

***CHAPTER 3: FACULTY: ACADEMIC PRACTICES AND POLICIES**

SECTION 3.1 FACULTY MEMBERSHIP

The faculty of Tulane University is defined as those engaged in teaching and/or research or creative activity appointed to appropriate faculty status by the Board of Administrators of the University in accordance with the existing policies of the University.

The faculty includes members of the teaching and research personnel holding titles including the following: Professor, Associate Professor, Assistant Professor (including all titles with modifiers such as Clinical, Research, Visiting, Adjunct, etc.), Professor of the Practice, Senior Professor of the Practice, Lecturer, Senior Lecturer, Instructor, and Senior Instructor. The faculty consists of those properly appointed members of the teaching and research personnel holding these tenured, tenure-track, and non-tenure-track faculty titles. The type of appointment of individual faculty is clearly specified in the initial and subsequent appointment letters.

Academic personnel such as graduate assistants (teaching or research assistants), postdoctoral and predoctoral fellows, visiting scholars, artists-in-residence, or administrative faculty are not designated as faculty. However, the same rights and responsibilities associated with academic freedom outlined below are applicable to all academic personnel affiliated with the University.

SECTION 3.2 FACULTY RIGHTS AND RESPONSIBILITIES

3.2.1 Academic Freedom

Tulane University adheres to national standards and procedures concerning the maintenance of academic and professional freedom, academic tenure, and full academic due process. (See also Chapter 4, Faculty Appointments, Promotions and Tenure; Chapter 7, Faculty Grievances; and Chapter 8, Faculty Code of Conduct, Corrective Actions, and Dismissals for details as to how this adherence is made specific.)

Tulane University, as an institution of higher learning, exists to sustain the creation, preservation and communication of knowledge. It serves the common good rather than the interest of individual teachers or the University as a whole. The common good depends upon the free search for truth and respect for the individual and the processes by which inquiry and teaching are pursued.

Academic freedom is essential in a university and applies to both teaching and research/creative activity. Freedom in research and creative activity is fundamental to the advancement of truth and artistic achievement. Academic freedom in teaching is fundamental to the protection of the rights of the teacher and the student. It carries with it corresponding duties.

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Tenure for faculty members is a means to an end and not the end in itself. It embraces specifically: (1) Freedom in teaching and research and extramural activities; and (2) A sufficient degree of economic security to make the teaching profession attractive to persons of ability. Guarantees of freedom and economic security to faculty members are indispensable to the success of a university in fulfilling its obligations to the students and to society.

Faculty members are entitled to academic freedom in the classroom. They have a corresponding responsibility to state the truth as they see it, and to the exercise of critical self-discipline and judgment in using, extending, and transmitting knowledge. At the same time, the faculty as a whole have a collective responsibility for the curriculum and academic programs. Academic departments or schools may adopt pedagogical, curricular and/or disciplinary standards.

Faculty members are entitled to full freedom in research and/or creative activity and the publication and/or exhibition of results. Academic freedom allows faculty to engage in research, inquiry, study, creative enterprise, and exhibition of the results of scholarly activity unfettered by unreasonable restrictions imposed by the institution. This freedom is consistent with the faculty and administration's role in evaluating scholarship and/or creative activity and in making rules concerning the ownership and conduct of university-related research and creative endeavor.

3.2.2 Academic Responsibilities

The faculty create and enhance the scholarly and artistic excellence of the University. Their importance to the intellectual life of the University and the community at large confers on them, individually and collectively, certain rights and responsibilities to the institution, to their students, and to their respective disciplines.

Faculty status and matters related thereto are primarily a faculty responsibility, as it is the faculty who undertake the processes whereby faculty are appointed; reviewed for reappointment, promotion and tenure; and/or disciplined or dismissed. The primary responsibility of the faculty for such matters is based upon the fact that judgement of faculty members is central to general educational policy and that scholars/artists in a particular field have the chief competence for judging the work of their colleagues, whether positively or adversely. Determinations in matters of faculty status should first be by faculty actions through established procedures and committees of the schools and university. The dean of the school and the Senior Vice President for Academic Affairs, as the designee of the President and the Board of Administrators, will review dossiers forwarded by the faculty committees and, in the case of disagreement, will consult with the appropriate faculty committees prior to the final decision. A final decision contrary to the faculty recommendation should be taken only in exceptional circumstances.

(a) Faculty Activities

Faculty discharge most of their responsibilities through teaching, research and/or creative activity, and service. The percentage of each will vary depending on the needs of the faculty

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member's academic unit, but it is expected that each tenured and tenure-track faculty member will make a significant contribution in each of the three areas of responsibility. Non-tenure-track faculty will have a different activity profile depending on the needs and expectations of the academic unit in which they serve. The specific nature of a faculty member's teaching, research, and/or service to the University may be adapted in accordance with the demands of the specific academic unit, or the terms of a particular faculty member's established profile, or both, in consultation between each faculty member and the dean or chair of the academic unit. Faculty members may pursue other professional activities, in accordance with the University's conflict of interest policies (See Section 3.7), as long as these endeavors do not interfere with the faculty member's responsibilities to the University.

(b) Teaching

Teaching includes classroom and other instruction of undergraduate, graduate, and professional and post-graduate students, academic advising, preparation, and the direction of research and/or creative activity. Faculty are expected to meet their classes, be accessible to their students through regularly scheduled and sufficient office hours and evaluate and grade student work in a timely fashion. Faculty are expected to teach courses that have been assigned to them. Assignments will be made after consultation with department faculty, on the basis of departmental or school needs. In case of faculty absences for professional reasons, it is incumbent on the faculty member to provide appropriate class coverage. Absences of two consecutive weeks or more require approval by the chair or dean. In addition, in the case of longer term university closures, faculty are responsible for maintaining instructional continuity to fulfill course contact hours through scheduled make up dates or alternative instructional delivery methods as outlined in "Instructional Continuity Policy for University Closures" at <https://academicaffairs.tulane.edu/policies/academic-policies>.

Mentoring is an important component of faculty responsibilities. Depending on the discipline, the research effort and/or creative activity involves the supervision and mentoring of undergraduate students, graduate students and those occupying post-doctoral or other research positions. Such mentoring is also part of a faculty member's teaching effort.

(c) Research and Artistic Work

Faculty are expected to engage in high quality, continuing research or creative activity of a type appropriate for the field, discipline, or interdisciplinary area. Typically, the product of the research effort is publication or its counterpart in the visual and performing arts (performances, exhibitions, and the like). Similarly, depending on the field or discipline, research and creative activity may require considerable effort in the writing of proposals or related endeavors to acquire extramural funding as may be needed to conduct a faculty member's research. Participation in conferences, professional societies, and peer review panels are common activities. Ultimately, the results of research and creative activity are expected to contribute to the scholar's national and international reputation.

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(d) Service

Service includes effort on committees and other activities at the departmental level through the University level. Mentoring of junior faculty is a significant service responsibility of senior faculty members. Depending on the field or discipline, service may include work outside the University.

Faculty holding clinical appointments may be expected to perform clinical responsibilities that have been assigned by the department chair, after consultation with the affected individual. Such clinical assignments shall be made on the basis of departmental needs.

3.2.3 Professional Rights of Faculty and the Obligations of the University to Protect Them

The University seeks to provide and sustain an environment conducive to the creation and sharing of knowledge. Effective performance of these central functions requires that faculty members be free within their respective fields of competence to pursue and teach in accord with appropriate standards of scholarly inquiry and artistic expression.

In support of the University's central function as an institution of higher learning, a major responsibility of the administration and the faculty is to protect and encourage the faculty in its teaching, learning, research, creative development, and public service. It is the responsibility of the administration and the faculty to respect and protect faculty rights, including:

1. free inquiry, artistic expression, and exchange of ideas;
2. presentation of controversial material relevant to a course of instruction;
3. enjoyment of protected freedom of expression;
4. freedom to address any matter of institutional policy or action when acting as a member of the faculty, whether or not as a member of an agency of institutional governance;
5. participation in the governance of the University, including
 - a. approval of course content and manner of instruction,
 - b. establishment of requirements for matriculation and for degrees,
 - c. appointment and promotion of faculty,

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- d. selection of chairs of departments and certain academic administrators,
- e. discipline of members of the faculty, and the formulation of rules and procedures for discipline of students in academic matters,
- f. establishment of norms for teaching responsibilities and for evaluation of both faculty and student achievement,
- g. determination of the forms of departmental governance, and
- h. evaluation by one's colleagues, in accordance with fair procedures and due process, in matters of promotion, tenure, and discipline, solely on the basis of the faculty members' professional qualifications and professional conduct.

3.2.4 Faculty Ethical Principles

This listing of faculty ethical principles is organized around the individual faculty member's relation to teaching and students, to scholarship, to the University, to colleagues, and to the community. They are drawn primarily from the 1966 Statement on Professional Ethics and its June 1987 revisions, issued by the American Association of University Professors. They comprise ethical prescriptions affirming the highest professional ideals. They are aspirational in character and represent objectives toward which faculty members should strive.

Teaching and Students

Ethical Principles

“As teachers, the professors encourage the free pursuit of learning of their students. They hold before them the best scholarly standards of their discipline. Professors demonstrate respect for students as individuals and adhere to their proper roles as intellectual guides and counselors. Professors make every reasonable effort to foster honest academic conduct and to assure that their evaluations of students reflect each student's true merit. They respect the confidential nature of the relationship between professor and student. They avoid any exploitation, harassment, or discriminatory treatment of students. They acknowledge significant academic or scholarly assistance from them. They protect their academic freedom.” (AAUP Statement, 1966; Revised, 1987)

In this section, the term student refers to all individuals under the academic supervision of faculty.

Scholarship

Ethical Principles

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“Professors, guided by a deep conviction of the worth and dignity of the advancement of knowledge, recognize the special responsibilities placed upon them. Their primary responsibility to their subject is to seek and to state the truth as they see it. To this end, professors devote their energies to developing and improving their scholarly competence. They accept the obligation to exercise critical self-discipline and judgment in using, extending, and transmitting knowledge. They practice intellectual honesty. Although professors may follow subsidiary interests, these interests must never seriously hamper or compromise their freedom of inquiry.” (AAUP Statement, 1966; Revised, 1987)

Faculty and the University

Ethical Principles

“As a member of an academic institution, professors seek above all to be effective teachers and scholars. Although professors observe the stated regulations of the institution, provided the regulations do not contravene academic freedom, they maintain their right to criticize and seek revision. Professors give due regard to their paramount responsibilities within their institution in determining the amount and character of the work done outside it. When considering the interruption or termination of their service, professors recognize the effect of their decision upon the program of the institution and give due notice of their intentions.” (AAUP Statement, 1966; Revised, 1987)

Faculty and Colleagues

Ethical Principles

“As colleagues, professors have obligations that derive from common membership in the community of scholars. Professors do not discriminate against or harass colleagues. They respect and defend the free inquiry of associates. In the exchange of criticism and ideas professors show due respect for the opinions of others. Professors acknowledge academic debts and strive to be objective in their professional judgment of colleagues. Professors accept their share of faculty responsibilities for the governance of their institution.” (AAUP Statement, 1966; Revised, 1987)

Faculty and the Community

Ethical Principles

“Faculty are simultaneously members of the public sphere, of learned professions, and of the University. When they speak as experts, i.e., within their own professional areas, they are entitled to identify themselves as members of the University. When they speak or write as private individuals, they should be free from institutional censorship or discipline, but their special position in the community imposes special obligations. As members of the academic community, they should remember that the public may judge their profession and the University by what they say. Hence, they should at all times be accurate, should exercise appropriate restraint, should

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show respect for the opinions of others, and should make every effort to indicate that they are not speaking for the University in any official capacity.” Faculty Handbook, Chapter 3.2.5 below.

3.2.5 Conditions of Appointment

Appointment letters shall be issued to all academic personnel, full-time or part-time, by the appropriate University officer, specifying academic rank and title, salary, any change in tenure status, starting and ending dates for all appointments, and any change in the tenure decision date (where appropriate). Any other conditions or limitations of employment also shall be given or incorporated by reference. Offer letters for all faculty are reviewed and approved by the Office of Academic Affairs and Provost.

3.2.6 Additional Professional Activities

Faculty members are citizens, members of learned professions, and officers of an educational institution. When they speak as experts, i.e., within their own professional areas, they are entitled to identify themselves as members of the University. When they speak or write as citizens, they should be free from institutional censorship or discipline, but their special position in the community imposes special obligations. As educational officers, they should remember that the public may judge their profession and the University by their utterances. Hence, they should always be accurate, should exercise appropriate restraint, should show respect for the opinions of others, and should make every effort to indicate that they are not speaking for the University in any official capacity.

a) **Political Participation:**

As individual citizens, faculty members are free to engage in political activities, including candidacy for public office. Where necessary, unpaid leaves of absence may be given for the duration of an election campaign or a term of office on timely application, and for a reasonable period of time. The terms of such leave of absence shall be set for in writing (see Section 3.5.9). Such a leave shall not affect the tenure status of a faculty member, except that time spent on such leave shall not count as probationary service unless otherwise agreed to.

There shall be no restraint upon the partisan political activity of a member of the Tulane faculty, provided that they are acting as a private citizen and scrupulously avoid giving the impression of representing the University.

b) **Other Extramural Activities:**

Tulane University encourages faculty involvement in outside consulting, research, and professional activities, as well as community service. However, the primary responsibility of a full-time faculty member is to the University. Extramural research and consultation shall be in accord with University policy. Within the limits specified below,

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such activities provide an opportunity for the professional development of the faculty member and the enhancement of the University's impact beyond the classroom and laboratory. However, the facilities and services of the University may not be used in connection with compensated outside effort except to a purely incidental extent, or for appropriate University-determined compensation and in accord with University regulations, including the University's Conflict of Interest and Conflict of Commitment Policy (see 3.7 below).

As a rule, the maximum expenditure of time on such outside consulting, research and professional activities should not exceed one day per seven-day week during the academic year. The faculty member is expected to inform the dean of the details of any extramural activity. No faculty member should accept employment or carry on professional or business activities that would conflict with Tulane's conflict of interest or conflict of commitment policies or that would interfere with the performance of his or her primary responsibilities of teaching and research.

The University assumes no responsibility for private consulting services, professional, or business activities by faculty members. A faculty member must make it clear to private employers that consulting work is personal and not related to the University and that the name of the University is not to be connected with the service rendered or the results obtained.

A formal agreement must be made between the appropriate university representative and the sponsor for consulting projects requiring the use of university facilities.

3.3 COMPENSATION

3.3.1 Payment of Salaries

Salary payments are made on the last business day of each month. Salary for full-time faculty is paid in twelve installments per year. Faculty with dual appointments or with both teaching and administrative assignments receive single monthly payments covering all compensation. Payment for Summer School teaching is normally made separately, usually with a one-time payment transaction. Please see the web site for Tulane's Human Resources Office for further details: <https://hr.tulane.edu/>

3.3.2 Changes in Compensation

Total University salary includes (a) base salary based on a nine-month academic year or a twelve-month fiscal year period of service (or other period based on individual appointment letters) and (b) can also include supplementary salary or stipends, which are set for a fixed period (one year at a time, unless a different period is specifically stated by appointment letter.)

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(a) Supplementary Salary for Summer Teaching

Full-time faculty are given first option to teach courses offered by their departments during the Summer Session(s). Full-time faculty on academic year (9-month) appointments may receive up to 3/9 of their base pay from non-grant funds during the summer months, subject to the approval of their dean.

(b) Supplementary Salary for Summer Research and Other Sponsored Activities.

The United States government and some private agencies do not permit extra compensation or overload payment during the academic year on grants or contracts. No overload payment is permitted for research by faculty with 12-month appointments. For faculty with 9-month appointments, grants and contracts may provide for additional earnings during the summer up to 3/9 of base salary. Payment for more than 11 months service for faculty with 9-month appointments is permitted only when approved by the awarding agency, and the arrangement should be included in the proposal to the government or private agency concerned.

(c) Other Supplementary Salary and Administrative Stipends

Full-time faculty members on 9-month or 12-month academic appointments may receive additional compensation from non-grant funds for additional administrative work during the academic year or fiscal year, respectively, subject to the approval of the Senior Vice President for Academic Affairs and Provost. Typically, no payments for activities that could be considered service to the University will be approved.

Faculty have the opportunity to accept a research or teaching assignment in another division or school for additional compensation upon the approval of the faculty member's home department chair and dean.

At the time of hire, the Dean may recommend a salary supplement for a faculty member who was a participant in a retirement plan immediately prior to his/her employment with Tulane. The supplemental salary may only continue for a maximum of two years at which time that faculty member will become eligible for the retirement plan. This supplemental salary will not be included in the base salary for calculating other benefits.

(d) Salary increases.

Merit-based increases in the base salary of continuing active faculty are considered annually as part of the salary setting process. University policies and school-based guidelines deal with the merit evaluation of faculty, including the participation of faculty committee(s).

3.4 LEAVES OF ABSENCE

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3.4.1 General

The following section summarizes leaves of absence for which faculty members may qualify. Failure to return to work after one year on leave of absence from duty may be a basis for termination of employment by the President or Vice President for Academic Affairs and Provost without formal proceedings, unless the Vice President for Academic Affairs and Provost approves an extension. Most types of leave are granted for one semester or one year as a maximum.

Faculty anticipating a leave without pay should consult Human Resources for information about the effect of the leave on their fringe benefits.

Tenure track faculty who have been granted leave may, under certain circumstances, request an extension of the tenure decision date, and special provisions are set out in Chapter 9, Academic and Work- Life Balance. Requests for extension of the tenure decision date shall be in writing and shall be directed to the dean of the school for review and recommendation in writing to the Provost, either prior to the leave or within six months after returning to regular activities.

A faculty member who has been granted leave of any kind (sabbatical, research, or other) is expected to return to the University for at least one full year of service, or, for longer leaves, a period equal to the leave taken.

3.4.2 Sabbatical Leave

Sabbatical leaves are considered to be a privilege of tenure track faculty, not a right, and will be granted only when the University is assured that the leave will not have adverse effects on departmental teaching, administrative responsibilities, or research, including the supervision of dissertations.

Sabbatical leaves may be granted for the primary purpose of enhancing the value of the recipient's further service to the University and his or her profession through study, research, creative activity or publication and/or exhibition undertaken to improve pedagogical techniques, solve administrative problems, or broaden the scope of one's knowledge in his or her chosen field.

Applications for sabbatical leave should be accompanied by a detailed description of the work to be accomplished during the leave, the applicant's curriculum vitae, and a supporting statement from the applicant's chair, stating how teaching duties are to be covered during the leave. The faculty member applying for a sabbatical must submit an acceptable project proposal and submit a report at the end of the sabbatical. All requests for sabbatical must be submitted to the Senior Vice President for Academic Affairs and Provost for final approval. Requests for sabbatical for the following academic year are typically due in the Office of Academic Affairs in the fall

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semester (due dates are published in the Office of Academic Affairs website: <http://tulane.edu/provost/>).

Sabbatical leave may be granted to faculty members after either six years or twelve semesters of accrued full-time service at the University. Faculty on any kind of leave of absence do not accrue full-time service towards sabbaticals.

Deans should take into consideration the following factors when making recommendations to the Senior Vice President for Academic Affairs and Provost; they will be directly considered by the Provost in making final decisions on sabbatical requests:

- Ongoing engagement with the scholarly and/or creative enterprise relevant to their discipline
- A definite and well-defined research or study program must be submitted for approval. A candidate should indicate a timetable for completion of the project.
- Sabbatical leave will be allowed for one semester on full salary or one academic year on half salary for each twelve semesters of service.
- A faculty member on sabbatical leave should not engage in other activities for remuneration that would intrude on their sabbatical research and should not receive extra compensation for any additional duties from Tulane (teaching TIDEs classes, other extra teaching, etc.).
- The absence of a faculty member should not jeopardize the academic program of his or her department.
- It is expected that the faculty member will return to the University for at least one year after sabbatical.
- A final report shall be provided to the dean upon the faculty member's return.
- Normally, sabbatical leave is taken immediately following the period of service to which the leave relates. The sabbatical leave privilege may not normally be accumulated, e.g., after 24 semesters, a sabbatical of four semesters may not normally be taken. On rare occasions when, at the specific request of the dean, a faculty member postpones sabbatical leave for the convenience of the department, an agreement with the dean may be made to bank time toward a future sabbatical. This mutual agreement in writing must be sought by the faculty member before the time is to be banked.
- Benefits shall continue during the paid sabbatical.

A department may recommend to the dean exceptions to these policies, however, to facilitate work or to meet other needs of the department, the school, or the University. Such exceptions must be approved in writing by the Provost.

(b) Eligibility

Full-time tenure track faculty holding the rank of assistant professor or above are eligible to request sabbaticals.

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3.4.3 Other Leaves of Absence With or Without Pay (Research, Fellowships, Visiting Professorship, Temporary Employment)

Leave of absence for an academic year or less may be granted to a faculty member to accept a fellowship, visiting professorship, or other temporary appointment. Each case is considered individually. A faculty member granted leave is expected to return to the University for at least one full year of service, or longer, depending on the length of the leave. Ordinarily, no leave of absence for employment elsewhere will exceed one year. The maximum period of such a leave is two successive years. Faculty members who wish to maintain health insurance, group life insurance, and other benefits, including TIAA/CREF payments, should contact the Office of Human Resources to arrange for payments. Such payments are the responsibility of the individual. When a faculty member is successful in obtaining salary support for a semester or a year of scholarly research from funds not administered by Tulane, the University will continue to pay the faculty member's health insurance and group life insurance benefits. A leave of absence is not credited as service toward sabbatical leave.

3.4.4 Medical Leaves

This subsection summarizes the types of medical leave available. An individual on unpaid medical leave may qualify for payment of disability benefits, or for University insurance benefits, or both; for information see the Human Resources website, <https://hr.tulane.edu/>

(a) Academic and Work-Life Balance

See Chapter 9.

(b) Medical Leave (UNPAID)

Faculty members who are unable to work due to an illness, injury, or disability (including pregnancy-related disability) may be eligible for an unpaid medical leave. Such individuals may qualify for disability benefits while on medical leave. The Senior Vice President for Academic Affairs and Provost may place eligible faculty members on medical leave for the period that they are unable to work. Medical leave runs concurrently with all other leave for which a faculty member qualifies. Medical leaves for longer than one year are not regularly available, although the Provost may extend the leave and the University will do so to the extent the law allows.

As an alternative, upon request, the University will consider any reasonable accommodations necessary to enable a faculty member with a qualifying disability (as defined under state and federal law) to perform the essential function of his or her position.

(c) Statutory Family Care and Medical Leave (UNPAID)

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Unpaid statutory Family Care and Medical Leave is governed by the provisions of the federal Family and Medical Leave Act. (FMLA). Eligible faculty members may take unpaid statutory Family Care Leave for the birth or adoption of a faculty member's child; the placement of a foster child with the faculty member; or the serious health condition (as defined under state and federal law) of a faculty member's child, spouse, domestic partner or parent. Eligible faculty members may take unpaid statutory Medical Leave for a faculty member's own serious health condition (as defined under state and federal law) including disability on account of pregnancy, childbirth, or related medical conditions.

A faculty member generally may take up to 12 weeks of unpaid statutory Family Care and Medical Leave in a 12-month period, as detailed in the policies posted on the Human Resources website. A faculty member who takes leave for a pregnancy-related disability, after exhausting the resources outlined in Chapter 9, may take longer leave as detailed in the Human Resources website. Family Care and Medical Leave runs concurrently with all other leaves for which a faculty member qualifies. The faculty member may also qualify for disability benefits.

A tenure track faculty member who has been granted statutory medical leave may request an extension of the tenure decision date. Such extensions shall be requested in writing and shall be directed to the dean of the school for review and recommendation in writing to the Vice President for Academic Affairs and Provost, either prior to the leave or within six months after returning to regular activities.

(d) Absences due to Illness

A faculty member who is absent because of illness for a brief period should make arrangements through their department chair to see that their teaching and other responsibilities are met. Faculty members do not have a specific number of days a year during which they are allowed sick leave, and therefore do not accrue days of sick leave. Absences for more than seven consecutive days that are due to accident, illness or other temporary medical disability (including pregnancy, childbirth, and related medical conditions) may qualify the faculty member for disability benefits. Additional information is available from Human Resources.

Insurance benefits ordinarily provided by the University and for which the faculty member is otherwise eligible, will be continued during the period the faculty member is medically certified as unable to work due to a medical disability or serious health condition. The cost of coverage normally borne by the faculty member will remain the responsibility of the faculty member. Once a doctor has certified that the faculty member is medically able to return to work, they are expected to do so unless there are extenuating circumstances. If they do not return to work promptly, the faculty member will be responsible for paying the full cost of benefit premiums until they return to active service.

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3.4.5 Bereavement Leave

Faculty are allowed a paid period of leave in the event of a death in their immediate family.

The maximum bereavement leave is three (3) working days for a funeral held within one hundred (100) miles of New Orleans or five (5) working days for a funeral held more than one hundred (100) miles from New Orleans.

3.4.6 Military Leave

The University grants military leave in accordance with law. Detailed policies are available on the Human Resources website.

3.4.7 Parental Leave (PAID)

See Chapter 9, Academic and Work-Life Balance.

3.4.8 Jury Duty

Leave for jury service is available to faculty as for other University employees as specified on the Human Resources website.

3.4.9 Vacation

Faculty members on nine-month appointments do not accrue vacation time. Faculty members on twelve-month appointments can earn twenty days of vacation time annually, but unused accrued vacation days will not be carried forward and there is no payment for unused accrued vacation days upon termination of employment at the University.

3.4.10 Personal Leave of Absence (UNPAID)

Unpaid personal leaves of absence may be granted at the discretion of the Senior Vice President for Academic Affairs and Provost for faculty members who are not eligible for another type of leave (Research, Illness, Family and Medical, Medical, or Parental Leave.) Personal leaves may be granted for one or two semesters and generally may not exceed one year.

3.4.11 Indefinite Leave

Both tenured and non-tenured faculty may be placed on “indefinite leave” without duties or pay only as provided by Chapter 8

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3.4.12 Part-Time Leave

The Senior Vice President for Academic Affairs and Provost may grant a short-term partial leave of absence, one or two semesters at proportionate pay for part-time service, to any full-time faculty member. Faculty anticipating a leave without pay should consult Human Resources for information about the effect of the leave on their fringe benefits.

Part-time service to accommodate family responsibilities or as a transition to retirement is provided for in Chapters 9: Academic and Work Life Balance and Chapter 10: Transition from Full-Time Work. Tenured and tenure-track faculty are otherwise on full-time appointments unless extraordinary permission is granted by the Senior Vice President for Academic Affairs and Provost.

3.5 BENEFITS

<https://hr.tulane.edu/benefits/benefits>

Tulane University offers an extensive array of benefits, which are described in the Human Resources website above. They include various insurance options, retirement plans, tuition waiver program, flexible spending accounts, and other valuable benefits. For benefits-related questions, please contact a Benefits Team member of Human Resources.

Tulane University property is insured for losses due to fire, windstorm, malicious mischief, and flood damage. However, faculty-owned personal property is not covered under the University property insurance; faculty members must confer with their own insurance advisers on ways and means of protecting their personal property including books, equipment, etc. Also, Tulane faculty members are covered while acting within the scope of their employment under Tulane University's liability policy. The Office of Insurance and Risk Management monitors these policies. <https://risk.tulane.edu/>

3.6 POLICIES ON CONFLICT OF COMMITMENT AND INTEREST

Tulane University is committed to compliance with legal and ethical standards addressing conflicts of interest in the academic, administrative and research activities of the University. The University has therefore implemented a policy addressing conflicts of commitment and interest in the following four parts:

- **Part A: Policy of Tulane University on Conflicts of Commitment and Interest.** This part of the policy applies to all employees of the University, certain researchers who are not University employees, and certain University subcontractors involved in research. This part establishes standards for identifying and responding to conflicts of commitment and interest.
 - **Part A-1** establishes basic standards applicable to all employees, with the exception of researchers involved in Public Health Service (“PHS”)-funded

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research.

- **Part A-2** establishes standards applicable to those employees, researchers and research subcontractors who are involved in PHS-funded research. These standards include additional requirements to comply with the Public Health Service conflict of interest regulations.
- **Part B –Policy of Tulane University on Conflicts of Commitment and Interest for Members of the Tulane University Medical Group and Health Care Providers.** This part of the policy applies only to members of the Tulane University Medical Group and certain other health care providers. This part incorporates federal and state laws addressing fraud and abuse.
- **Part C –Conflicts of Interest for Investigators in Human Subjects Research.** This part of the policy applies only to certain researchers that are involved in human subjects research. This part establishes enhanced disclosure requirements for such researchers. The standards, as applied to certain researchers and research subcontractors involved in federally-funded research, include additional requirements to comply with the Public Health Service conflict of interest regulations.
- **Part D –Policy for Conflicts of Interest of Research Oversight Officials.** This part of the policy applies only to Research Oversight Officials, for instance, all IRB, IACUC, and IBC members and certain other University Faculty and Staff who oversee research. This part, as applied to Institutional Review Board members, assists the University in complying with federal laws precluding such members from participating in the review of research in which the member has a conflicting interest.

These parts of the policy are collectively intended to promote conducting academic, administrative and research activities of the University in a fair and objective manner in accordance with the law and the best interests of the University.

A copy of this policy will be posted on the University website on a page accessible to the general public, all employees of the University, certain researchers (whether or not University employees), and certain University subcontractors involved in research. A revised copy will be posted within 30 days if and when the policy is amended and approved by the university senate.

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

[All terms in Bold are defined in this Part A of the policy.]

A. 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, to act and to lead with integrity and wisdom. Accordingly, the University recognizes that its **Faculty** and

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Staff participate in **Leadership Roles**, such as consulting, serving on boards of companies, whether for-profit or non-profit, and other **Secondary Commitments** that benefit the participant and the University, its students and patients, and the public at large. The University, **Faculty**, and **Staff** have a shared interest in assuring the institutional integrity of the University as well as the personal and professional integrity of the **Faculty** and **Staff**. The University is committed to maintaining the highest standards of excellence in teaching, research, patient care, and welfare.

This policy provides guidelines and mechanisms for identifying and addressing **Conflicts of Interest** and Conflicts of Commitment that pertain to conducting research, academic, and administrative activities in a fair and unbiased manner. An integral part of this policy is therefore disclosure by **Faculty**, **Staff**, and **Investigators** of their commitments, **Financial Interests**, and outside activities. The guidelines and mechanisms, as applied to **Faculty**, **Staff**, and **Investigators** participating in **PHS-Funded Research**, are intended to comply with the **PHS-Funded Research Conflict of Interest** regulations outlined at 42 C.F.R. Part 50 Subpart F and 45 C.F.R. Part 94 and should be interpreted consistent with those regulatory requirements and any implementing guidance.

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

B. Conflict of Commitment

Faculty and **Staff** owe their **Primary Commitment** to University activities and responsibilities, must act in the University's best interests in fulfilling their obligations to the University, and must not permit any **Leadership Roles** or **Secondary Commitments** to an outside organization, entity or project to jeopardize this **Primary Commitment**. A Conflict of Commitment occurs when these efforts for the University are compromised by one or more **Leadership Roles** or **Secondary Commitments**. For example, a Conflict of Commitment would occur if a **Faculty** member exceeded permitted time limits on outside consulting, or if, as a result of a **Leadership Role** in an outside organization, entity or project, an individual's primary professional loyalty was not to the University.

C. Conflict of Interest

A **Conflict of Interest** arises whenever **Faculty**, **Staff**, or an affiliated **Investigator's Professional Interests**, such as professional obligations or judgment owed to the University and its constituencies, are compromised by, or could reasonably be perceived as being compromised by, his or her **Leadership Roles** or **Financial Interests**. In the case of **PHS-Funded Research**, a **PHS Financial Conflict of Interest** arises when the **Financial Interests** of an **Investigator** could directly and significantly affect the design, conduct, or reporting of **PHS-Funded**

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Research.

A **Conflict of Interest** is based on the situation and not on the character of the individual.

A **Conflict of Interest** can also occur when the academic work or research activities of a **Faculty** member could affect a **Financial Interest** of the University or of a **Faculty** or **Staff** member. Academic integrity is compromised when a **Faculty** member modifies his or her work to augment or shield that **Financial Interest**, such that the work product does not accurately reflect the **Faculty** member's research, beliefs, and opinions. For example, depending on the circumstances, academic integrity may be compromised when a **Faculty** member prepares the content of a book, article, audit or other report or conducts research with knowledge that such content or research results could reasonably be expected to affect a **Financial Interest** of that **Faculty** member, or of one or more other Faculty members, the University, or one or more University officials.

D. Special Concerns about Vendor Relationships

Relationships with **Vendors** to the University can also give rise to **Conflicts of Interest**. As a rule, **Faculty** and **Staff** should not be involved in decisions about purchasing or contracting for goods or services received by the University if their interests in or relationships with the involved **Vendor** conflict with, or reasonably appear to conflict with, their duty to act in the University's best interests. This applies not only where **Faculty** or **Staff** themselves have a **Financial Interest** in a **Vendor** but also where they know of a **Financial Interest** held by their **Immediate Family** (for purposes of **Vendor** relationships, the definition of **Immediate Family** also includes parents, parents-in-law, siblings and siblings-in-law)¹. Where **Immediate Family** holds the interest, note that the potential **Conflict of Interest** for the **Faculty** or **Staff** member might be of a financial or non-financial nature, or both.

In some instances, a **Conflict of Interest** arising from a **Vendor** relationship can be sufficiently averted by voluntary self-recusal or by an externally imposed requirement (for example, through a COI management plan) that the individual abstain from participating in the nomination, screening, or selection of **Vendors**. In other instances, however, the nature of the relationship and resulting risk may be so pervasive that recusal or exclusion from discrete transactional decisions may not be adequate.

E. General Definitions and Descriptions

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

¹ For the complete definition of **Immediate Family**, see p. xx.

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Financial Interest(s), Research Leadership Role(s), or Research Financial Interest(s).²

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

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

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

Designated Officials: The designated officials of the University for purposes of reviewing, administering, and implementing Conflicts of Commitment and **Conflicts of Interest** determinations shall be the President, the Senior Vice President for Academic Affairs and Provost, the Senior Vice President and Dean of the School of Medicine, the Deans and the Vice Deans of the Schools of Medicine, Public Health and Tropical Medicine, Architecture, Business, Science and Engineering, Newcomb-Tulane College, Law, Liberal Arts, Professional Advancement and Social Work; the Director of the Tulane National Primate Research Center, the Vice President for Research, the Senior Vice President for Operations and Chief Financial Officer, the Executive Vice President for University Relations, the Chief of Staff and Vice President for Administrative Services, the CEO of TUMG, the Internal Auditor and the Office of the General Counsel. Chairs of the IACUC, **IRB** and other University administrators or staff may be called upon, as needed, by the Senior Vice Presidents or by the **COI Committee** for specific purposes.

Faculty: Persons holding academic appointments of employment with the University.

² See Part C of the Policy for the definition of **Research Financial Interest**. See Part D of the Policy for the definition of **Research Leadership Role**.

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

- (a) Any payment(s) received from, or equity interest(s) held in a publicly traded entity during the 12-month period prior to the disclosure with a value that, in the aggregate, exceeds \$5,000;
- (b) Any payment(s) received from a non-publicly traded entity during the 12-month period prior to the disclosure with a value that, in the aggregate, exceeds \$5,000;
- (c) Any equity interest in a non-publicly traded entity;
- (d) Income of more than \$5,000 (from any one entity) generated from intellectual property rights and interests, unless paid by the University to an individual employed or appointed by the University;
- (e) Reimbursed or **Sponsored** travel with a value that exceeds \$5,000, unless reimbursed or **Sponsored** by the University or a federal, state or local government agency, an institution of higher education as defined in 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

A **Financial Interest** must be disclosed by **Faculty**, **Staff** and **Investigators** if it is related to that individual's professional responsibilities on behalf of the University. These responsibilities may include, for example, activities such as research and research consultation, teaching, professional practice, institutional committee memberships, and service on **IRBs** or safety monitoring boards.

Notwithstanding the foregoing, a **Financial Interest** does not include the following:

- (a) Salary, royalties, or other remuneration paid by the University to an individual if the individual is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights.
- (b) Salary, royalties, or other remuneration paid by a **Subrecipient** to an individual if the individual is currently employed or otherwise appointed by the **Subrecipient**, including intellectual property rights assigned to the **Subrecipient** and agreements to share in royalties related to such rights. This exception may not apply to **Faculty**, **Staff** or **Investigator** companies, which will be evaluated on a case-by-case basis.
- (c) Any ownership interest in a **Subrecipient** held by the **Investigator**, if
 - 1) the entity is a commercial or for-profit organization, and
 - 2) the **Investigator** is participating in the research as an **Investigator** only at the

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Subrecipient level.

- (d) 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.
- (e) Income from teaching engagements, seminars or lectures paid by a federal, state or local government agency, an institution of higher education as defined in 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center or a research institute affiliated with an institution of higher education.
- (f) Income from service on advisory committees or review panels for a federal, state or local government agency, an institution of higher education as defined in 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

Immediate Family: Spouse, children (including adoptees) and other dependents. Because of strict **Conflict of Interest** rules required by federal and state law, the definition of **Immediate Family** for a member of the Tulane University Medical Group and for other health care providers is broader than the definition for other **Faculty** and **Staff** members. Members of the Tulane University Medical Group or other health care providers must refer to Part B of this policy for the definition of **Immediate Family**. Note that for purposes of evaluating **Vendor** relationships under Part IV above, **Immediate Family** also includes parents, siblings, parents-in-law, and siblings-in-law.

Institutional Review Board (“IRB”): Any board, committee or other group formally designated by the University to review human subjects research, and which was established and which functions and operates in conformity with Part 46 of Title 45 and Part 56 of Title 21 of the Code of Federal Regulations. **IRB Members** are those persons who constitute the **IRB**.

Investigator: Any **Faculty**, **Staff** or affiliated person who serves as a project director or principal **Investigator** or who, regardless of title or position, is responsible for the design, conduct or reporting of research. **Investigator** may include, for example, a collaborator, consultant, or contractor.

Leadership Role:

- (a) Employment in any executive or administrator capacity,
- (b) consulting in any executive or administrator capacity, or
- (c) serving as
 - 1) a member of a board of trustees, directors or administrators,
 - 2) an officer or
 - 3) a member of an advisory committee, advisory board or subcommittee of a board of trustees, directors or administrators. (Note that any such employment, consultancy, or service by an **Immediate Family** member of an individual subject

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to this policy constitutes a **Leadership Role** on the part of such individual.) A **Leadership Role** may be compensated or non-compensated.

PHS-Funded Research: Research funded by the Public Health Service or by an entity with Public Health Service-delegated authority, including the National Institutes of Health.

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

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

Professional Interests: Academic, research, personal, professional and/or institutional integrity, patient safety and welfare, or any other interest that may be added to this policy from time to time.

Secondary Commitment: Activities that are not part of the **Primary Commitment** and which impose demands from outside entities, organizations, or projects for the time, energy, fiduciary obligations, or loyalty of **Faculty** or **Staff**. These may include but are not limited to employment, consulting, or participation in outside businesses or organizations, as well as **Leadership Roles** and other compensated or non-compensated extramural activities. **Secondary Commitments** do not include activities conducted entirely on personal time, which have no conflicting effect on one's Primary Commitment and which do not reasonably create the appearance of such a conflict.

Staff: Persons holding non-academic employment with the University. For purposes of this policy, **Staff** shall include administrators who do not have academic appointments with the University.

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

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 A-1 Standards Applicable To Faculty And Staff Other Than Investigators Involved In PHS-Funded Research

[All terms in Bold are defined either in Part A or this Part A-1.]

Scope

These standards apply to **Faculty**, **Staff**, and **Investigators** not involved in **PHS-Funded Research**.

Process

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.

- (a) All **Faculty** and **Staff** must complete Form A by January 31st of each year.
- (b) Newly hired **Faculty** and **Staff** must submit Form A within 60 days of employment or association and must thereafter comply with the annual filing deadline of January 31st.
- (c) Any **Faculty** or **Staff** must promptly, but no later than 30 days, after the acquisition or discovery of any new **Leadership Role**, **Secondary Commitment** or **Financial Interest** or the material modification of any **Leadership Role**, **Secondary Commitment** or **Financial Interest** provide an updated Form A.

Information Required

Form A requires the individual to report any and all **Leadership Roles**, **Secondary Commitments** and **Financial Interests** that reasonably appear to be related to the individual’s professional responsibilities on behalf of the University, such as research and research consultation, teaching, professional practice, institutional committee memberships, and service on **IRBs** or safety monitoring boards. In addition, this form requires the individual to report any and all **Leadership Roles**, **Secondary Commitments** and **Financial Interests** that the individual’s **Immediate Family** may have that reasonably appear to be related to the individual’s professional responsibilities on behalf of the University, such as research and research consultation, teaching, professional practice, institutional committee memberships, and service on **IRBs** or safety monitoring boards. Further information may be requested by the **COI Committee** as appropriate.

Form A requires the individual to report the following information concerning reimbursed or **Sponsored** travel: **Sponsor**/organizer, purpose, duration and destination. The **COI Committee** may also request further information such as the value of the reimbursed or **Sponsored** travel.

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Individuals should retain documentation of such travel for reporting purposes and requests for further information by the **COI Committee**. Individuals should seek to obtain documentation of reimbursed or **Sponsored** travel from the **Sponsor**/organizer if documentation is not readily provided.

Submission of Forms

Faculty and **Staff** must submit completed disclosure forms through an electronic online process. The online submissions for **Faculty** and **Staff** in academic units are forwarded to their department supervisor, chair or the dean if the unit does not have a departmental chair structure. The online submissions for **Staff** in non-academic units are forwarded to their direct supervisor. Supervisors, chairs, or deans, as applicable, are responsible for reviewing the completed Form A prior to its submission to the University's **COI Committee**. A list of names of individuals who have not provided the required Form A will be forwarded to the Senior Vice President responsible for their unit.

Review by the COI Committee

1) Timing

- i. Review of Annual Disclosure Forms. As promptly as practicable after the January 31st filing deadline, the **COI Committee** will review disclosures, determine whether a conflict exists, and implement a management plan if necessary. The **COI Committee** may ask that an **Investigator** or **Faculty** or **Staff** member who has a potential conflict provide additional information or discuss the matter with the **COI Committee** in person. The **COI Committee** will examine disclosed conflicts to assess the degree of risk they carry to **Primary Commitments** and **Professional Interests**.
- ii. Review of New and Updated Disclosure Forms. Within 60 days of receiving an updated disclosure form or a disclosure form from a newly hired **Faculty** or **Staff** member, the **COI Committee** will complete its review and determination as to whether a Conflict of Commitment or **Conflict of Interest** exists and implement a management plan, if necessary.

2) Nature of Review

- i. Generally. The **COI Committee** will review all disclosures to determine whether a Conflict of Commitment or a **Conflict of Interest** exists.
- ii. Guidelines. The University will maintain guidelines for the **COI Committee** to assist the committee in assessing whether any Conflict of Commitment or **Conflict of Interest** exists. The guidelines will be developed and updated by the **COI Committee**.

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3) Response

If the **COI Committee** determines that a Conflict of Commitment or **Conflict of Interest** exists, then the **COI Committee** will endeavor to work with the **Faculty** or **Staff** member to manage, reduce, or eliminate the Conflict of Commitment or **Conflict of Interest**.

Management or Elimination of Conflicts

- 1) Generally. The **COI Committee** will develop and implement a management plan to manage, reduce or eliminate any identified Conflicts of Commitment or **Conflicts of Interest**. While the **COI Committee** will endeavor to work with the **Faculty** or **Staff** member in developing the management plan, the **COI Committee** may require, if necessary, that the **Faculty** or **Staff** member comply with a particular management plan for managing a conflict.
- 2) Management Plan. The management plan developed by the **COI Committee** will be based upon an assessment of the nature, scope and severity of the Conflict of Commitment or **Conflict of Interest**. Methods of controlling or managing conflicts include, but are not limited to, the following:
 - i. Modifying the University employment or research 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 Commitments**);
 - 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 Commitments**).

Other methods may be used consistent with any applicable law and guidance. The COI Committee will monitor compliance with the management plan until the completion of the plan or the end of any Conflict of Commitment or **Conflict of Interest**.

Certification

**Any change to this chapter requires two readings at separate regular meetings of the University Senate and a 2/3 vote of those present.*

In the case of applications for National Science Foundation funding awards, the Office of **Sponsored Projects Administration** is responsible for certifying to the National Science Foundation that all identified conflicts have been reviewed by the **COI Committee** and have been satisfactorily managed, reduced or eliminated prior to the University's expenditure of any funds under the National Science Foundation award.

Appeal of the COI Committee Decision

Any **Faculty** or **Staff** member who disagrees with the **COI Committee's** findings or required management strategies may appeal in writing to the Senior Vice President responsible for that **Faculty** or **Staff** member's unit. A copy of the appeal must be sent to the **COI Committee**. The applicable Senior Vice President may agree with the **COI Committee's** findings and/or management strategy, or may amend such findings and/or strategy. The applicable Senior Vice President shall promptly notify the **Faculty** or **Staff** member and the **COI Committee** in writing of the conclusions of his or her review, including the actions that must be taken by the **Faculty** or **Staff** member to comply with this policy. Upon receipt of the applicable Senior Vice President's written report, the **Faculty** or **Staff** member must promptly comply with the actions specified in that report.

Audit and Sanctions for Non-Compliance

At the request of a **Designated Official** of the University, a **Faculty** or **Staff** member may be audited for the purpose of verifying whether the individual truthfully and accurately disclosed his or her **Leadership Roles, Secondary Commitments** and **Financial Interests** in Form A (and in any updates thereto), and for the purpose of verifying whether the individual is complying with the actions, if any, that were specified in the written report of the **COI Committee** (or the applicable Senior Vice President where there has been an appeal). Any **Faculty** or **Staff** member who fails to file a completed Form A by the annual deadline, or who fails to comply with any other action specified by this policy, the **COI Committee** or applicable Senior Vice President (as relates to this policy), will be subject to potential sanctions in accordance with applicable University policy and procedures. These sanctions may include formal admonition or censure; suspension; non-renewal of appointment; and/or dismissal.

Confidentiality

All financial and other confidential information disclosed by a **Faculty** or **Staff** member pursuant to this policy will be maintained in strict confidence. The **COI Committee** may disclose such information only to other University administrators defined as **Designated Officials** or personnel within the Office of **Sponsored Projects Administration** to carry out the purpose of this policy. No other uses or disclosures of the financial and other confidential information of any **Faculty** or **Staff** member will be permitted, unless required by law.

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Part A-2 Standards Applicable To Investigators Involved In PHS-Funded Research

[All terms in Bold are defined either in Part A or this Part A-2.]

Scope

These standards apply to **Faculty** and **Staff** who are **Investigators** for **PHS-Funded Research**, **Affiliated PHS Investigators** (as defined below), and **Subrecipient PHS Investigators** (as defined below). Any references to **Faculty** and **Staff** in this Part A-2 shall include only **Faculty** and **Staff** who are **Investigators** for **PHS-Funded Research**.

Communication and Training

Faculty, **Staff** and **Affiliated PHS Investigators** who may or will participate in **PHS-Funded Research** as **Investigators** will receive a copy of this policy; specific information about their obligations to disclose **Financial Interests**; and the **PHS-Funded Research Conflict of Interest** regulations.

These **Investigators** will also receive training on these topics:

- (a) immediately upon employment or association with the University;
- (b) every four years afterwards;
- (c) when this policy is revised; and
- (d) if and when the University finds that a **Faculty**, **Staff** or **Affiliated PHS Investigator** is non-compliant with this policy or with a management plan implemented to address a **PHS Financial Conflict of Interest** (as defined below).

Process

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.

- (a) All **Faculty**, **Staff** and **Affiliated PHS Investigators** must complete Form A by January 31st of each year.
- (b) Newly hired **Faculty**, **Staff** and **Affiliated PHS Investigators** must submit Form A within 60 days of employment or association, and must thereafter comply with the annual filing deadline of January 31st.
- (c) Any **Faculty**, **Staff** or **Affiliated PHS Investigators** must promptly, but no later than 30 days, after the acquisition or discovery of any new **Leadership Role**,

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Secondary Commitment or **Financial Interest** or the material modification of any **Leadership Role**, **Secondary Commitment** or **Financial Interest** provide an updated Form A.

- (d) **Faculty**, **Staff** or an **Affiliated PHS Investigator** planning to participate in **PHS-Funded Research** must have submitted an up-to-date Form A prior to the submission of an application for **PHS-Funded Research**.

Information Required

Form A requires the individual to report any and all **Leadership Roles**, **Secondary Commitments** and **Financial Interests** that reasonably appear to be related to the individual's professional responsibilities on behalf of the University, such as research and research consultation, teaching, professional practice, institutional committee memberships, and service on **IRBs** or safety monitoring boards. In addition, this form requires the individual to report any and all **Leadership Roles**, **Secondary Commitments** and **Financial Interests** that the individual's **Immediate Family** may have that reasonably appear to be related to the individual's professional responsibilities on behalf of the University, such as research and research consultation, teaching, professional practice, institutional committee memberships, and service on **IRBs** or safety monitoring boards. Further information may be requested by the **COI Committee as appropriate**.

Form A requires the individual to report the following information concerning reimbursed or **Sponsored** travel: **Sponsor**/organization, purpose, duration and destination. The **COI Committee** may also request further information such as the value of the reimbursed or **Sponsored** travel. Individuals should retain documentation of such travel for reporting purposes and requests for further information by the **COI Committee**. Individuals should seek to obtain documentation of reimbursed or **Sponsored** travel from the **Sponsor**/organizer if documentation is not readily provided.

Submission of Forms

Faculty and **Staff** must submit completed disclosure forms through an electronic online process. The online submissions for **Faculty** and **Staff** in academic units are forwarded to their department supervisor, chair or the dean if the unit does not have a departmental chair structure. The online submissions for **Staff** in non-academic units are forwarded to their direct supervisor. **Affiliated PHS Investigators** must submit their completed disclosure forms through the University's electronic online process. Supervisors, chairs, or deans, as applicable, are responsible for reviewing the completed Form A prior to its submission to the University's **COI Committee**. A list of names of individuals who have not provided the required Form A will be forwarded to the Senior Vice President responsible for their unit.

**Any change to this chapter requires two readings at separate regular meetings of the University Senate and a 2/3 vote of those present.*

Review by the COI Committee

Timing

Review of Annual Disclosure Forms. As promptly as practicable after the January 31st filing deadline, the **COI Committee** will review disclosures, determine whether a conflict exists and implement a management plan, if necessary. The **COI Committee** may ask that the Faculty or Staff member or **Affiliated PHS Investigator** who has a potential conflict provide additional information or discuss the matter with the **COI Committee** in person. The **COI Committee** will examine disclosed conflicts to assess the degree of risk they carry to Primary Commitments and Professional Interests.

Review of New and Updated Disclosure Forms. Within 60 days of receiving an updated disclosure form or a disclosure form from a newly hired Faculty or Staff member or **Affiliated PHS Investigator**, the **COI Committee** will complete its review and determination as to whether a Conflict of Commitment, **Conflict of Interest**, or **PHS Financial Conflict of Interest**³ exists and implement a management plan, if necessary.

PHS-Funded Research. The **COI Committee** must review current disclosures and reports prior to the expenditure of any funds for **PHS-Funded Research**.

Nature of Review

Generally.

The **COI Committee** will review all disclosures to determine whether a Conflict of Commitment or a **Conflict of Interest** exists.

- (a) **PHS-Funded Research.** The **COI Committee** will additionally review the disclosures of Faculty, Staff and **Affiliated PHS Investigators** to determine whether any Financial Interest is: related to **PHS-Funded Research**; and
- (b) a **PHS Financial Conflict of Interest.** If the Financial Interest could be affected by the **PHS-Funded Research** project or is held in an entity whose financial interest could be affected by the **PHS-Funded Research** project, the Financial Interest will be considered related to the **PHS-Funded Research** project.

³ The differentiation made here and in subsequent paragraphs, between **Conflict of Interest** and **PHS Financial Conflict of Interest** mirrors the definition of conflict of interest in this policy and the conflict of interest definitions in the PHS rules. This policy defines a conflict of interest essentially as an interest or leadership role that could compromise the integrity of one's professional activities. The PHS rules point to whether a financial interest is related to PHS-funded research and could directly and significantly affect the design, conduct, reporting, or review of the research.

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Guidelines.

The University will maintain guidelines for the **COI Committee** to assist the committee in assessing whether any Financial Interest is related to **PHS-Funded Research** and whether any **PHS Financial Conflict of Interest** exists. The guidelines will be developed and updated by **COI Committee**.

Response

If the **COI Committee** determines that a Conflict of Commitment, **Conflict of Interest** or **PHS Financial Conflict of Interest** exists, then the **COI Committee** will endeavor to work with Faculty or Staff members or **Affiliated PHS Investigators** to manage, reduce or eliminate the Conflict of Commitment or **Conflict of Interest** or **PHS Financial Conflict of Interest**.

Management or Elimination of Conflicts

Generally.

The **COI Committee** will develop and implement a management plan to manage, reduce or eliminate any identified Conflict of Commitment, **Conflict of Interest** or **PHS Financial Conflict of Interest**. While the **COI Committee** will endeavor to work with the Faculty, Staff or **Affiliated PHS Investigator** in developing the management plan, the **COI Committee** may require, if necessary, that Faculty, Staff or **Affiliated PHS Investigator(s)** comply with a particular management plan for managing a conflict. The management plan must be implemented before the expenditure of any funds under a **PHS-Funded Research** project. Management Plan. The management plan developed by the **COI Committee** will be based upon an assessment of the nature, scope and severity of the Conflict of Commitment, **Conflict of Interest** or **PHS Financial Conflict of Interest**. The primary methods of controlling or managing conflicts shall include:

- (a) Modifying the University employment or research responsibilities of the conflicted Faculty, Staff or **Affiliated PHS Investigator**;
- (b) Disclosing the conflicting **Leadership Role, Secondary Commitment** or Financial Interest to the public, for example, during conference presentations and/or in journals and other publications;
- (c) Reducing the conflict by reducing or altering the **Leadership Role, Secondary Commitment** or Financial Interest (e.g., partial divestiture or sequestration of one or more **Financial Interests**, reduction of time spent in furtherance of one or more **Leadership Roles** or **Secondary Commitments**);
- (d) Eliminating the conflict by eliminating the **Leadership Role, Secondary Commitment** or Financial Interest (e.g., total divestiture or sequestration of one or more **Financial Interests**, resignation from one or more **Leadership Roles** or **Secondary Commitments**).

Other methods may be used consistent with any applicable law and guidance. The **COI Committee** will monitor compliance with the management plan until the completion of the plan or the end of any Conflict of Commitment or **Conflict of Interest** or **PHS Financial Conflict of Interest** (e.g., the completion of the **PHS-Funded Research** project).

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Expedited Action

If the University identifies a Financial Interest of **Faculty, Staff** or an **Affiliated PHS Investigator** that was not timely disclosed or reviewed in accordance with this policy, the following actions must occur within 60 days:

- (a) the Faculty, Staff or **Affiliated PHS Investigator** must fully disclose the Financial Interest to the **COI Committee** through the submission of an updated Form A;
- (b) the **COI Committee** must review the Financial Interest and determine whether the disclosed Financial Interest is:
 - 1) related to **PHS-Funded Research** and
 - 2) a **PHS Financial Conflict of Interest**; and
- (c) the **COI Committee** must implement a management plan if necessary.

If a **Conflict of Interest** of a financial nature or a **PHS Financial Conflict of Interest** is identified, the **COI Committee** will complete and document a **Retrospective Review** (as defined below) of the **PHS-Funded Research** within 120 days to determine if the research was biased. Depending on the findings of the review, the **COI Committee** will update any reports previously submitted under Section III.G (Reporting of Conflicts). If the **COI Committee** determines that the research was biased, the **COI Committee** will notify the Office of Sponsored Projects Administration. The Office of Sponsored Projects Administration will then promptly notify the Public Health Service entity funding the research and submit a Mitigation Report (as defined below) developed by the **COI Committee** in consultation with the Office of Sponsored Projects Administration.

Reporting of Conflicts

PHS-Funded Research. The Office of Sponsored Projects Administration will provide to the Public Health Service entity funding any **PHS-Funded Research** project an initial report on any **Conflict of Interest** of a financial nature and on any **PHS Financial Conflict of Interest** as follows:

- (a) prior to the expenditure of funds for a **PHS-Funded Research** project (unless the **Conflict of Interest** is eliminated before such expenditure);
- (b) within 60 days of any such **Conflict of Interest** arising in an ongoing **PHS-Funded Research** project; and
- (c) as required under Section III.F (Expedited Action). The Office of Sponsored Projects Administration will provide an annual update on previously reported conflicts of interest for the duration of the **PHS-Funded Research** project.

The initial report will identify:

- (a) the **PHS-Funded Research** project and the **Faculty, Staff** or **Affiliated PHS Investigator**;

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- (b) the entity with which the **Financial Interest** is held;
- (c) the nature and value of the **Financial Interest**;
- (d) in the case of a **Conflict of Interest** under Part A of the policy, how the Financial Interest could compromise, or appear to compromise, the Professional Interests of the **Investigator**;
- (e) in the case of a **PHS Financial Conflict of Interest**, how the Financial Interest relates to the **PHS-Funded Research** project and the basis for the determination that a **PHS Financial Conflict of Interest** exists; and
- (f) a description of the management plan in place to address the **Conflict of Interest** or **PHS Financial Conflict of Interest**.

Information to be reported concerning the management plan will include:

- (a) the role and duties of the Faculty, Staff or **Affiliated PHS Investigator** with the **Conflict of Interest**;
- (b) the conditions of the management plan;
- (c) how the management plan will protect the research from bias;
- (d) the Faculty, Staff or **Affiliated PHS Investigator**'s agreement to the management plan; and
- (e) how the management plan will be monitored.

Annual updates to the report will include information on the current status of the **Conflict of Interest** or **PHS Financial Conflict of Interest**, as applicable, and any changes to the management plan.

Public Disclosure. If a Faculty or Staff member or **Affiliated PHS Investigator** of a **PHS-Funded Research** project who is the project director, principal **Investigator** or otherwise identified by the University as senior/key personnel on the grant application has been determined by the **COI Committee** to have a **Conflict of Interest** of a financial nature or a **PHS Financial Conflict of Interest**, (where the **Conflict of Interest** was disclosed and is still held by the project director, principal **Investigator** or senior/key personnel), then, the University will, prior to the University's expenditure of any funds under a PHS-funded research project, ensure public accessibility as provided herein to certain information about such conflicts of interest, by providing in writing, within five days of a valid request

(<http://tulane.edu/counsel/upload/Request-for-Report-of-Financial-Conflict-of-Interest-2.pdf>):

- (a) the name, title and role of the individual with the Financial Interest;
- (b) the entity with which the Financial Interest is held; and
- (c) the nature and approximate value of the Financial Interest.

When the University responds to such a request, the University will indicate in its written response that, "The information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the University's identification of a new financial **Conflict of Interest**; updates are not provided automatically, but may be requested".

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Such information regarding Conflicts of Interest of a financial nature and PHS Financial Conflicts of Interest is to be retained and available for three years from the date that the information was most recently updated and will be updated annually and within 60 days of the receipt of any new information.

Other Reporting and Corrective Action

Non-Compliance. If the **COI Committee** determines that the failure of the Faculty, Staff or **Affiliated PHS Investigator** to comply with this policy or a management plan appears to have biased the design, conduct or reporting of **PHS-Funded Research**, the Office of **Sponsored Projects Administration** will promptly notify the Public Health Service entity funding the research of the corrective action taken or to be taken. The **COI Committee** will exercise oversight regarding compliance with any additional corrective actions imposed by the Public Health Service entity funding the research.

Disclosure. If the U.S. Department of Health and Human Services determines there has been non-compliant management or reporting of a **Conflict of Interest** of a financial nature or of a **PHS Financial Conflict of Interest** related to **PHS-Funded Research** to evaluate the safety and effectiveness of a drug, medical device or treatment, the **COI Committee** will require the Faculty, Staff or **Affiliated PHS Investigator** to disclose the **Conflict of Interest** in each public presentation of the **PHS-Funded Research** and to request addenda adding the disclosure of the **Conflict of Interest** to previously published presentations of the **PHS-Funded Research**.

PHS Subrecipients

The University shall require any PHS Subrecipient by contract to either comply with this policy or to comply with its own financial conflicts of interest policy if such policy is compliant with the **PHS-Funded Research Conflict of Interest** regulations. If the PHS Subrecipient will comply with this policy, **Subrecipient PHS Investigators** will be treated as **Affiliated PHS Investigators** for purposes of Section III (Process). **Subrecipient PHS Investigators**, however, will not have to provide information regarding **Leadership Roles** or **Secondary Commitments** on Form A. If the PHS Subrecipient will comply with its own conflicts of interest policy, the University will report any financial conflicts of interest of **Subrecipient PHS Investigators** that have been reported by the PHS Subrecipient to the Public Health Service entity funding the research in accordance with Section III.G (Reporting of Conflicts). Additional information on implementation of these provisions is set forth in the University Subrecipient Monitoring Policy.

Certification

The Office of **Sponsored Projects Administration** is responsible for certifying to the Public Health Service that the University:

- (a) has a written, up-to-date and enforced administrative process to manage Conflicts of

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- Interest;
- (b) promotes and enforces Faculty, Staff or **Affiliated PHS Investigator** compliance and manages Conflicts of Interest;
 - (c) provides ongoing reports to the Public Health Service;
 - (d) agrees to make information concerning Faculty, Staff or **Affiliated PHS Investigator** disclosures and review of the disclosures available to the U.S. Department of Health and Human Services upon request; and
 - (e) fully complies with federal regulations at 42 C.F.R. Part 50 Subpart F.

Appeal of the COI Committee Decision

Any Faculty, Staff or **Affiliated PHS Investigator** who disagrees with the **COI Committee**'s findings or required management strategies may appeal in writing to the Senior Vice President responsible for that Faculty, Staff or **Affiliated PHS Investigator**'s unit. A copy of the appeal must be sent to the **COI Committee**. The applicable Senior Vice President may agree with the **COI Committee**'s findings and/or management strategy, or may amend such findings and/or strategy. The applicable Senior Vice President shall promptly notify the Faculty, Staff or **Affiliated PHS Investigator** and the **COI Committee** in writing of the conclusions of his or her review, including the actions that must be taken by the Faculty, Staff or **Affiliated PHS Investigator** to comply with this policy. Upon receipt of the applicable Senior Vice President's written report, the Faculty, Staff or **Affiliated PHS Investigator** must promptly comply with the actions specified in that report.

Audit and Sanctions for Non-Compliance

At the request of a Designated Official of the University, a Faculty, Staff or **Affiliated PHS Investigator** may be audited for the purpose of verifying whether the individual truthfully and accurately disclosed his or her **Leadership Roles, Secondary Commitments and Financial Interests** in Form A (and in any updates thereto), and for the purpose of verifying whether the individual is complying with the actions, if any, that were specified in the written report of the **COI Committee** (or the applicable Senior Vice President where there has been an appeal). Any Faculty, Staff or **Affiliated PHS Investigator** who fails to file a completed Form A by the annual deadline, or who fails to comply with any other action specified by this policy, the **COI Committee** or applicable Senior Vice President (as relates to this policy), will be subject to potential sanctions in accordance with applicable University policy and procedures. These sanctions may include: formal admonition or censure; suspension; non-renewal of appointment; prohibition on expending PHS funds; and/or dismissal.

Confidentiality

All financial and other confidential information disclosed by Faculty, Staff, and **Affiliated PHS Investigators** pursuant to this policy will be maintained in strict confidence, unless the information must be disclosed under Section III.G (Reporting of Conflicts). The **COI**

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Committee may disclose such information only to other University administrators defined as Designated Officials or personnel within the Office of **Sponsored Projects Administration** to carry out the purpose of this policy. No other uses or disclosures of the financial and other confidential information of any Faculty, Staff and **Affiliated PHS Investigators** will be permitted, unless required by law.

Record Retention

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

Additional Definitions

Affiliated PHS Investigator: Any person other than a Faculty or Staff member, who serves as project director or principal **Investigator** or who, regardless of title or position, is responsible for the design, conduct or reporting of research funded by the Public Health Service and conducted by the University. **Affiliated PHS Investigator** may include, for example, a collaborator or consultant.

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

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

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

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

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

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

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 Tulane University Policies on Conflicts of Commitment and Interest incorporate 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 “physician self-referral laws”). Considering such laws, the definition of **Immediate Family** in this Addendum shall apply to members of the Tulane University Medical Group and other health care providers in lieu of the definition included in the policy to which this Part B is attached:

Immediate Family. Spouse, 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 Conflicts of Interest for Investigators in Human Subjects Research

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

A. Applicability

This Part C of the policy applies to **Investigators** involved in research involving human subjects.

B. Principles

Federal law and policy require that for federally-funded research studies, the university hosting the research gather information related to each **Investigator's Research Financial Interests** (as defined below) that may be affected by the research itself. Although these requirements originated in a concern for assuring the integrity of federally-funded research data, the University is also concerned, as are various professional organizations, with the possible influence of such **Research Financial Interests** on research integrity and on the safety and welfare of human subjects involved in research protocols, regardless of the source of research funding. The University's policy in this regard is consistent with prevailing standards for professional conduct, which require that physicians and other licensed professionals not exercise undue influence over patients and clients and act at all times in the best interests of their patients and clients. The University is also concerned about **Leadership Roles of Investigators** in entities that **Sponsor** research. The University's policies therefore incorporate those concerns as well.

Consistent with federal laws and the ethical principles of human subjects research, the University seeks to ensure that its **Investigators** can carry out their responsibilities to protect the rights and welfare of human subjects participating in research projects at the University. Since the University recognizes that Conflicts of Interest may occur during research, this policy is intended to assist **Investigators** in determining when they have Conflicts of Interest in research, and to guide them in disclosing all potential conflicts and in cooperating with the management or elimination of the conflicts, where necessary. The guidelines and mechanisms, as applied to **Investigators** and **Subrecipient PHS Investigators** (as defined below) participating in **PHS-Funded Research**, are intended to comply with the **PHS-Funded Research Conflict of Interest** regulations outlined at 42 C.F.R. Part 50 Subpart F and at 45 C.F.R. Part 94 and should be interpreted consistently with those regulatory requirements and any implementing guidance. While this policy governs Conflicts of Interest of **Investigators**, the policy does not regulate disputes between two or more **Investigators** or between one or more **Investigators** and the University. Such disputes are to be resolved according to the University's established dispute resolution procedures.

C. Communication and Training

Investigators who may or will participate in human subjects research will receive a copy of this policy, specific information about their obligations to disclose **Research Financial Interests**,

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and **PHS-Funded Research Conflict of Interest** regulations.

These **Investigators** will also receive training on these topics

- (a) immediately upon employment or association with the University;
- (b) every four years afterwards;
- (c) when this policy is revised; and
- (d) if and when the University finds that an **Investigator** is non-compliant with this policy or with a management plan implemented to address a **Conflict of Interest**.

D. Process

Timing

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

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

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

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

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

Other Disclosures.

Investigators must also forward to the **COI Committee** without delay any amendments or changes that they make to any reports of **Research Financial Interests** that are submitted to any **Sponsor** (as defined below) of the research.

In the application for **IRB** approval of a human subjects research protocol, and at the time of continuing review of the protocol, each **Investigator** must attest using the Tulane University **Investigator Conflict of Interest** Attestation Form that they have supplied the **COI Committee**

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with a complete Conflicts of Commitment and Interest Disclosure Form, including Form C (and any required updates thereto), and must indicate whether the research they are conducting could be affected by any of his or her **Research Financial Interests** and/or **Leadership Roles**. The **IRB** will forward a copy to the **COI Committee**. The **IRB** may not approve a human subjects research protocol until each **Investigator** has provided this required information and the **COI Committee** has determined that there is no **Conflict of Interest** or provided assurance regarding management or elimination of the conflict. If, at the time for continuing review of a study, all necessary information has not been provided, no new subjects shall be enrolled in the study. Unless the **IRB** determines that it is in the best interests of the previously enrolled subjects to continue the study and their participation, the study shall not be authorized to continue, and shall not be allowed to continue until such time as all required information has been provided.

Information Required

Form C requires **Investigators** to report any and all **Leadership Roles** and **Research Financial Interests**. In addition, this form requires **Investigators** to report any and all **Leadership Roles** and **Research Financial Interests** that the **Investigator's Immediate Family**⁴ may have in any research or health care-related organization, including any not-for-profit or tax-exempt health-care related companies or foundations.⁵ Further information may be requested by the **COI Committee**. **Investigators** must append to Form C a copy of every report of their **Research Financial Interests** that they are required to submit to any **Sponsor** of research.⁶

Submission of Forms

Investigators must submit completed disclosure forms through an electronic online process. The online submissions are forwarded to their department chair or the dean if the unit does not have a departmental chair structure. Supervisors, chairs or deans, as applicable, are responsible for reviewing the completed Form C prior to its submission to the University's **COI Committee**. A list of names of individuals who have not provided the required Form C will be forwarded to the Senior Vice President responsible for their unit.

Review by the COI Committee

Timing

Review of Annual Disclosure Forms. As promptly as practicable after the January 31st filing deadline, the **COI Committee** will review disclosures and reports, determine whether a conflict exists and implement a management plan if necessary. The **COI Committee** may ask that an **Investigator** who has a potential conflict provide additional information or discuss the matter with the **COI Committee** in person.

Review of New and Updated Disclosure Forms.

Within 60 days of receiving an updated disclosure form or a disclosure form from a newly hired

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or affiliated **Investigator**, the **COI Committee** will complete its review, determine whether a **Conflict of Interest** exists and implement a management plan if necessary.

Review of Disclosure Forms from IRB.

As promptly as practicable after receiving a disclosure form from the **IRB**, the **COI Committee** will complete its review, determine whether a **Conflict of Interest** exists and implement a management plan if necessary.

PHS-Funded Research. The **COI Committee** must review current disclosures and reports prior to the expenditure of any funds for **PHS-Funded Research**.

Nature of Review

Generally. The **COI Committee** will review all disclosures to determine whether any disclosed **Research Financial Interests** or **Leadership Roles** constitute a **Conflict of Interest** with regard to an **Investigator**'s research, that is, whether any disclosed **Research Financial Interest** or **Leadership Role** could compromise or could reasonably be perceived to compromise the Professional Interests of the **Investigator**. If one or more Conflicts of Interest are identified in this process, then the **COI Committee** shall examine those conflicts to assess the degree of risk they carry with regard to research integrity and the safety and welfare of human subjects. The more significant the **Research Financial Interest** or **Leadership Role** of the **Investigator** in the research being conducted by that **Investigator**, the greater the potential risk that the conflicts may inappropriately influence research outcomes and/or subject safety and welfare.

PHS-Funded Research. The **COI Committee** will additionally review the disclosures of **Investigators** involved in **PHS-Funded Research** to determine whether any **Research Financial Interest** is:

- (a) related to **PHS-Funded Human Subjects Research**; and
- (b) a **PHS Financial Conflict of Interest** (as defined below).

If the **Research Financial Interest** could be affected by the **PHS-Funded Human Subjects Research** project or is held in an entity whose financial interest could be affected by the **PHS-Funded Human Subjects Research** project, the **Research Financial Interest** will be considered related to the **PHS-Funded Human Subjects Research** project.

Guidelines. The University will maintain guidelines for the **COI Committee** to assist the committee in assessing whether any Financial Interest is related to **PHS-Funded Human Subjects Research** and whether any **PHS Financial Conflict of Interest** exists. The guidelines will be developed and updated by the **COI Committee**.

Response

Generally. If the **COI Committee** determines that a **Conflict of Interest** exists, and the

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Conflict of Interest consists of a financial interest that is \$10,000 or less, then the **COI Committee** will endeavor to work with the **Investigator** to manage, reduce or eliminate the **Conflict of Interest**.

Per se Conflicts of Interest. The **COI Committee** shall deem any **Research Financial Interest** that exceeds \$10,000 and is related to human subjects research to be a per se **Conflict of Interest**. An **Investigator** with a per se **Conflict of Interest** may not participate in the related human subjects research unless the conflicting interest is eliminated or reduced to \$10,000 or below. (Note that the reduced **Research Financial Interest** might still be deemed a **Conflict of Interest**, necessitating action under subparagraph (a) above.) If, for any reason, the **Conflict of Interest** cannot be reduced to \$10,000 or less or eliminated altogether, the **Investigator** will be disqualified from participating in the research, subject only to (1) a showing of compelling and necessary reasons for being permitted to participate, and (2) a **COI Committee** established management plan consistent with maintaining the integrity of the research and the safety of human subjects participating in the research.

Compelling and Necessary Reasons. The showing of compelling and necessary reasons required to justify participation in human subjects research by an **Investigator** with a per se **Conflict of Interest** is within the discretion of the **COI Committee** but should be substantial. The **COI Committee** may, for example, require a showing of such factors as: that the **Investigator** has special expertise regarding the particular drug, device, or method under investigation that uniquely qualifies that **Investigator** to conduct the investigation; that the University has facilities or equipment that are needed for the research and unavailable at most other institutions in the United States; or that the **Investigator** or the University is particularly well situated to enroll study subjects because of the patient population of University-affiliated health care providers or of the **Investigator**.

Notification. The **COI Committee** shall promptly notify the **Investigator** and the **IRB** of its finding(s) regarding whether the **Research Financial Interest** and/or **Leadership Role** of the **Investigator** constitutes a **Conflict of Interest**, and if so, the method(s) the committee recommends for addressing any such **Conflict of Interest**.

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**.

Management or Elimination of Conflicts

Generally. Subject to the provisions concerning per se Conflicts of Interest, the **COI Committee** will develop and implement a management plan to manage, reduce or eliminate any identified **Conflict of Interest**. While the **COI Committee** will endeavor to work with the **Investigator** in developing the management plan, the **COI Committee** may require, if necessary, that the

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Investigator comply with a particular management plan for managing a conflict.

Management Plan. The **COI Committee**'s findings and/or management strategy will be based upon an assessment of the seriousness of the **Conflict of Interest**, and the likelihood that the **Conflict of Interest** could in fact influence persons to make inappropriate, unfair or unwise decisions in their conduct or oversight of human subjects research. Methods of controlling or managing Conflicts of Interest include but are not limited to:

- (a) Public disclosure of the conflicting **Research Financial Interest** or **Leadership Role** to **Sponsors** and research subjects (i.e., during the informed consent process) and during presentations or publication of the research;
- (b) Appointment of an independent monitor capable of taking measures to protect the research from bias resulting from the conflict;
- (c) Providing independent monitoring of the subject recruitment and/or informed consent processes;
- (d) Requiring independent monitoring and oversight of subject-researcher interactions, data gathering, data analysis, and/or data reporting;
- (e) Modifying the research plan;
- (f) Eliminating the conflict by: changing the responsibilities of conflicted **Investigators**; referring the study to non-conflicted **Investigators** at the University; or referring the study to another site at which **Investigators** are not conflicted;
- (g) Eliminating the conflict by divesting or sequestering the conflicting **Research Financial Interest** or relinquishing the **Leadership Role**;
- (h) Requiring that investments posing a **Conflict of Interest** in a research study be "frozen" for a designated period of time lasting beyond the termination of the study, with the **Investigator** allowed neither to sell nor transfer those interests until the end of that time period, thus providing for a forced segregation of the research study and its results from the **Investigator**'s conflicting **Research Financial Interest**;
- (i) Arranging for review of all adverse events, including review of subject records on a comprehensive, periodic or sampled basis to assure that reports of adverse events have been timely and properly made; and/or
- (j) Adopting procedures for a routine periodic updating of information relating to the **Conflict of Interest**, if it appears that the **Conflict of Interest** might change in any appreciable way over the course of a research study.

Other methods may be used consistent with any applicable law and guidance. The **COI Committee** will monitor compliance with the management plan until the completion of the plan or the end of any **Conflict of Interest** (e.g., the completion of the **PHS-Funded Research** project).

IRB Review. The **IRB** shall review the findings and management strategies of the **COI Committee**. The **IRB** may accept the management strategies, or may strengthen them. If the **IRB** elects to strengthen the management strategies, it must document its reasons for doing so and submit a copy of its written report to the **COI Committee**. The **IRB** must promptly notify

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the **Investigator** in writing of its determination regarding the **Investigator's** real or perceived **Conflict of Interest**; the **Investigator** must then comply with the management strategies as modified by the **IRB**.

Expedited Action – Research Financial Interests in PHS-Funded Human Subjects Research

If the University identifies a **Research Financial Interest** of an **Investigator** involved in **PHS-Funded Human Subjects Research** that was not timely disclosed or reviewed in accordance with this policy, the following actions must occur within 60 days:

- (a) the **Investigator** must fully disclose the **Research Financial Interest** to the **COI Committee** through the submission of an updated Form C;
- (b) the **COI Committee** must review the **Research Financial Interest** and determine whether it is a **Conflict of Interest** as defined in Part A of the policy;
- (c) the **COI Committee** must review the **Research Financial Interest** and determine whether it is:
 - 1) related to the human subjects research and
 - 2) a **PHS Financial Conflict of Interest**; and
- (d) the **COI Committee** must implement a management plan, if necessary.

If a **Conflict of Interest** of a financial nature or a **PHS Financial Conflict of Interest** is identified, the **COI Committee** will complete and document a **Retrospective Review** (as defined below) of the **PHS-Funded Human Subjects Research** within 120 days to determine if the research was biased. Depending on the findings of the review, the **COI Committee** will update any reports previously submitted under Section IV.G (Reporting of Conflicts). If the **COI Committee** determines that the research was biased, the **COI Committee** will notify the Office of **Sponsored Projects Administration**. The Office of **Sponsored Projects Administration** will then promptly notify the Public Health Service entity funding the research and submit a Mitigation Report (as defined below) developed by the **COI Committee** in consultation with the Office of **Sponsored Projects Administration**.

Reporting of Conflicts

PHS-Funded Human Subjects Research. The Office of **Sponsored Projects Administration** will provide to the Public Health Service entity funding any **PHS-Funded Human Subjects Research** project an initial report on any financial **Conflict of Interest** or **PHS Financial Conflict of Interest** as follows:

- (a) prior to the expenditure of funds for a **PHS-Funded Human Subjects Research** project (unless the conflict is eliminated before such expenditure);
- (b) within 60 days of any such conflict arising in an ongoing **PHS-Funded Human Subjects Research** project; and
- (c) as required under Section IV.F (Expedited Action). The Office of **Sponsored Projects Administration** will provide an annual update on previously reported conflicts of interest for the duration of the **PHS-Funded Human Subjects Research** project.

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The initial report will identify:

- (a) the **PHS-Funded Human Subjects Research** project and **Investigator**;
- (b) the entity with which the **Research Financial Interest** is held;
- (c) the nature and value of the **Research Financial Interest**;
- (d) in the case of a **Conflict of Interest** as defined in Part A of the policy, how the **Research Financial Interest** could compromise or reasonably appear to compromise the Professional Interests of the **Investigator**;
- (e) in the case of a **PHS Financial Conflict of Interest**, how the **Research Financial Interest** relates to the **PHS-Funded Human Subjects Research** project and the basis for the determination that a **PHS Financial Conflict of Interest** exists; and
- (f) a description of the management plan in place to address the **Conflict of Interest**.

Information to be reported concerning the management plan will include:

- (a) the role and duties of the **Investigator** with the **Conflict of Interest**;
- (b) the conditions of the management plan;
- (c) how the management plan will protect the research from bias;
- (d) the **Investigator**'s agreement to the management plan; and
- (e) how the management plan will be monitored.

Annual updates to the report will include information on the current status of the **Conflict of Interest** and any changes to the management plan.

Public Disclosure. If the **Investigator** of a **PHS-Funded Human Subjects Research** project who is the project director, principal **Investigator** or otherwise identified by the University as senior/key personnel on the grant application has been determined by the **COI Committee** to have a **Conflict of Interest** of a financial nature or a **PHS Financial Conflict of Interest**, (where the **Conflict of Interest** was disclosed and is still held by the project director, principal **Investigator** or senior/key personnel), then, the University will, prior to the University's expenditure of any funds under a PHS-funded research project, ensure public accessibility as provided herein to certain information about such conflicts of interest, by providing in writing, within five days of a valid request (<http://tulane.edu/counsel/upload/Request-for-Report-of-Financial-Conflict-of-Interest-2.pdf>):

- (a) the name, title and role of the individual with the **Research Financial Interest**;
- (b) the entity with which the **Research Financial Interest** is held; and
- (c) the nature and approximate value of the **Research Financial Interest**. When the University responds to such a request, the University will indicate in its written response that, "The information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the University's identification of a new financial **Conflict of Interest**; updates are not provided automatically, but may be requested". Such information regarding Conflicts of Interest of a financial nature and PHS Financial Conflicts of Interest is to be retained and available for three years from the date that the information was most recently updated and

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will be updated annually and within 60 days of the receipt of any new information.

Other Reporting and Corrective Action

Non-Compliance. If the **COI Committee** determines that the failure of an **Investigator** to comply with this policy or a management plan appears to have biased the design, conduct or reporting of **PHS-Funded Human Subjects Research**, the Office of **Sponsored Projects Administration** will promptly notify the Public Health Service entity funding the research of the corrective action taken or to be taken. The **COI Committee** will ensure compliance with any additional corrective actions imposed by the Public Health Service entity funding the research.

Disclosure. If the U.S. Department of Health and Human Services determines there has been non-compliant management or reporting of a **Conflict of Interest** of a financial nature or of a **PHS Financial Conflict of Interest** related to **PHS-Funded Human Subjects Research** to evaluate the safety and effectiveness of a drug, medical device or treatment, the **COI Committee** will require the **Investigator** to disclose the **Conflict of Interest** in each public presentation of the **PHS-Funded Human Subjects Research** and to request addenda adding the disclosure of the **Conflict of Interest** to previously published presentations of the **PHS-Funded Human Subjects Research**.

PHS Subrecipients

The University shall require any PHS Subrecipient by contract to either comply with this policy or to comply with its own financial conflicts of interest policy if such policy is compliant with the **PHS-Funded Research Conflict of Interest** regulations. If the PHS Subrecipient will comply with this policy, **Subrecipient PHS Investigators** will be treated as **Investigators** for purposes of Section IV (Process) of Part C of this policy. **Subrecipient PHS Investigators**, however, will not have to provide information regarding **Leadership Roles** or **Secondary Commitments** on Form C. If the PHS Subrecipient will comply with its own conflicts of interest policy, the University will report any financial conflicts of interest related to **PHS-Funded Human Subjects Research** of **Subrecipient PHS Investigators** that have been reported by the PHS Subrecipient to the Public Health Service entity funding the research in accordance with Section IV.G (Reporting of Conflicts). Additional information on implementation of these provisions will be set forth in the University Subrecipient Monitoring Policy.

Certification

PHS-Funded Human Subjects Research. The Office of **Sponsored Projects Administration** is responsible for certifying to the Public Health Service that the University: (i) has a written, up-to-date and enforced administrative process to manage conflicts of interest; (ii) promotes and enforces compliance for **Investigators** involved in **PHS-Funded Human Subjects Research** and manages conflicts of interest; (iii) provides ongoing reports to the Public Health Service; (iv)

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agrees to make information concerning disclosures of **Investigators** involved in **PHS-Funded Human Subjects Research** and review of the disclosures available to the U.S. Department of Health and Human Services upon request; and (v) fully complies with federal regulations at 42 C.F.R. Part 50 Subpart F and 45 C.F.R. Part 94.

National Science Foundation Research. In the case of National Science Foundation funding applicants, the Office of **Sponsored Projects Administration** is responsible for certifying to the National Science Foundation that all identified conflicts have been reviewed by the **COI Committee** and have been satisfactorily managed, reduced or eliminated prior to the University's expenditure of any funds under the National Science Foundation award.

Appeal of the **COI Committee** Decision

Generally, **Investigators** who disagree with the **COI Committee's** findings and/or management strategy may appeal in writing to the Senior Vice President responsible for that **Investigator's** unit. A copy of the appeal must be sent to the **COI Committee**. The **COI Committee** will promptly notify the **IRB** of the appeal. The applicable Senior Vice President may agree with the **COI Committee's** findings and/or management strategy, or may amend such findings and/or strategy by, for example, strengthening or weakening the management strategies. The applicable Senior Vice President shall promptly notify the **Investigator** and the **COI Committee** of the conclusions of his or her review. The **COI Committee** will forward to the **IRB** a revised copy of its findings and management strategy should these require amendment as a result of the appeal. The **IRB** shall suspend its ultimate determination regarding the study pending the resolution of the appeal.

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

E. Audit and Sanctions for Non-Compliance

At the request of a Senior Vice President of the University, an **Investigator** may be audited for the purpose of verifying whether the **Investigator** truthfully and accurately disclosed his or her **Leadership Roles, Secondary Commitments and Research Financial Interests** in Form C (and in any updates thereto), and for the purpose of verifying whether the **Investigator** is complying with the actions, if any, that were specified in the written report of the **COI Committee** (or applicable Senior Vice President where there has been an appeal, or **IRB** where management strategies were strengthened). An **Investigator** who fails to file a completed Form C with the **COI Committee** by the annual deadline, or who fails to comply with any other action

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specified by the **COI Committee** or applicable Senior Vice President (as modified by the **IRB**) will be subject to potential sanctions in accordance with applicable University policy and procedures. These sanctions may include formal admonition or censure; suspension or termination of the **Investigator's** eligibility for grant applications and/or **IRB** approval; non-renewal of appointment; prohibition on expending PHS funds; and/or dismissal.

F. Confidentiality

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

G. Record Retention

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

H. Additional Definitions and Descriptions

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

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

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

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**,

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research or health care-related organization;

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

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

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.

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

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Part D

A. Policy for Conflicts of Interest of Research Oversight Officials

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

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.

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

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Immediate Family's⁴ 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.

Process

Disclosure

All Research Oversight Officials must complete Form D of the Conflicts of Commitment and Interest Disclosure Form.⁵ 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.

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).

Confidentiality

⁴ 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.

⁵ **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.

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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 financial and other confidential information of a Faculty or Staff member will be permitted, unless required by law.

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.

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 they hold 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

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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.

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 they are an inventor and/or serves as an **Investigator** on that protocol, present or assist in presenting the protocol to the **IRB** Members.

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.

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

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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.

Additional Definitions

Research Leadership Role:

- (a) Employment in any executive or administrator capacity,
- (b) consulting in any executive or administrator capacity, or
- (c) serving as
 - 1) a member of a board of trustees, directors or administrators,
 - 2) an officer, or
 - 3) 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.

Research Financial Interest:

- (a) 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;
- (b) Royalties on any patent or other intellectual property interests, unless paid by the University;
- (c) 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.

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 they are an **Investigator**.

Sponsor: The entity that is **Sponsoring** or funding the research and the entity's affiliates and

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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.

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March 25, 2022