

SOP for Grant Applications

- I. **PURPOSE:** To ensure that researchers benefit from the full services available to them; to meet Federal standards for internal control.
- II. **SCOPE:** Includes Lead Investigators, CRCs, and sponsored projects staff working on research grants/sponsored project applications.

III. DEFINITIONS

Primary Applicant ("Prime"): Institution submitting a sponsored project application. Often referred to as a Pass Through Entity (PTE).

Consortium Partner: Institution collaborating as a key component of a sponsored project application, but not serving as the Primary Applicant. If any Ochsner employee is serving as an investigator on another institution's application, Ochsner should be a Consortium Partner.

Lead Investigator: Investigator leading Ochsner's research efforts under a sponsored project. This person is responsible for ensuring that all information provided in the application materials is accurate and complete. S/he will be responsible for ensuring that the Ochsner scope of work is completed within the terms of the award.

Sponsored Project: An investigator-initiated activity funded by a grant, cooperative agreement, contract, or subaward such that the sponsor provides support for a specific activity, and the activity delivers something back to the sponsor. All government-funded research projects and most industry trials are sponsored projects. If you aren't sure, ask!

IV. PROCEDURES

A. Lead Investigators

- i. Immediately contact your supervisor and your administrative Research Director and/or Research Manager about the application; secure their support for moving forward.
 - If you are not sure who your appropriate Research Director/Manager is, ask <u>Samantha Bright</u>, <u>Dr. Nick Duesbery</u>, or <u>Dr. Courtney</u> <u>Parke</u>.
- ii. Complete—or have a knowledgeable CRC complete—an <u>Application Initiation Form</u>. This form is due at least:

- Three weeks before the external due date if Ochsner is a consortium partner, not the lead applicant.
- A <u>month</u> before the external due date if Ochsner is to be the lead applicant.
- <u>Two months</u> before the external due date if any of the following situations apply:
 - Ochsner's budget will specifically include patient care costs.
 - The application includes a partner institution that will be paid through Ochsner.
 - The project requires lease or purchase of major equipment.
 - The project requires construction, significant renovation to facilities, or either purchase or lease of real estate.
- iii. Coordinate with the appropriate informatics, epidemiological, and/or biostatistical team in a timely manner to ensure their support and obtain budget information.
 - For informatics support, contact <u>Dr. Dan Fort.</u> Requests for budget information (including effort determinations) and feasibility/site assessments should be made at a week before the budget justification is due. Requests for data retrieval should be made as early as possible, as the feasibility and time for data retrieval depends on multiple factors. For information about available services, see the <u>Clinical Informatics webpage</u>.
 - For epidemiology or biostatistics support or cost information for budgeting, request an appointment with the Office of Epidemiology and Biostatistics (OEB) via this online <u>form</u>. As per the OEB protocol, request should be made 3 and 6 months prior the external due date for R21/R03 and R01 applications, respectively.
- iv. Have each member of the study team confirm the expected level of effort; supervisor approval should be secured.
- v. Provide all requested information, materials, and assurances to the grants management team by the internal due dates (see <u>Table 1</u>). For large grants, such as federal program grants (U01, P20, etc.), the internal due dates may differ to provide additional time for review.

B. Grants Management Staff

- i. For invitations by another institution, verify the Ochsner Lead Investigator's interest before responding.
- ii. Collect the information specified in <u>Application Initiation Form</u>.
- iii. Communicate internal deadlines to Ochsner Lead Investigator in a timely manner.
- iv. Secure all necessary approvals and assurances.
 - a. For government applications, ask the Ochsner Lead Investigator to provide the assurances listed in Exhibit A.

- b. Inform the AVP Corporate and Foundation Relations of in a timely manner of any applications to private foundations or corporations, and secure written approval to proceed with the application prior to submission of application materials.
- c. Ask the Grants Manager in a timely manner to
 - Prepare any subrecipient commitment/information form;
 - Approve budget materials and any other documents providing financial information:
 - Resolve any outstanding issues with the application—including problems with due dates;
 - Follow-up with the Lead Investigator if the <u>Application Initiation Form</u> indicates any "Additional research characteristics" other than vertebrate animals.
 - (If the Grants Manger is unavailable, work with the OSP Director as necessary.)
- d. Confirm using SAM.gov that that no Ochsner key personnel is excluded from participation in Federal grants.
- v. Complete administrative components of application and coordinate, collect, submit, and store all materials in a timely manner.
- vi. Provide the Lead Investigator and his/ her Research Director with copies of submitted application materials.

C. Administrative Research Director and Research Managers

- i. Reinforce the importance of following this SOP with your researchers.
- ii. Discuss planned applications with Project Leaders in a timely manner and inform the Grants Manager immediately if you have any reservations about moving forward with an application.

	Ochsner is Lead Applicant	Ochsner is Consortium Institution	Comments
Application Initiation Form Due	 Sixty (60) days before the sponsor deadline if project includes or requires: Patient care costs; A Consortium Institution/Partner to be paid through Ochsner; Lease or purchase of major equipment; or Construction, significant renovation to facilities, or either lease or purchase of real estate. Thirty (30) days before external deadline if none of the above pertain. 	 Sixty (60) days before the external deadline if project includes or requires: Patient care costs; A Consortium Institution/Partner to be paid through Ochsner; Lease or purchase of major equipment; or Construction, significant renovation to facilities, or either lease or purchase of real estate. Twenty-one (21) days before external deadline if none of the above pertain. 	
Budget Justification Narrative.	At least three weeks before the sponsor deadline. For complex applications with the above- specified costs, budget information will be requested sooner.	At least two weeks before the external deadline. For complex applications with the above- specified costs, budget information will be requested sooner.	 To provide the budget narrative information, either Email a WORD document including the information specified in the <u>Budget</u> justification guidance, or Complete the <u>REDCap</u> <u>Budget Information Form</u>.
Biosketches and all other application documents; any outstanding signatures.	Five (5) working days before sponsor due date.	Three (3) working days before sponsor due date.	Current NIH biosketch forms and instructions can be found <u>here</u> .

* Situations may arise that prevent Lead Investigators from meeting the standard due dates. Examples include a late invitation to participate in a proposal. In these situations, the Grants Manager will work with the Lead Investigator to set appropriate due dates; however, we cannot guarantee

timely submission of application materials in all such situations.

I. OWNERSHP AND DOCUMENT HISTORY

Owner: Heidi Davis, PhD, Grants Manager, <u>grants@ochsner.org</u>, 504-703-9382. Version 1.3 April 13, 2021

Exhibit A – Assurances

The Ochsner Lead investigator should be asked to do the following:

Please confirm that the following statements are all correct—or let the Grants Manager know about any issues you may have so that we can resolve them together.

- As the Ochsner Lead Investigator, you accept responsibility for completing Ochsner's work on this project.
- You have informed your supervisor and administrative research director and/or research manager of this application.
- Each contributor named in the application has agreed to participate and been asked to secure approval from his or her supervisor.
- You will adhere to the terms of the resulting award/subaward.
- In conducting the work, you will follow all relevant Ochsner policies, including "Principal Investigator Responsibilities."
- The information provided, or to be provided, in or for this application/subaward is complete and accurate.
- You understand that any false, fictitious, or fraudulent statements may subject you to criminal, civil, or administrative penalties. (I don't mean to offend you; this assertion is requested to meet federal oversight requirements.)
- No funds have been paid for lobbying activities to influencing or attempting to influence any person or entity in any matter regarding the success of this grant or subaward.
- In accordance with Ochsner's Research Conflict of Interest (COI) policy:
 - You have disclosed all Significant Financial Interests (SFI);
 - No material changes have occurred since your last disclosure; AND
 - You have no SFI which could directly and significantly affect the design, conduct, or reporting of the proposed research.

(The NIH definition of Significant Financial Interest can be found here. (The Ochsner COI policy is can be found on the Ochweb as OHS.COI.003.)

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