SUBMISSION AND ROUTING OF PROPOSALS FOR EXTRAMURAL FUNDING
AND AWARD ACCEPTANCE
(TULANE UNIVERSITY POLICY)

Responsible University Official: Director, Research Administration
Responsible Office: Office of Research Administration (“ORA”)
Coordinating Departments: Research Administration, all departments participating in sponsored projects

Issued Date: July 1, 2009 Effective Date: July 1, 2009
Last Reviewed Date: October 8, 2009 Next Review Date: September 3, 2010

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 submit proposals through Tulane and have awards made to the University insures that research and extramural funding conducted by university employees or with the use of university resources or facilities are approved by the university. Such approval is necessary to insure compliance with relevant university policies and guidelines pertaining to the conduct of research. 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 directly to Tulane through a subaward, subcontract, or consortium agreement.

II. Policy

A. Tulane University requires that employees submit all proposals for grant and contract funding through the appropriate university routing process. An employee whose sponsored activities involve the use of Tulane resources or facilities is required to submit proposals for extramural funding through the Office of Research Administration. Persons who are not affiliated with Tulane are not eligible to use Tulane resources or conduct research at Tulane unless special appointments and exceptions are granted. The policy further requires that all awards for projects conducted by Tulane employees be made to the Administrators of the Tulane Educational Fund (Tulane). The processes by which proposals are reviewed and awards are established are described in the Investigators’ Manual. Any proposal submission requires a completed routing form which provides a summary of relevant information about the proposal. This form may be downloaded from the Office of Research Administration at http://tulane.edu/asvpr/ora/forms.cfm.

B. Any exceptions to these requirements to submit proposals and have the 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, Associate Senior Vice President for Research, and the Provost after consideration of
the request and the circumstances. Unless authorized in writing, employees may not submit grant proposals or accept awards outside of Tulane. In the event such an exception is granted, neither Tulane’s name nor any resources or facilities may be used in such a proposal and Tulane assumes no responsibility and/or liability for the work.

C. All proposals are reviewed by the department, school or college, and the Office of Research Administration before they are signed by an authorized institutional official and sent to a sponsor. This review assures conformance to University and agency policies and ensures that necessary components of the proposal have been incorporated. A PI should initiate this review process as soon as possible, but no less than seven days before a signature is needed by preparing a draft of the proposal for preliminary review by ORA. At a minimum, the Office of Research Administration should review administrative forms, certification pages and the budget during the draft stage to avoid making changes close to the deadline. If the sponsor has not provided specific forms, the PI should contact the Office of Research Administration for guidance. Failure to conform to sponsor requirements may result in the proposal being deemed ineligible.

III. Procedure:

A. Necessary Components for the Routing/Signature Process:

1. General

In order to expedite the routing process, the following components of a proposal shall be routed through the regular channels for signature prior to finalization of the proposal:

a. Proposal Routing Form signed by the PI, Department Chair, and the Dean (signoff by the Dean is always required but only for exceptional circumstances for the School of Medicine. Consult with a representative of the ORA).
b. The proposed budget, budget justification, subawardee budget, if applicable, and other administrative forms required by the sponsor.
c. For clinical trials: The complete proposed Clinical Trial Contract, and copy of the protocol may be attached to the completed Proposal Routing Form and sent to ORA so they may begin the review and negotiation process. At the same time the protocol may be submitted to the IRB to begin review and approval procedures.

2. Proposal Routing Form: A Proposal Routing Form must be completed and submitted with each proposal. Used for statistical and tracking purposes by the deans and the Office of Research Administration, it records basic data such as the PI’s name, the title of the proposal, the funding agency, and budget information. Special requirements or commitments such as cost sharing, renovations of space, etc., are noted on this form, which is also used to track federal regulations concerning conflict of interest, animal care, and human subjects. The PI, the PI’s department chair, and the dean are required to sign the completed Proposal Routing Form. One exception is that the Proposal Routing form does not have to be signed by the School of Medicine Dean unless the project involves cost sharing. If personnel from other schools are included in the proposal, additional signatures of Chairs and Deans may be required.
3. **PI signature requirements for PHS (NIH) proposals:** Effective for proposals submitted to NIH on May 10, 2006 and thereafter, the signature of the Principal Investigator is no longer required as a part of a submitted application. The NIH now requires the applicant organization to secure and retain at the organization a written assurance from the Principal Investigator (PI) prior to submitting an application to the PHS. While this assurance is no longer required as part of the submitted application, it remains a compliance requirement. In order to remain in compliance with this requirement, Tulane University uses the Proposal Routing Form and requires a signature and date from the PI for each submitted application. This assurance must be available to the sponsoring agency or other authorized HHS or Federal officials upon request. The Proposal Routing Form contains the following certifications: (1) that the information submitted within the application is true, complete and accurate to the best of the PI's knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the PI to criminal, civil, or administrative penalties; and (3) that the PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application. When multiple PIs are proposed in an application, this assurance must be retained on Proposal Routing Forms for all named PIs.

4. **Conflict of Interest and Attestation to Truthfulness and Accuracy of Proposal:** In addition to the annual conflicts of interest certification required by Section III(D) of the Tulane University Faculty Handbook the Proposal Routing Form includes a statement relative to Conflict of Interest. The PI must certify the presence or absence of certain conditions on each proposal submission. PIs provide certification that they will abide by Tulane University policy on conflict of interest and that no conflict of interest exists for any key personnel involved in the project. The PI’s signature on the routing form provides assurance that the proposal contains information that is true, complete and accurate.

5. **Protocol Forms for Animal Care or Human Subjects:** Research involving humans or animals are subject to additional regulations. Prior to the initiation of any such research, the proposed work must be approved by the respective internal committee. IRB protocol forms can be downloaded from the Office of Human Research Protections web page. Animal use forms and information are available at the IACUC website.

B. **Budget Preparation and Guidelines:**

1. **General Information**

   a. A budget constitutes the cost proposal and should conform to the statement of work. It also corresponds to the proposed time frame and should be arranged in clearly defined categories, usually provided by the sponsor. The PI should consider sponsor guidelines in preparing a budget as some have specific regulations about allowable costs and acceptable categories of expenditures.

   b. Budget costs fall into two broad categories: direct and indirect (called Facility and Administrative or F &A costs). Direct costs are those that can be clearly allocated to
an individual project, such as salaries, supplies, equipment, etc. Indirect (F&A) costs are less easily assigned to a project but rather are shared with the entire research enterprise. For Clinical Trials Indirect (F&A) costs are calculated as a 25% of direct costs minus the IRB fees. Federally negotiated indirect costs rates must be used for all budgets unless specified in a published policy of the sponsor. Waivers of indirect costs rates must be approved by the Associate Senior Vice President for Research and the Provost. Contact a staff member of the Office of Research Administration for instructions on requesting a waiver or reduction in F&A costs.

2. Award Initiation

a. An award may be issued as a grant, cooperative agreement or contract. The sponsoring agency 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 agency.

b. A sponsoring agency 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. The Office of Research Administration is designated as Tulane’s authorized institutional representative and is responsible for securing authorized signatures on awards. It serves as the intermediary between an agency and the PI for purposes of negotiation, budget changes, modifications to an award, award extensions, and other administrative matters. In consultation with the PI and/or Grants and Contracts Accounting, it reviews the award terms and conditions and the budget before obtaining authorized signatures. The Office of Research Administration and the PI are responsible for ensuring University compliance with the terms and conditions of the award, as well as any applicable federal, state, and University regulations and guidelines.

d. For commercially sponsored clinical trials under the purview of Tulane’s IRB, when subject informed consent must be obtained, ORA will undertake the following:

i. The ORA Director (or delegate) will review sponsored 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 responsibilities to notify the Tulane IRB, as soon as reasonably possible, of any information the sponsor discovers that could affect the safety or medical care for the subjects.
G. 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.

ii. The ORA 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.

iii. The ORA 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, ORA will notify the IRB of the objectionable language, and the IRB will then communicate the inconsistencies to the PI. It is the ultimate responsibility of the PI to edit the informed consent and ensure that it is consistent with the sponsored agreement.

e. Upon request, ORA 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 investigators or individuals who are not employees or agents of Tulane (regardless of whether human subject research is involved), ORA shall ensure that an agreement or sub-agreement is executed, which shall require 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 sponsoring agency. Any such request from a funding organization 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 the Office of Research Administration. If a budget revision is requested, it will generally involve a downward adjustment of the cost proposal with a "not to exceed" limitation. A PI may discuss project objectives or the ramifications of a budget adjustment with a sponsoring agency, but it is the responsibility of the Office of Research Administration to formally negotiate with the sponsor and to commit the institution.

IV. Related Policies

A. Tulane University Faculty Handbook
V. Related Forms

A. Proposal Routing Forms