

SOP for Processing Research Grant Contracts

- I. **PURPOSE:** To promote timely startup of investigator-initiated research projects through efficient processing of a contract conferring grant or other sponsored project funding.
- II. **SCOPE:** Contracts, subcontracts, or amendments providing funding for a grant or other type of sponsored project.
- III. **DEFINITIONS**

Pass Through Entity (PTE): Institution issuing a subaward to Ochsner.

Processing Request Date: Official date of the contract request to OSP. See Section IV for details.

PRMC: Refers to submissions, reviews, and approvals by the Protocol Review and Monitoring Committee. The term derives from OnCore.

Research Grant Contract ("Contract"): A contract, subcontract, or amendment providing funding for a grant or other type of sponsored project. For the purposes of these SOP, this term includes Data Use Agreements and other agreements associated with the Contract.

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. This term includes all activities funded by subawards and subcontracts associated with such instruments. All government-funded research projects are sponsored projects.

Study Team: The Ochsner Project Leader/Principal Investigator (PI), clinical research coordinator(s), and other employee(s) designated by the PI to manager contract-related issues associated with a sponsored project.

IV. PROCEDURES

A. Study Team

Once you receive a Contract, follow the procedures listed in Table 1 to initiate formal processing. The procedures will depend on the type of research underlying the award:

- [A. Human Subjects Research – Consent Required](#)

- [B. Human Subject Research – Consent Requirement Waived](#)
- [C. Non-Human Subject Research](#)

Table 1. Steps Required to Initiate Processing of Sponsored Project Award

Research Type	Required Steps	Comments
A. Human Subjects Research – Consent Required by Ochsner.	<ol style="list-style-type: none"> 1. Review the Contract and ensure the work statement and budget are satisfactory. If not, contact grants@ochsner.org for assistance in negotiating new terms. 2. Upload the entire Contract, including the budget, and the cover email containing the return email address. Provide enrollment projections and all other information necessary for PRMC review. 	<p>The Processing Request Date is the date on which the PRMC is approved and all requested information is received.</p> <ul style="list-style-type: none"> • If there is an urgent need to execute the agreement prior to PRMC approval, immediately contact the OSP team (osp@ochsner.org) to request an expedited signature. • If consent is required, but the lead institution is consenting the subjects centrally and Ochsner will not need to track them, the Contract does not need to be uploaded onto OnCore. See Case B.
B. Human Subjects Research – No Consent Required	<ol style="list-style-type: none"> 1. Review the Contract and ensure the work statement and budget are satisfactory. If not, contact grants@Ochsner.org for assistance in negotiating new terms. 2. Complete an Agreement Submission Form and submit that, the IRB approval number, the Contract, including budget, and the cover email from the PTE or sponsor who issued the Contract to OSP (osp@ochsner.org). <ul style="list-style-type: none"> • This step is required even if OSP or grants administrators are copied on the Contract transmission. 	<p>The Processing Request Date is the first date on which OSP is in receipt of all requested documents and information.</p> <ul style="list-style-type: none"> • Attach any IRB approvals, exemption letters.

C. Non-Human Subjects Research	<ol style="list-style-type: none"> 1. Review the contract and ensure the work statement and budget are satisfactory. If not, contact grants@Ochsner.org for assistance in negotiating new terms. 2. Complete an Agreement Submission Form and submit that, the Contract, including budget, and cover email from the PTE or sponsor who issued the Contract to OSP (osp@ochsner.org). <ul style="list-style-type: none"> • This step is required even if OSP or grants administrators are copied on the Contract transmission. 	<p>The Processing Request Date is the first date on which OSP is in receipt of all requested documents information.</p> <ul style="list-style-type: none"> • You may be asked to provide documentation that the project does not include Human Subjects Research.
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Once a Contract has been submitted according to the above-specified procedures, the OSP staff will coordinate with the legal team and Dean of Research to negotiate and execute the agreement and provide the Study Team with a copy of the final document.

If you receive an amendment to an executed agreement, forward that and an Amendment Submission Form to osp@ochsner.org. Include the IRB protocol number in the subject line.

ENFORCEMENT

Failure to follow these procedures may result in contract delay. The OSP assumes responsibility for an agreement only upon receipt of all pertinent information and documents and completion of any applicable PRMC reviews.

VI. OWNERSHIP AND DOCUMENT HISTORY

Owner: Office of Sponsored Programs (OSP)

For additional information, contact either Beth Kettenring, OSP Director, osp@ochsner.org, or Heidi Davis, Grants Manager, grants@ochsner.org, 504-703-9382.

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