All terms in **Bold** are defined at the end of the policy.

I. **Principles**

Tulane University is committed to compliance with the 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 Institutional Research Conflicts of Interest.

Institutional Research Conflicts of Interest raise concerns when financial interests create the potential for inappropriate influence over research activities conducted by or on behalf of the University. Inappropriate influence potentially threatens the integrity of the research and the welfare of any human subjects participating in the research.

The University interacts with a variety of commercial interests to promote the University’s research, education and clinical care missions. These interactions may involve various financial benefits for the University, including charitable donations and grants, royalty payments and equity from licensing intellectual property, and sponsored research agreements. In particular, the University may collaborate with a commercial interest to undertake research that advances science and enables the commercial development of academic discoveries to the benefit of the public. The University must take care that these interactions are not allowed to compromise, or appear to compromise, the integrity of the University’s missions.

This policy provides guidelines and mechanisms for identifying and addressing potential, actual or perceived Institutional Research Conflicts of Interest to ensure that the University and University Research Officials conduct or oversee research in a fair and unbiased manner that ensures the integrity of the research and the welfare of any human subjects participating in the research.

The principles of this policy are consistent with the University Policies on Conflicts of Commitment and Interest governing individual conflicts. Administration of the various policies are also coordinated to promote consistency and ease of administration (e.g., with respect to University Research Officials, this policy relies upon processes established in the University Policies on Conflicts of Commitment and Interest for the collection of information about financial interests of the individuals). Individual conflicts addressed by the University Policies on Conflicts of Commitment and Interest, do not necessarily give rise to Institutional Research Conflicts of Interest.

A copy of this policy will be posted on the University website on a page accessible to University personnel as well as to the public.
II. Institutional Conflict of Interest

An Institutional Research Conflict of Interest exists whenever the financial interests of the University, or of University Research Official acting within his or her authority on behalf of the University, could directly and significantly affect or reasonably appear to affect University processes for the design, conduct, reporting, review or oversight of research.

III. Identification of Potential Institutional Conflicts of Interest

A. Generally

This policy sets forth financial or other interests of the University or a University Research Official involving research sponsors that warrant formal review as Potential Institutional Research Conflicts of Interest, as defined in Sections III.B and C below. Information about these interests will be specifically sought as set forth in this policy to ensure formal review.

The interests listed are not intended to be exhaustive. There may be other interests that, depending on the particular circumstances, could potentially give rise to an Institutional Research Conflict of Interest. The University will assess such interests, if and when identified, in accordance with the review standards set forth in this policy.

B. Institutional Interests

The following significant financial and fiduciary interests of the University constitute a Potential Institutional Research Conflict of Interest and warrant formal review:

(1) **Royalties:** University has the potential to receive significant milestone payments and/or royalties from the licensing or sale of an investigational product or technology that is the subject of the research;

(2) **Non-publicly Traded Equity:** University, through its technology licensing activities or investments related to such activities, has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a non-publicly traded company that is: (i) the sponsor of research at the University, or (ii) the manufacturer of a product or technology to be studied or tested in research at or under the auspices of the University;

(3) **Publicly Traded Equity:** University, through its technology licensing activities or investments related to such activities, has obtained an ownership interest or an entitlement to equity (including options or warrants) exceeding $100,000 in value (when valued in reference to current public prices, or, where applicable, using accepted valuation methods), in a publicly-traded company that is (i) the sponsor of research at the University, or (ii) the manufacturer of a product or technology to be studied or tested through research at or under the auspices of the University.

(4) **Gifts from Sponsors:** University has received substantial gifts (including gifts in kind) from a current or potential commercial sponsor of research or a company
that owns or controls products being studied or tested through research and one or more of the following circumstances exist:

(a) Gift is of sufficient magnitude that even when held in the general endowment for the benefit of the entire University, the gift might affect, or reasonably appear to affect, oversight of research at the University;

(b) Gift is held for the express benefit of the college, school, department, institute or other unit where the research is to be conducted; or

(c) A University Research Official who has the authority, by virtue of his or her position, to affect or appear to affect the conduct, review or oversight of the proposed research has been involved in solicitation of the gift.

C. University Research Official Interests

The following significant financial and fiduciary interests of University Research Officials (and their Immediate Families) constitute a Potential Institutional Research Conflict of Interest and warrant formal review when those interests involve the sponsor of research at the University, or the manufacturer of a product or technology to be studied or tested through research at or on behalf of the University, unless excepted from review below:

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

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

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

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

(5) Reimbursed or sponsored travel with a value that exceeds $5,000, unless reimbursed or sponsored by the University or a federal, state or local government agency, an institution of higher education as defined in 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center or research institute affiliated with an institution of higher education;

(6) An appointment to serve, in either a personal or representative capacity, in a fiduciary role for an entity (e.g., officer or director) whether or not remuneration is received for such service. Typically, the appointment will involve service as an officer, director, or other board member of the company;

(7) An appointment to serve on the scientific advisory board of an entity unless the official has no current significant financial interest in the sponsor or the investigational product and agrees not to hold such an interest for a period of no
less than three years following completion of any related research conducted at or under the auspices of the University.

The following interests are not considered to create a Potential Institutional Research Conflict of Interest and are excepted from formal review: income from investments in which the day-to-day control of investments is held by a person not subject to this policy or any other University conflict of interest policy; remuneration paid by the University to the individual if the individual is employed or appointed by the University; or income from teaching, seminars or lectures paid by a federal, state or local government agency, an institution of higher education as defined in 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center or research institute affiliated with an institution of higher education.

D. Particular Activities

The procurement decision of the University may warrant formal review if a University Research Official participates materially in a procurement or purchasing decision involving major institutional purchases from, or non-routine supply contracts with, an entity that sponsors research at the University, or manufactures a product to be studied or tested in research at or on behalf of the University.

IV. Process

A. Collection of Information and Reporting

Administration of Institutional Research Conflict of Interest matters will be handled by the COI Administrator, which will provide information to the Institutional Research Conflict of Interest ("COI") Committee for review.

(1) Institutional Interests. In order to make the COI Administrator aware of Potential Institutional Research Conflict of Interest situations and transactions, the following offices should report on a periodic basis as determined by the Institutional Research COI Committee but no less than annually, to the COI Administrator on the Institutional Interests described in Section III.B of this policy:

(a) Technology transfer office (for licensing arrangements, patents, invention disclosures);

(b) Office of Sponsored Projects Administration (for sponsored research agreements and products and technology that are the subject of research);

(c) Development office (for gifts, including but not limited to any provision of funding, grants, or charitable donations);

(d) Institutional Review Board ("IRB") (for human subjects research protocols including information on sponsors);

(e) Procurement office (for major institutional purchases).
The COI Administrator will organize and forward the reported information to the Institutional Research COI Committee for review.

The COI Administrator will work with the Institutional Research COI Committee and the offices with reporting responsibilities to develop guidelines to ensure reporting obligations are met and that any necessary technology is developed to facilitate reporting. Such guidelines may address dissemination of information to the reporting officers (e.g., a list of research sponsors) to allow identification of relevant information.

(2) University Research Official Interests. Information will be collected from University Research Officials in accordance with requirements of the Tulane Policies on Conflicts of Commitment and Interest. This process will capture information concerning any Potential Institutional Research Conflict of Interest and the Institutional Research COI Committee will be able to rely on the information obtained through this process. These requirements are summarized as follows:

(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.

(i) All University Research Officials must complete Form A by January 31 of each year.

(ii) Newly hired or affiliated University Research Officials must submit Form A within 60 days of employment or association, and must thereafter comply with the annual filing deadline of January 31.

(iii) University Research Officials must promptly, but no later than 30 days, after the acquisition or discovery of any new information or material modification that would necessitate the submission of an updated Form A.

(b) Information Required. Form A requires the University Research Official to report financial and fiduciary interests and commitments that could give rise to a Potential Institutional Research Conflict of Interest. In addition, this form requires the University Research Official to report financial and fiduciary interests and commitments that the University Research Official’s Immediate Family may have that could give rise to a Potential Institutional Research Conflict of Interest or could reasonably be expected to affect, or appear to affect, the professional judgment of the University Research Official. Further information may be requested by the Institutional Research COI Committee if necessary.

(c) Submission of Forms. University Research Officials must submit completed disclosure forms through an electronic online process. The
online submissions are forwarded to supervisory representatives for review and comment. The COI Administrator will ensure that, for any University Research Official, the completed Form A with comments will be forwarded to the Institutional Research COI Committee along with a list of names of individuals who have not provided the required Form A.

B. Review by Institutional Research COI Committee

The Institutional Research COI Committee will review information collected.

(1) Review of the University’s Interests. Within twenty-one days, unless extended by the Institutional Research COI Committee, of receiving a periodic report concerning significant financial and fiduciary interests of the University, the Institutional Research COI Committee will complete its review and determination as to whether an Institutional Research Conflict of Interest exists and implement a management plan if necessary.

(2) Review of University Research Officials’ Interests.

   (a) Review of Annual Disclosure Forms. As promptly as practicable after the January 31 filing deadline, the Institutional Research COI Committee will review the disclosure forms, determine whether a conflict exists and implement a management plan if necessary. The Institutional Research COI Committee may ask that a University Research Official who has a potential conflict provide additional information or discuss the matter with the Institutional Research 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 University Research Official, the Institutional Research COI Committee will complete its review and determination as to whether an Institutional Research Conflict of Interest exists and implement a management plan if necessary. The Institutional Research COI Committee may ask that a University Research Official who has a potential conflict provide additional information or discuss the matter with the Institutional Research COI Committee in person.

(3) Nature of Review

   (a) Generally. The Institutional Research COI Committee will review all disclosures and reports to determine whether an Institutional Research Conflict of Interest exists and will provide a written recommendation based on its review.

   (b) Guidelines. The University will maintain guidelines for the Institutional Research COI Committee to assist the committee in assessing whether an Institutional Research Conflict of Interest exists. The guidelines will be periodically reviewed and updated if necessary.
Response

(a) Generally. If the Institutional Research COI Committee determines that an actual Institutional Research Conflict of Interest exists, the Institutional Research COI Committee will seek to manage, reduce or eliminate the Institutional Research Conflict of Interest. For University Research Officials, the Institutional Research COI Committee will work with University Research Officials to address the Institutional Research Conflict of Interest.

(b) Compelling and Necessary Exceptions. The Institutional Research COI Committee may consider “compelling and necessary” exceptions that would allow the research to proceed. Whether compelling and necessary exceptions exist will depend in each case upon an analysis of the following factors (to the extent applicable):

(i) the nature of the science;

(ii) the nature of the overlapping interests;

(iii) how closely the interest is related to the research;

(iv) the degree to which the interest may be affected by the research;

(v) the degree of risk that the research poses to human subjects and to the integrity of the research;

(vi) the degree to which the Institutional Research Conflict of Interest can be effectively managed;

(vii) whether the University is uniquely qualified, by virtue of its attributes (e.g., special facilities or equipment, unique patient population) and the experience and expertise of its investigators, to conduct the research and safeguard the welfare of the human subjects involved;

(viii) how direct and immediate the University Research Official’s authority is over the research and the people involved in conducting the research;

(ix) status of the company (e.g., privately-held start-up company, small publicly-traded or large publicly-traded company) and the importance or perceived importance of the research to the finances of the company;

(x) risk to the academic freedom and unbiased treatment of the faculty member who has proposed the research;
(xi) perceived risk to the reputation of the University;

(xii) whether the studies involve institutional intellectual property that is used as a platform technology or a generic method used broadly;

(xiii) likelihood that a societally important development project will be substantially impeded if the research is not performed at the University;

(xiv) societal impact of successful development, relative to potential risk to the University;

(xv) magnitude of potential risks posed to students or trainees engaged in the research project;

(xvi) whether the trial is at multiple sites and, if so, whether the University’s role is relatively passive or the site that gathers and/or monitors the data from all other sites;

(xvii) whether the University’s resources are fundamentally important to the progress of the science;

(xviii) proportion of the total subjects in the study that are under the supervision of the University; and

(xix) unique expertise of the University Research Official

If the Institutional Research COI Committee determines that there are compelling circumstances for allowing the research to proceed in the presence of the Institutional Research Conflict of Interest, those circumstances should be documented in the Institutional Research COI Committee’s recommendation.

When an Institutional Research Conflict of Interest that involves human subjects research is identified, the Institutional Research COI Committee will notify the Institutional Review Board and the Office of Sponsored Projects Administration (if the Institutional Research Conflict of Interest involves a sponsored project).

(c) Note that the expectation of the University is that, if the University holds an equity interest in a non-publicly traded company, the University will not conduct research sponsored by the company or involving the company’s products.

C. Management of Institutional Research Conflicts of Interest

(1) If it is determined that there are compelling circumstances for allowing the research to proceed in the presence of the Institutional Research Conflict of
Interest, the **Institutional Research COI Committee** will develop a recommended management plan. The management plan should take into account the nature of the conflict; the specific risks to human subjects (if human subjects research is implicated); the perceived risk to the integrity of the research as a result of the conflict; and the perceived risk to the reputation of the University.

(2) One or more of the following management strategies should be used:

(a) Disclosure of the Institutional Research Conflict of Interest in the informed consent process;

(b) If the Institutional Research Conflict of Interest involves a senior official, formal recusal of the conflicted official from the chain of authority over the project and possibly also from authority over salary, promotion, and space allocation decisions affecting the investigator, as well as communication of the recusal arrangements to the official’s superior and colleagues;¹

(c) If the Institutional Research Conflict of Interest involves a senior official, designation of a “safe haven” (e.g., a non-conflicted senior individual) with whom the investigator can address Institutional Research Conflict of Interest-related concerns;

(d) Use of an external IRB;

(e) External monitoring of the study, particularly endpoint assessments;

(f) Use of an external data safety monitoring board or similar review board to evaluate the design, analytical protocols, and primary and secondary endpoint assessments, and to provide ongoing evaluation of the study for safety, performance issues and the reporting of results;

(g) Disclosure of the Institutional Research Conflict of Interest in public presentations and publications;

(h) Disclosure of the Institutional Research Conflict of Interest to other centers in a multi-center trial;

(i) Reduction/restriction (rather than divestiture/elimination) of financial interests;

(j) Disclosure of the conflict to others involved in research;

¹ Note that recusal is not an effective management strategy when the individual, by virtue of conflicts arising from personal financial holdings, would be precluded from fulfilling the responsibilities of his or her position. In such cases, the best interests of the University may necessitate that the individual divest the interests or vacate the position.
(k) Limitation of research role (e.g., to conduct of certain procedures, non-primary site/not coordinating site);

(l) Presence at IRB meeting of community member and community member’s approval;

(m) Third party opinion on whether to conduct research; and

(n) Other management strategies as deemed appropriate by the Institutional Research COI Committee.

D. Approval and Appeal of the Determination

(1) After the Institutional Research COI Committee makes its recommendation concerning an Institutional Research Conflict of Interest and any required management strategies, the COI Administrator will transmit the recommendation to the Senior Vice President for Academic Affairs and Provost for final determination.

(2) If the Institutional Research Conflict of Interest involves a University Research Official, the recommendations will also be forwarded to the University Research Official who will be given an opportunity to comment on the recommendation before any final decision is made.

(3) If the Institutional Research Conflict of Interest involves the University, the President, in his or her discretion with advice from the General Counsel, may seek confirmation from the Board of Administrators.

V. Implementation

Each Institutional Research Conflict of Interest management plan should state specifically who will be responsible for the plan’s implementation.

The COI Administrator will communicate the management plan, once finalized, to all University officials and personnel with responsibility for compliance with, or implementation of, the plan. The COI Administrator will also provide the Institutional Research COI Committee’s recommendation to the University IRB (if the Institutional Research Conflict of Interest involves human subjects research) and the Office of Sponsored Projects Administration (if the Institutional Research Conflict of Interest involves a sponsored research project) so that the IRB review of the project can consider the Institutional Research Conflict of Interest, and so that the Office of Sponsored Projects Administration can meet any applicable reporting obligations.

Adherence to the management plan will be evaluated by the University’s COI Administrator. Review of compliance with management plans will be performed by the COI Administrator.
VI. Audits and Non-Compliance

Consistent with the Tulane Policies on Conflicts of Commitment and Interest, at the request of a Designated Official of the University, a University Research Official may be audited for the purpose of verifying whether the individual truthfully and accurately disclosed his or her financial and fiduciary interests and commitments 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 Institutional Research COI Committee.

Any University Research Official 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, or the Institutional Research COI Committee 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.

VII. Confidentiality

Consistent with the Tulane Policies on Conflicts of Commitment and Interest, all financial and other confidential information disclosed by a University Research Official pursuant to this policy will be maintained in strict confidence. The Institutional Research COI Committee may disclose such information only to other University administrators defined as Designated Officials. No other uses or disclosures of the financial and other confidential information of any University Research Official member will be permitted, unless required by law.

VIII. Definitions and General Descriptions

A. Designated Officials: Consistent with the Tulane Policies on Conflicts of Commitment and Interest, the designated officials of the University for purposes of this policy shall be the President, the Senior Vice President for Academic Affairs and Provost, the Senior Vice President and Dean of the School of Medicine, the Deans and the Vice Deans of the Schools of Medicine, Public Health and Tropical Medicine, Architecture, Business, Science and Engineering, Newcomb-Tulane College, Law, Liberal Arts, Social Work, and Continuing Studies, the Director of the Tulane National Primate Research Center, the Vice President for Research, the Senior Vice President for Operations and Chief Financial Officer, the Executive Vice President for University Relations, Chief of Staff and Vice President and the General Counsel. Chairs of the IACUC, IRB and other University administrators may be called upon, as needed, by the Senior Vice Presidents or by the Institutional Research COI Committee for specific purposes.
B. **Immediate Family:** For University Research Officials *other than* members of the Tulane University Medical Group and other health care providers, the spouse or domestic partner, children (including adoptees) and other dependents. For University Research Officials *who are* members of the Tulane University Medical Group or other health care providers, the 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.

C. **Institutional Research Conflict of Interest ("COI") Committee:** The Institutional Research COI Committee will consist of seven members as follows: two members from the University’s individual Conflict of Interest Committee; the Chair of the University’s IRB; the University’s Vice President for Research; and at least two external community members. The external community members will be appointed by the University’s President (or his/her designee) and neither the Members nor his or her Immediate Family may be on the University’s payroll. A quorum will consist of four voting members, at least one of whom should be an external community member.

Members of the Institutional Research COI Committee should abstain from Institutional Research COI Committee business when they have a personal conflict of interest or involvement in an Institutional Research COI that relates to a research proposal under review, as provided by University policy.

D. **University Research Official:** An individual who, because of his or her position with the institution, has the capacity to affect, or can reasonably appear to affect, University processes for the design, conduct, reporting, review, or oversight of research. All Research Oversight Officials in the policy of Tulane University on Conflicts of Commitment and Interest are also University Research Officials under this Policy. The Institutional Research COI Committee may identify additional positions as warranted and such positions shall be listed on Attachment A of this Policy as amended from time to time. Individuals occupying these positions will be notified of their status when they are required to submit a Disclosure Form.
Attachment A

University Research Officials

Individuals occupying the positions below, as identified and amended from time to time by the Institutional Research COI Committee, shall be included in the definition of University Research Officials. The Institutional Research COI Committee from time to time may identify additional individuals occupying other positions as University Research Officials.