

| NUMBER | APPROVED BY | EFFECTIVE DATE | PAGE |
|-------------|-------------------------|----------------|-------------|
| SOP 1.03(a) | Executive Director, ORS | 12.07.2022 | Page 1 of 5 |

1. OBJECTIVE

To ensure that the Clinical Trials Office (CTO) Staff are informed about their obligations and responsibilities as they pertain to applicable regulations, guidance, and institutional policies. This Standard Operating Procedure (SOP) applies to the written procedures followed by all members of a CTO staff at LSU Health Sciences Center.

SOP 1.03(a) describes the process for the review and negotiation of new clinical research agreements and amendment, review and negotiation of clinical research budgets, routing of the final agreement/amendment and budget, and account setup once the agreement or amendment is executed.

2. RESPONSIBILITY

The HSC, SSSCC and HN Clinical Trials Offices develop, implement, and maintain SOPs. The need to write a new or revise an existing SOP is based upon changes to federal regulations, guidelines, institutional policies, or procedures. These documents will be provided to staff of the HSC CTO.

The Supervisor of the CTO is ultimately accountable for all CTO activities and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks.

3. DEFINITIONS

Clinical Trial Agreement (CTA): A legally binding agreement that manages the relationship between the sponsor that may be providing the study drug or device, the financial support and /or proprietary information and the institution that may be providing data and/or results, publication, input into further intellectual property.

Clinical Trials Office (CTO): LSU Health Offices at the Health Sciences Center, Healthcare Network and Cancer Center serving as a central resource for initiating and conducting clinical trials for LSU Health investigators.

Contract: A written, dated and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters.

Electronic Signature: A computer data compilation of any symbol or series of symbols executed, adopted or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

4. PROCEDURES

A. Initial Receipt of New Documents

When a research team receives contact from a sponsor with a request for LSUHSC to be a clinical research site or for an LSUHSC faculty member to be a PI, the study team should provide the clinical trial or research agreement (CTA), protocol, draft informed consent, and Sponsor Budget to the HSC CTO via email or Kuali Negotiations.

When a research team receives an amendment from a sponsor for an ongoing clinical research study, the study team should provide the amendment to the HSC CTO via email or Kuali

Negotiations.

The CTO staff responsible for review will create a negotiation record in Quali if the documents were received via email. All documents received in the email should be uploaded as attachments to the activity.

B. Medicare Coverage Analysis

If the study is a qualified trial, the CTO staff member will submit a request to the appropriate third-party service provider to complete a Medicare Coverage Analysis. Budget review should not occur until the MCA is received from the third-party provider.

C. Clinical Research Agreement Review and Negotiation

Using the terms and conditions checklist, the responsible CTO staff member will review the CTA or amendment. Any changes to the document should be made using tracked changes. The reason for the requested additional or removal of language should be included as a comment for the sponsor to review.

On the terms and conditions checklist, the CTO staff member should document where each term can be found in the contract as well as if any changes were made to a certain term. This review should be documented as a new activity in the associated Quali Negotiation, with the tracked version of the agreement and the terms and conditions checklist uploaded as an attachment to that activity.

After initial review, if the agreement involves a non-LSU Health clinic or hospital that must be a third party to the agreement, the CTO staff member should email the tracked version of the agreement or amendment to the appropriate contact at that location for review. This event should be documented as a new activity in the associated Quali Negotiation.

Once all local parties have reviewed the agreement or amendment, the tracked version should be returned to the sponsor for review. This event should be documented as a new activity in the associated Quali Negotiation.

The sponsor should return the agreement with their responses to comments and edits. This event should be documented as a new activity in the associated Quali Negotiation with the sponsor-tracked version of the document uploaded as an attachment to that activity.

The process will repeat until the terms of the agreement or amendment are agreed to. Once that occurs, the sponsor should provide a clean copy for execution.

D. Budget Development and Negotiation

Upon receipt of a Medicare Coverage Analysis, the CTO staff member should draft an in-house budget on the CTO-approved template. Any information the CTO staff member does not have should be requested from the study team and any associated non-LSU Health clinic(s) or hospital(s) involved in the study.

Once the in-house budget is finalized, the CTO staff member should compare the HSC actual costs to what the sponsor is offering. The CTO staff member should send the in-house budget as well as an outline of differences between the Sponsor Costs and the HSC costs to the PI and their Business Manager for review and feedback. The MCA should be provided to them as well.

If the sponsor budget covers all the local study costs, then the budget can be accepted.

If the sponsor budget requires edits, those changes should be made on the Sponsor-provided budget and sent to the Sponsor for review. This review should be documented as a new activity in the associated Kualu Negotiation, with the Sponsor budget and in-house budget uploaded as an attachment to that activity.

This process will repeat until the budget is agreed to. Once that occurs, the sponsor should add a copy of the budget to the executable version of the CTA.

E. Routing for Execution

Routing for PI Signature

Once the agreement/amendment and budget are finalized, the executable version of the agreement/amendment and a copy of the in-house budget should be sent to the PI for execution via email, Kualu Negotiations, or electronic signature portal.

NOTE: When using an electronic signature portal (i.e., DocuSign, Adobe Sign), ask the Sponsor to hold off sending the invitation to sign until the routing process gets to the Authorized Official.

This event, regardless of signature method, should be documented as a new activity in the associated Kualu Negotiation, with the documents uploaded as attachments to that activity.

Routing for Sponsored Projects Approval of the Budget

Once the agreement/amendment is signed by the PI, the partially executed agreement, a copy of the Sponsor Budget (if separate from the CTA), and the in-house budget should be sent via Kualu Negotiations as a new activity to Sponsored Projects' Clinical Trials Billing Operations Manager for review of the budget.

Once reviewed, Sponsored Projects will document their approval within Kualu Negotiations as a new activity.

Routing for Authorized Official Signature

After Sponsored Projects grants approval, the partially executed agreement and the in-house budget should be sent via Kualu Negotiations as a new activity to the Vice Chancellor for Academic Affairs. This step should still occur even if execution is occurring via an electronic signature portal.

Once reviewed, the VCAA will upload the signed document within Kualu Negotiations as a new activity, unless signature occurs via an electronic signature portal.

Signatures from Third-Party Clinic or Hospital

If a non-LSU Health clinic or hospital is involved in the project and are party to the agreement, once the agreement/amendment and budget are finalized, the executable version of the agreement/amendment should be sent to that location for execution via email. This event should be documented as a new activity in the associated Kualu Negotiation with the agreement/amendment uploaded as attachments to that activity.

Note: When using an electronic signature portal, the hospital should sign second to ensure that the HSC routing process occurs prior to execution.

Returning to Sponsor for Countersignature

Once executed by local parties, the agreement should be returned to the sponsor for countersignature. This event should be documented as a new activity in the associated Kualu Negotiation with the partially executed agreement/amendment uploaded as attachments to that activity.

Receipt of Fully Executed Agreement/Amendment

Upon receipt of the fully executed agreement, it should be uploaded as an attachment to a new activity in the associated Kualu Negotiation documenting this receipt. At this point, the Negotiation should be marked complete.

F. After Execution

Account Setup Request

The CTO Staff member should complete the Sponsored Projects Project Number Request form. This form, along with the final documents, should be sent to the study team with a request for the business manager and department to sign the request form and return it to the CTO.

The CTO will send the signed request form, the executed agreement, and the in-house budget to Sponsored Projects via email for account setup.

Sponsored Projects will assign the project an account number and provide it to the CTO and study team via email.

Clinical Research Database Entry

Once all the steps outlined above are complete, any clinical trial agreements, clinical research agreements, or amendments need to be added as a new record into the Clinical Research Database by the CTO staff member.

Invoicing for Start-Up and IRB Fees

Once an account number is received for a project, the CTO staff member should draft invoices for the start-up fee and the IRB initial review fee. The invoices should be sent to the Business Manager. Once the Business Manager signs the invoices and send them to the sponsor, the Business Manager should return the signed invoice to CTO.

The CTO will then draft the journal entry for these fees. Invoices should be added as supporting documents as part of the journal entry. Any additional documentation such as IRB approval letter should be added to the journal entry as well.

The completed journal entry should be sent to Sponsored Projects who will allocate the funds to the appropriate account.

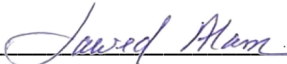
| | BUSINESS UNIT | LEDGER | ACCOUNT | FUND | DEPT | PROGRAM | CLASS |
|------------|----------------------|---------------|----------------|-------------|-------------|----------------|--------------|
| | LSUNO | ACTUALS | 532505 | 113 | | 10001 | 35200 |
| CTO | LSUNO | ACTUALS | 491165 | 113 | 1622300 | 51000 | 90165 |
| | LSUNO | ACTUALS | 532500 | 113 | | 10001 | 35200 |
| IRB | LSUNO | ACTUALS | 491160 | 113 | 1622300 | 51000 | 90160 |

5. APPLICABLE REGULATIONS AND GUIDANCE

| LSU Health Guidance/Policy | Title |
|-------------------------------|--|
| LSUHSC Clinical Trials Office | Legal and Financial Review |

6. MATERIALS

- 6.1. Clinical Trial Agreement Template
- 6.2. Clinical Trial Amendment Template
- 6.3. LSUHSC In-House Budget Template
- 6.4. Project Number Request Form
- 6.5. Journal Entry Template
- 6.6. Workflow: Routing when Hospitals ARE Involved
- 6.7. Workflow: Routing when Hospitals ARE NOT Involved

Approved by:


Jawed Alam, PhD, MBA
Executive Director, Office of Research Services