Tulane University

Research Compliance Program
Index

Index .......................................................................................................................... 2
I. Preamble .................................................................................................................. 3
II. Program Overview .................................................................................................. 3
III. Written Policies and Procedures .......................................................................... 4
   A. Related University Policies on Research Compliance ....................................... 4
   B. Researcher Code of Conduct ............................................................................. 5
IV. Oversight of Research Compliance Program ...................................................... 5
   A. University Compliance Steering Committee ...................................................... 6
   B. Research Compliance Operations Committee (“RCOC”) .................................. 7
   C. Vice President for Research (“VPR”) ................................................................. 8
   D. Office of Research Compliance (“ORC”) ........................................................... 9
V. Education and Training .......................................................................................... 10
VI. Effective Lines of Communication ....................................................................... 10
   A. Access to ORC and Supervisors ....................................................................... 10
   B. Complaints and Non-Compliance ................................................................... 11
VII. Internal Reviews and Monitoring ....................................................................... 13
VIII. Research Compliance Program Revisions ......................................................... 13
IX. Coordination .......................................................................................................... 13
X. Commonly Used Acronyms ................................................................................ 14
I. Preamble

Tulane University (“Tulane” or “University”) is committed to lawfully and ethically conducting its research activity. Additionally, as a recipient of extramural research awards from the Public Health Service (“PHS”), National Science Foundation (“NSF”), and other Federal and State sponsoring agencies, Tulane is obligated to comply with applicable statutes, regulations and Federal policies.

Tulane has formalized this commitment through the adoption and implementation of this Research Compliance Program (“Program”). The purpose of the Program is to establish a framework for research compliance at Tulane and to promote adherence to research-related Federal and State laws and regulations. Tulane expects the Program to further its fundamental missions of instruction, research, and healthcare. The Program is cognizant of and takes into account the Draft Office of Inspector General (“OIG”) Compliance Program Guidance for Recipients of PHS Research Awards. The Program not intended to set forth, replace, or define all the substantive policies, programs, and practices of Tulane designed to achieve research compliance. Tulane already maintains various research compliance practices, and those practices may be incorporated as part of this Program.

II. Program Overview

Tulane's research compliance activities rely on the combined efforts of researchers, support staff, study participants, and others, as well as collaboration among departmental, administrative, and business units of the University.

The University's goal is to provide information, support, and systems needed to meet the laws, rules, and policies governing research in the most reasonable, efficient, and effective way. The
University designed the Program to be proactive, transparent, and integrated to prevent problems before they happen without impairing research.

The Program is founded upon the following core elements:

1. **Written Policies and Procedures**
   Design standards and policies that effectively enable researchers and others to meet compliance requirements. (See Section III).

2. **Compliance Officer & Compliance Committee**
   Designate a research compliance officer and research compliance committee that are integrated into University-wide compliance. (See Section IV).

3. **Awareness, Education, and Training**
   Communicate standards, policies, and responsibilities to researchers, administrators, and others through timely, appropriate and effective education and training on responsible conduct in research. (See Section V).

4. **Effective Lines of Communication**
   Develop and maintain effective systems of communication, including resources for promptly responding to research compliance questions or concerns. (See Section VI).

5. **Internal Monitoring and Auditing**
   Implement monitoring and auditing systems to assure research compliance, detect breakdowns, and identify potential problem areas. (See Section VII).

6. **Enforce Standards**
   Enforce standards fairly, consistently & through well publicized disciplinary guidelines. (See Sections III(B) and VI).

7. **Response and Corrective Action**
   Responding promptly to detected problems and undertake corrective action. This includes evaluation and modification of the Program where appropriate to prevent similar problems. (See Section VI(B)).

8. **Defined Roles and Responsibilities**
   Maintain clear roles and research compliance responsibilities for all parties; using due care and appropriate oversight when assigning compliance responsibilities. (See Section IV).

### III. Written Policies and Procedures

#### A. Related University Policies on Research Compliance.

In addition to this program, Tulane has developed the following written policies and procedures to address compliance with Federal and State award and research requirements:

<table>
<thead>
<tr>
<th>Topic</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Welfare/Institutional Animal Care and Use Committee (“IACUC”)</td>
<td><a href="http://tulane.edu/asypr/iacuc/index.cfm">http://tulane.edu/asypr/iacuc/index.cfm</a></td>
</tr>
<tr>
<td>Biosafety and Select Agents/Institutional Biosafety Committee (“IBC”)</td>
<td><a href="http://tulane.edu/asypr/biosafety/index.cfm">http://tulane.edu/asypr/biosafety/index.cfm</a></td>
</tr>
<tr>
<td>Conflicts of Interest and Commitment (Section III(D) of Faculty Handbook)</td>
<td><a href="http://tulane.edu/provost/faculty-handbook.cfm">http://tulane.edu/provost/faculty-handbook.cfm</a></td>
</tr>
</tbody>
</table>
### Effort Reporting

http://tulaneeffortreporting.tulane.edu/

### Hazardous Waste

http://www.som.tulane.edu/oehs/Hazmat.htm

### Health Insurance Portability and Accountability Act ("HIPAA")

Privacy and Security

http://tulane.edu/counsel/upco/privacy-policies.cfm

### Human Research Protection Program / Institutional Review Board ("IRB")

http://tulane.edu/asvpr/irb/policies.cfm

### Radiation Safety

http://www.som.tulane.edu/oehs/radiation.htm

### Research Integrity & Misconduct (Section III(H) of Faculty Handbook)

http://tulane.edu/provost/faculty-handbook.cfm

### Sponsored Research

http://tulane.edu/asvpr/ora/policies.cfm

### Technology Transfer & Licensing

http://tulane.edu/ott/

## B. Researcher Code of Conduct

Tulane has a strong commitment to ensure that its research affairs are conducted in accordance with applicable laws and regulations. Also, Tulane considers ethical conduct and accountability for research and researchers as core values to achieve its mission of instruction, research, and healthcare. Therefore, all Tulane members (e.g., faculty, staff, students, and postdoctoral scholars) must comply with Federal and State laws and regulations applicable to any research programs.

All Tulane members are expected to report through normal supervisory channels or through the Tulane ORC any violations or concerns of violations of any Federal or State requirements related to research and any violations of Tulane policies and procedures related to research.

Tulane employees will be subject to disciplinary action as a result of any failure to comply with applicable Federal or State requirements related to research and/or with Tulane policies and procedures related to research, which includes knowing failure to report non-compliance.

Tulane will neither discriminate nor retaliate against any Tulane member who reports in good faith any instances of conduct that do not comply or appear not to comply with Federal or State laws and regulations and/or Tulane policies and procedures related to research. A Tulane member has the right to remain anonymous and to use confidential mechanisms provided by Tulane to disclose non-compliant activity without fear of retaliation of such reports.

## IV. Oversight of Research Compliance Program

This section addresses the process by which Tulane designates appropriate officers and committees to oversee and coordinate research compliance. It also defines the respective roles and responsibilities by which Tulane addresses research compliance oversight.
A. University Compliance Steering Committee

1. Purpose and Authority

The University Compliance Steering Committee ("Steering Committee") is a Tulane-wide committee that reports to the Audit Committee of the University’s Board of Administrators. The purpose of the Steering Committee is to provide strategic guidance and oversight with respect to University-wide compliance matters. This includes, among other things, oversight of compliance as it relates to the following: teaching and administration operations, clinical operations, conflicts of interest and commitment, and research compliance.

The responsibilities and functions of the Steering Committee include guidance for an effective Program at Tulane, which are accomplished through the following functions:

- Setting specific compliance objectives on an annual basis, including annual review of the effectiveness of the Program;
- With regard to research, providing leadership and direction regarding the Program;
- With regard to audit findings or allegations of non-compliance brought to the Steering Committee’s attention, taking action it deems necessary;
- Coordinating research compliance initiatives on a University-wide basis. This includes review to ensure that there are consistent standards for areas of common concern as well as ensuring more effective communication and use of resources.

2. Steering Committee Chair

The VPR shall be the Chair of the Steering Committee. If the Steering Committee Chair is unable to attend a meeting, the Chair shall appoint and otherwise delegate to another member of the Steering Committee the Chair's responsibilities, as circumstances require.

3. Steering Committee Membership

The President of Tulane is responsible for appointing members to the Steering Committee. Standing members of the Steering Committee include the following:

- VPR (Chair)
- Dean of the School of Medicine
- Dean of the School of Public Health and Tropical Medicine
- Dean of the School of Science and Engineering
- Chief Financial Officer of Tulane University
- Executive Vice Dean, School of Medicine
- Director of the Primate Center
- Chief Executive Officer of Tulane University Medical Group
- Chief Technology Officer of Tulane University
Standing committee members may nominate delegates in the event that they are unable to attend a meeting. The Chair also may invite guests, as appropriate, to attend Steering Committee meetings. All committee members should have the requisite seniority in their respective areas to recommend necessary changes to ensure compliance. Members of the Office of the General Counsel shall attend Steering Committee meetings in an ex officio capacity to provide legal counsel to the Steering Committee.

4. Steering Committee Meetings

Steering Committee members may attend meetings in-person or via electronic means (i.e., conference call, video conferencing). All Steering Committee proceedings shall have minutes recorded for approval by the membership. Minutes shall be maintained by the Office of General Counsel.

B. Research Compliance Operations Committee (“RCOC”)

1. Purpose and Authority

The RCOC is a subcommittee of the Steering Committee and exists to provide guidance and recommendations to the Compliance Steering Committee for an effective Program and for matters involving research compliance and to ensure a dialogue is maintained between the various compliance entities at the University (see Tulane Human Research Protection Program (“HRPP”) SOPs 1.10.8.5). The RCOC accomplishes this through the following:

- Advising and assisting the VPR and ORC in the development and maintenance of the Program;
- Reviewing and providing guidance for proposed changes to the Program;
- Facilitating the formation and maintenance of an adequate system of communication for reporting, education, and training concerning research compliance throughout Tulane;
- Analyzing specific risk areas for non-compliance;
- Reviewing and providing input on existing and new policies and procedures that address specific research compliance risk areas and that promote research compliance;
- Recommending appropriate approaches to promote compliance with the Program and detection of potential violations; and
- Advising regarding a system to solicit, evaluate, and respond to research compliance complaints and issues.

2. RCOC Chair
The Research Compliance Officer (“RCO”) shall be the Chair of the RCOC, and shall, in consultation with the VPR, be responsible for appointing members to RCOC. If the Chair is unable to attend a meeting, he shall appoint and otherwise delegate to another member of RCOC to serve as Chair, as circumstances require.

3. RCOC Membership

Standing members of RCOC include the following:

- RCO (Chair)
- Assistant Dean of Finance, School of Public Health and Tropical Medicine
- Director, IACUC
- Director, Office of Research Administration
- Associate Director, National Primate Research Center
- Director, Human Research Protection Office
- Director, Biosafety Office
- Research Faculty Member(s)

In addition to the standing members, the RCOC Chair may appoint any additional members to serve on the RCOC as determined necessary. The Chair also may invite guests, as appropriate, to attend RCOC meetings. Standing committee members may appoint temporary delegates. The Associate General Counsel for Research shall attend RCOC meetings in an ex officio capacity to provide legal counsel to the RCOC.

4. RCOC Meetings

Upon a duly constituted quorum (greater than 50 percent of the membership), RCOC shall meet regularly (i.e., at least four times per year). RCOC members may attend meetings in-person or via electronic means (i.e., conference call, video conferencing). Any action of the RCOC shall require a simple majority vote (greater than 50 percent of the quorum present).

All RCOC proceedings shall have minutes recorded for approval by the membership. Minutes shall be maintained by the Office of General Counsel.

C. Vice President for Research (“VPR”)

The VPR has overall responsibility for oversight and implementation of the Program. The VPR also serves as the Institutional Official of the University’s HRPP/IRB and the IACUC. The VPR is responsible for ensuring that sufficient resources and support exist to implement the Program and comply with all University policies and applicable Federal laws, regulations and guidelines with respect to research.

Although delegable, the VPR is responsible for the following:

- Monitor all investigations and audit findings of potential and actual research non-compliance;
• Ensure that reports of research compliance activities are disseminated, as appropriate, to Tulane senior management and appropriate unit heads;
• Evaluate the effectiveness of the Program;
• Assess existing policies and procedures that address significant compliance risk areas;
• Review and approve new policies and procedures addressing research compliance risk areas;
• Determine whether new or amended research policies and procedures should be presented for review and/or approval by the Steering Committee or other senior advisory groups;
• Supervise and oversee the activities and efforts of the RCO;
• Ensure the formation and maintenance of an adequate system of communication for reporting, education, and training concerning research compliance throughout Tulane; and
• Maintain a system to solicit, evaluate, and respond to complaints and issues.

D. Office of Research Compliance (“ORC”)

The ORC was created to develop, coordinate, communicate, plan, implement, and monitor compliance in research conducted at Tulane or involving Tulane faculty, staff or students. The VPR shall designate the RCO, who is responsible for overseeing the ORC and directing efforts to enhance research compliance, including implementation of the Program. The responsibilities and functions of the ORC include the following:

• Overseeing and monitoring implementation of the Program;
• Reporting on a regular basis to the VPR, RCOC, and the Compliance Steering Committee on research compliance matters and assisting these individuals or groups to establish methods to reduce the institution’s vulnerability to fraud and abuse;
• Periodically reviewing and, as appropriate, recommending revisions to the Program to respond to changes in the institution’s needs and applicable Program requirements, identified weaknesses in the compliance program, or identified systemic patterns of noncompliance;
• Developing, coordinating, and participating in a multifaceted educational and training program that focuses on the elements of the Program, and seeking to ensure that all affected employees understand and comply with pertinent Federal and State standards and applicable University policies;
• Developing policies and procedures;
• Assisting the institution’s internal or independent auditors in coordinating compliance reviews and monitoring activities;
• Reviewing and, where appropriate, acting in response to reports of noncompliance brought to the RCO’s attention;
• Independently investigate and act on matters related to research compliance. The RCO should have the flexibility to design and coordinate internal investigations (e.g., responding to reports of problems or suspected violations) and any resulting corrective action (e.g., making necessary improvements to policies and practices, and taking appropriate disciplinary action) with particular departments or institution activities; and
Participating with the Office of General Counsel in the appropriate reporting of any self-discovered violations of Federal or State requirements.

- Reviewing and investigating unanticipated problems or undue influence a Chair, Member, or staff member of a Tulane research oversight committee (see Tulane HRPP SOPs 2.15).

The RCO has full authority to review all research-related documents, financial records, contracts, and other information necessary to ensure compliance with regulatory requirements pertaining to research.

V. Education and Training

One of the primary goals of the Program is to provide education and training of appropriate administrators, both at the institutional and departmental levels, research faculty (including investigators), other research staff, and if warranted, contractors, on award administration and research compliance requirements. The nature and scope of training and its level of detail will depend on the type of activity and institutional needs. The level and frequency of compliance training is depending on the extent of an individual's involvement in the research process as well as the requirements of the sponsor. Training mechanisms shall include:

- Training seminars related to current issues in research compliance and responsible conduct in research; and
- Web-based communications and training on responsible conduct in research, responsible conduct in use of human subjects in research, and responsible conduct in use of animals in research.

The RCO shall maintain a schedule of research compliance seminars and available research compliance resources on the ORC website. (See http://tulane.edu/asvpr/responsible-conduct-in-research-training.cfm).

Documentation of training and education required by this Program (e.g., attendee lists and training materials) shall be maintained by the Tulane unit that provides such training/education.

VI. Effective Lines of Communication

A. Access to ORC and Supervisors

The ORC shall have an open-door policy and shall be available to:

- answer questions from the research community about the Program and the University’s research-related policies and procedures; and
- confidentially receive reports of research compliance problems.
University officials, department chairs, and other supervisors play a key role in responding to employee concerns. It is appropriate that these individuals serve as the first line of communication.

**B. Complaints and Non-Compliance**

1. **Background**

   As part of its commitment to compliance with applicable laws, regulations and guidelines with respect to research, Tulane reviews all complaints and allegations of research non-compliance and takes any necessary action.

   Tulane maintains an open door policy of communication with regard to research related conduct that may be unethical or that may potentially or actually violate Federal or State laws and/or regulations. Knowledge or suspicion of improper research-related activity may originate from academic personnel, staff, administrators, internal or external auditors, law enforcement, regulatory agencies, customers, vendors, students, scholars, or third parties.

   All faculty, staff and students and other individuals involved in research at Tulane are required to comply with all laws and regulations governing their research activities, as well as with requirements and determinations by Tulane research oversight entities (e.g, IRB, IACUC). This section describes how complaints and allegations of research non-compliance are handled by Tulane.

2. **Allegations of Research Misconduct**

   The University has three policies regarding reporting and reviewing allegations of research misconduct. They include the following:

<table>
<thead>
<tr>
<th>Document</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tulane Research Misconduct Policy, located in Faculty Handbook Section III(H) (housed at <a href="http://tulane.edu/provost/faculty-handbook.cfm">http://tulane.edu/provost/faculty-handbook.cfm</a>)</td>
<td>For all research sponsored by neither PHS nor NSF</td>
</tr>
<tr>
<td>Tulane University Policies and Procedures for Responding to Allegations of Research Misconduct Involving Public Health Service Funded Research (housed at <a href="http://tulane.edu/asvpr/research-compliance.cfm">http://tulane.edu/asvpr/research-compliance.cfm</a>);</td>
<td>If PHS is a sponsor of involved research</td>
</tr>
<tr>
<td>Tulane University Policies and Procedures for Responding to Allegations of Research Misconduct Involving National Science Foundation-Funded Research (housed at <a href="http://tulane.edu/asvpr/research-compliance.cfm">http://tulane.edu/asvpr/research-compliance.cfm</a>);</td>
<td>If NSF is a sponsor of involved research</td>
</tr>
</tbody>
</table>

   The above referenced policies define “research misconduct” and the specific steps required to report and investigate such allegations.
3. Allegations of Research Non-Compliance (Excluding Research Misconduct)

All allegations of research non-compliance (excluding research misconduct) typically should be initially raised with the Tulane person with responsibility over the affected area or the authority to review the allegation. Persons receiving such reports must exercise appropriate judgment in determining which matters can be reviewed under their authority and which matters should be referred to a higher level of management or to the RCO. When it is not clear whether the person receiving the report should handle the matter or should refer it to a higher level, the RCO should be consulted.

Nothing in this Program precludes an individual from raising directly with the RCO concerns, complaints or allegations regarding research non-compliance. The RCO ordinarily notifies the Tulane individual with responsibility over the affected area or the authority to review the allegation. However, if the RCO has reason to believe that the allegation involves the Tulane individual with responsibility over the affected area or the authority to review the allegation, such person will not be notified.

Reports should be factual rather than speculative, and should contain as much specific information as possible to allow for proper assignment of the nature, extent, and urgency of preliminary investigative procedures.

Comments, concerns, requests, and reports regarding suspected compliance issues may be made by contacting the RCO at 504.988.1147 or via email at researchcompliance@tulane.edu. This phone number and email are answered only by ORC personnel. When personnel are not available, calls are forwarded to a confidential voice mailbox maintained by the ORC. Anyone reporting research misconduct via the phone or email has the right to remain anonymous. To the extent possible within the limitations of law and regulation, all information will be treated and maintained as confidential.

Tulane individuals to whom complaints or allegations are made must document in writing the allegations, relevant facts, and outcome of the inquiry. Managers, administrators, and employees must report allegations/complaints to the RCO when any of the following apply:

- The matter is the result of a significant internal control or policy deficiency that is likely to exist at other units within Tulane or Tulane-related entities;
- The matter is likely to receive media or other public attention;
- The matter involves significant misuse of Tulane research resources or creates an exposure to potentially significant liability from improper research activity;
- The matter involves a potential criminal act based on research-related activity;
- The matter involves significant threat to the health and safety of persons from research-related activity; and/or
- Any matter that is judged to be significant or sensitive for other reasons.

If in doubt, contact the RCO for assistance and guidance.
4. Response and Corrective Action for Allegations of Research Non-Compliance

All allegations and complaints of research non-compliance (excluding research misconduct) will be reviewed by the appropriate unit of the University (e.g., RCO, Human Research Protection Office (“HRPO”), Office of Research Administration) that has the responsibility for reviewing the allegation (see section 10.4.1 of the HRPP SOPs, “Review of Allegations of Non-Compliance”). Such review will consider all information and documents relevant to the allegation and any other pertinent information (e.g., interviews of witnesses, reviews of policies). In addition, confidential consultation with other areas with topical expertise may be prudent to ensure a reasonable and thorough review.

Upon completion of the review, the RCO shall recommend to the VPR one of the following findings:

<table>
<thead>
<tr>
<th>Conclusion</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliant</td>
<td>Conformity with applicable regulations, policies, requirements or guidelines</td>
</tr>
<tr>
<td>Non-Compliant</td>
<td>Failure to conform or adhere with applicable regulations, policies, requirements or guidelines. Non-compliance can be minor or serious and sporadic or continuing.</td>
</tr>
</tbody>
</table>

VII. Internal Reviews and Monitoring

The Program shall include monitoring and auditing functions designed to determine compliance with statutory and regulatory requirements and/or University policy pertaining to research activity at Tulane. Such internal monitoring or auditing may be conducted solely by the RCO or in conjunction with Tulane units (e.g., Grants and Contracts Accounting, Office of Research Administration, HRPO, IACUC). Audits of research may include such activities as on-site visits, interviews with personnel, reviews of written materials and documentation, financial accounting practices, and statistical analyses. The RCO shall report the results of monitoring and auditing to the VPR, RCOC, and Steering Committee at least annually.

VIII. Research Compliance Program Revisions

The Program shall be amended by the VPR and, as appropriate, the Steering Committee to ensure that it is sufficiently tailored to the University and adaptable to changes in regulatory requirements. The Program will be revised as experience shows that a certain approach is not effective or suggests a better alternative exists.

IX. Coordination

The RCO shall serve on the following committees in a capacity as specified in each committee’s policies and procedures oversee and ensure that research conducted at the University is in compliance with applicable regulations and University policies:
For research activity subject to two or more of the above listed oversight committees, the RCO shall liaise and serve as a common link among the involved committees regarding:

- protocol review;
- quality improvement findings;
- non-compliance inquiries; and
- non-compliance reporting.

### X. Commonly Used Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>VPR</td>
<td>Vice President for Research</td>
</tr>
<tr>
<td>HIPAA</td>
<td>Health Insurance Portability and Accountability Act</td>
</tr>
<tr>
<td>HRPO</td>
<td>Human Research Protection Office</td>
</tr>
<tr>
<td>HRPP</td>
<td>Human Research Protection Program</td>
</tr>
<tr>
<td>IBC</td>
<td>Institutional Biosafety Committee</td>
</tr>
<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
</tr>
<tr>
<td>IRG</td>
<td>International Research Group</td>
</tr>
<tr>
<td>NSF</td>
<td>National Science Foundation</td>
</tr>
<tr>
<td>OIG</td>
<td>Office of Inspector General</td>
</tr>
<tr>
<td>ORC</td>
<td>Office of Research Compliance</td>
</tr>
<tr>
<td>PHS</td>
<td>Public Health Service</td>
</tr>
<tr>
<td>RCO</td>
<td>Research Compliance Officer</td>
</tr>
<tr>
<td>RCOC</td>
<td>Research Compliance Operations Committee</td>
</tr>
<tr>
<td>SOPs</td>
<td>Standard Operating Procedures</td>
</tr>
</tbody>
</table>