials** must complete Form D of the Conflict of Interest and Conflict of Commitment Disclosure Form.² 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 Interest and Conflicts of Commitment and must be updated on an annual basis (by January 31 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 Form prior to beginning their research oversight duties, and must thereafter comply with the January 31 filing deadline. **IRB Members** and **Research Oversight Officials** must indicate upon the form any and all **Research Financial Interests** and/or **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 **Leadership Roles** could affect, or appear to affect, their review of any particular research projects.
- 2) Updating: If at any time over the course of the year one or more **Research Financial Interests** or **Leadership Roles** of an **IRB Member** or **Research Oversight Official** or their **Immediate Family** in any research or health care-related organization changes in any material 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).

¹ As required by law, the term Immediate Family is defined differently for members of the Tulane University Medical Group and other health care providers. Such members and health care providers must refer to the definition of Immediate Family that can be found in the addendum to 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.

² **IRB Members** and other **Research Oversight Officials** who are also **Investigators** must complete Form C of the Annual Conflicts of Interest and Conflicts of Commitment Disclosure Form in their capacity as Investigator, and Form D in their capacity as a member of the University's research oversight personnel. Please see Tulane's [Conflict of Interest Policy for Investigators](#).

- 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 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 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 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 any research or health care-related **Research Financial Interests**, or any **Leadership Roles** that could 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 **Leadership Roles** that could 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 **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.

- 5) Management or Elimination of Conflicts of Interests: Where an **IRB Member** or **Research Oversight Official** is out of compliance with this policy due to one or more **Research Financial Interests**, the **COI Committee** will require that the Member or Official reduce every **Research Financial Interest** in any research **Sponsor** 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**, which 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 one or more **Leadership Roles** that could affect his or her review of research, the **COI Committee** will require that the Member or Official either terminate that **Leadership Role** or recuse himself or herself from the review of any research protocol that could be affected by that role. While an **IRB Member** or **Research Oversight Official** may not review a study that is being funded by a **Sponsor** in which he or she holds a **Leadership Role**, **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.

- 6) **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**.
- 7) **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 lie in regard to whether the **IRB Member's** or **Research Oversight Official's Leadership Role** is likely to affect his or her review of research, but **IRB Members** and **Research Oversight Officials** 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.

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 **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.

Additional Definitions

- a. **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.
- b. **IRB (“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 persons who comprise the IRB.
- c. **Leadership Role**: Employment, consulting in any administrative or executive capacity, or serving as (i) a member of a board of trustees or board of directors, (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, whether remunerated or non-remunerated, in a research **Sponsor** or research-related organization.
- d. **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 any interest in a **Sponsor**, research or healthcare-related organization; royalties on any patent or intellectual property interests, unless paid by Tulane; or income, salary or remuneration in cash or 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.
- e. **Research Oversight Official**: Personnel and staff of any institutional office or body 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 on Conflicts of Commitment and Interest are also Research Oversight Officials.
- 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 assisting in applications or responses to the FDA.