

**ACCEPTANCE OF AWARDS AND EXTRAMURAL FUNDING
(TULANE UNIVERSITY POLICY)**

Responsible University Official: Director, Sponsored Projects Administration
Responsible Office: Sponsored Projects Administration (“SPA”)
Coordinating Departments: Sponsored Projects Administration, all departments participating in sponsored projects

Issued Date: March 18, 2015 **Effective Date:** March 18, 2015
Last Reviewed Date: March 18, 2015 **Next Review Date:** March 18, 2018

WHO NEEDS TO KNOW THIS POLICY: Deans, Department Chairs, and Faculty Members and Staff participating in sponsored projects.

WEBSITE ADDRESS FOR THIS POLICY: [Tulane University - Research Policies and Information](#)

I. Background

The requirement to have awards made to the University insures that sponsored projects conducted by university employees or with the use of university resources or facilities are approved by the university and to insure compliance with relevant university policies and guidelines pertaining to the conduct of research.

II. Policy

All awards for projects conducted by Tulane employees are made to the Administrators of the Tulane Educational Fund (Tulane). Any exceptions to the requirement to have awards made through Tulane must be requested in writing and accompanied by an explanation of the circumstances for which an exception is sought. A determination will be made in consultation with the Dean, Senior Vice President for Research, and the Provost after consideration of the request and the circumstances. In the event such an exception is granted, neither Tulane’s name nor any resources or facilities may be used in the conduct of the project and Tulane assumes no responsibility and/or liability for the work.

Procedure:

A. Award Initiation

- a. An award may be issued as a grant, cooperative agreement or contract. The sponsor designates the type of award to be made and provides an official document to obligate funds for the project. In accordance with federal regulations, a grant or cooperative agreement is issued when the project supports a public purpose. A cooperative agreement requires substantial involvement between the agency and recipient in carrying out the contemplated activity whereas a grant does not. Contracts are typically used when the principal purpose is the

acquisition of property or services for the direct benefit or use of the sponsor. In the event a project is conducted jointly with a third party entity or through another academic organization, the resources to fund the Tulane scope of work are awarded to Tulane through a subaward, subcontract, or consortium agreement.

- b. A sponsor makes the award to Tulane, not to an individual investigator. Since an award is a legally binding document, only certain individuals designated by the Board of Administrators are empowered to negotiate or sign on behalf of Tulane. PIs, department chairs, and deans are not authorized to negotiate or sign on behalf of the University. Tulane reserves the right to decline any award that is not consistent with its practices and policies.
- c. Sponsored Projects Administration (SPA) is designated as Tulane's authorized institutional representative and is responsible for providing signatures on award documents. In consultation with the PI and/or Grants and Contracts Accounting, it reviews the award terms and conditions and the budget before endorsing award documents.
- d. For commercially sponsored clinical trials under the purview of Tulane's IRB, when subject informed consent must be obtained, SPA will undertake the following:
 - i. The SPA Director (or delegate) will review sponsored clinical trial agreements to ensure that the terms and conditions reflect:
 - A. Tulane's commitment to the protection of human subjects involved in research;
 - B. That Tulane and sponsor will follow the protocol, applicable laws and regulations and ethical standards.
 - C. The responsible party for payment with respect to research-related injuries.
 - D. Sponsor indemnification, as appropriate, for subject injury and use of research data and results.
 - E. A summary of the study's scope and a description of services to be provided by Tulane, Tulane University Hospital and Clinic (if applicable), a study budget, and the reporting obligations of the parties.
 - F. The sponsor's responsibility to notify the Tulane IRB, as soon as reasonably possible, of any information a study monitor uncovers that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the IRB(s) approval to continue the study.
 - G. Communication of study results to participants for safety –When participant safety or medical care could be directly affected by study results, the agreement provides that the Sponsor will promptly communicate such information directly to the participants. Alternatively, we can accept language providing that the sponsor will communicate such language to TU and that TU shall communicate such information to study participants. Contracts or other funding agreements describe the steps followed to communicate findings from a closed research study to the researcher or organization when those findings directly affect participant safety.
 - H. Specify a timeframe after closure of the study during which the sponsor will communicate such findings (e.g., two years). This should be based on the appropriate timeframe for each individual study.
 - I. The sponsor follows Tulane's policies and procedures regarding the publication of findings from sponsored research.

- J. The sponsor promptly (no longer than within 30 days) reports to Tulane any findings that could affect the safety of participants or influence the conduct of the study or alter the IRB's approval to continue the study.
- K. The steps followed to communicate findings from a closed research study to the researcher or Tulane when those findings directly affect participant safety.
- L. The SPA Director (or delegate) will notify Tulane's IRB that a fully executed sponsored agreement is in place between Tulane and the sponsor, which is a condition that must be met, in addition to IRB approval, before any subject enrollment can occur.
- ii. The SPA Director (or delegate) will review sponsored agreements and study information as necessary for each sponsored protocol to ensure that the informed consent and sponsored agreement language are consistent. To the extent that the informed consent is not consistent, SPA will notify the IRB of the objectionable language, and the IRB will then communicate the inconsistencies to the PI. Ultimately it is the responsibility of the PI to edit the informed consent and ensure that it is consistent with the sponsored agreement.
- e. Upon request, SPA will furnish to the Human Research Protection Office copies of sponsored research agreements involving clinical trials under the purview of Tulane's IRB.
- f. When an award includes activities conducted by individuals who are not employees or agents of Tulane (regardless of whether human subject research is involved), SPA shall ensure that a sub-agreement is executed, which shall include language that requires compliance with applicable federal, state and local regulations as well as applicable flow-through sponsor requirements.
- g. Before an award is made, additional information may be required by the sponsor. Any such request from a sponsor should be coordinated with the appropriate offices. A PI who receives notice that a site visit is proposed, or a "best and final" offer is required, should contact SPA. A PI may discuss project objectives or the ramifications of a budget adjustment with a sponsor, but it is the responsibility of SPA to act as the intermediary, formally negotiate with the sponsor and to commit the institution.

IV. Related Policies

- A. [Tulane University Faculty Handbook](#)
- B. [Submission and Routing of Proposals for Extramural Funding](#)