PART D

POLICY FOR CONFLICTS OF INTEREST OF RESEARCH OVERSIGHT OFFICIALS

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

I. Applicability

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

II. Principles

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

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

Because IRB Members and other Research Oversight Officials have primary responsibility for protecting the safety and welfare of subjects participating in research at the University, it is the policy of the University that IRB Members and Research Oversight Officials, may not review any research protocol in which a decision to approve or disapprove the protocol could affect or reasonably be perceived to affect the IRB Member’s or Research Oversight Official’s or their
Immediate Family’s Research Financial Interests. Research Oversight Officials whose Research Financial Interests or Research Leadership Roles could affect or reasonably be perceived to affect their review of a research protocol must reduce such interests, eliminate such roles, and/or recuse themselves from reviewing the protocol in accordance with Sections III.E and F below.

III. Process

A. Disclosure

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

B. Updating

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

C. Confidentiality

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

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1 The applicable definition of Immediate Family can be found in the Definitions section of Part A of the Policy. Pursuant to relevant federal law, the Policy defines the term Immediate Family differently for members of the Tulane University Medical Group and other health care providers. Such members and health care providers must refer to the definition of Immediate Family that can be found in Part B of this policy regarding such definition. Note that for purposes of evaluating Vendor relationships, Immediate Family also includes parents, siblings, parents-in-law, and siblings-in-law.

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

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

E. **Management or Elimination of Conflicts of Interests**

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

F. **Recusal**

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

G. Appeal of COI Decision

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

IV. Audits and Sanctions for Non-Compliance

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

V. Additional Definitions

A. Research Leadership Role: (a) Employment in any 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 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:** **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 Tulane University Policies on Conflicts of Commitment and Interest are also **Research Oversight Officials**. An **Investigator** is not a **Research Oversight Official** simply because he or she 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.