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 3.01 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.

Disaster: any event that renders the LSU Health Campuses inoperable or unusable so that it interferes with LSU Health's ability to deliver essential business services.

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 will 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 will provide the amendment to the HSC CTO via email or Kuali Negotiations.

The CTO staff responsible for review will create a negotiation record in Kuali if the documents were received via email. All documents received in the email will 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, including in the request the protocol, draft consent, draft CTA, and sponsor budget. 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 will document where each term can be found in the contract as well as if any changes were made to a certain term. This review will be documented as a new activity in the associated Kuali 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 will email the tracked version of the agreement or amendment to the appropriate contact at that location for review. This event will be documented as a new activity in the associated Kuali Negotiation.

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

The sponsor will return the agreement with their responses to comments and edits. This event will be documented as a new activity in the associated Kuali 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 will provide a clean copy for execution.

D. Budget Development and Negotiation

Upon receipt of a Medicare Coverage Analysis, the CTO staff member will draft an in-house budget on the CTO-approved template. Any information the CTO staff member does not have will 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 will compare the HSC actual costs to what the sponsor is offering. The CTO staff member will send the in-house budget as well as the Sponsor budget to the PI and their Business Manager for review and feedback. The MCA will be provided to them as well.

After PI and Department review, if the budget includes non-LSU Health clinic or hospital costs, the CTO staff member will email a copy of the in-house budget, Sponsor budget, and MCA to the appropriate contact at that location for review. This event will be documented as a new activity in the associated Kuali Negotiation.

Once all local parties have reviewed the budget, if the sponsor budget covers all the local study costs, then the budget can be accepted. If the sponsor budget requires edits, those changes will be made on the Sponsor-provided budget and sent to the Sponsor for review. This review will be documented as a new activity in the associated Kuali 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 will add a copy of the budget to the executable version of the CTA.

E. Routing for Execution

Routing for Sponsored Projects Approval of the Budget

Once the agreement/amendment and budget are finalized, the executable agreement, a copy of the Sponsor Budget (if separate from the CTA), and the in-house budget will be sent via Kuali 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 Kuali Negotiations as a new activity.

Routing for PI Signature

Once the agreement/amendment is signed off on by Sponsored Projects, the executable version of the agreement/amendment, a copy of the in-house budget, and the MCA will be sent to the PI for execution via an electronic signature portal (i.e., AdobeSign) unless wet ink is required.

NOTE: When using a Sponsor's electronic signature portal, 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, will be documented as a new activity in the associated Kuali Negotiation, with the documents uploaded as attachments to that activity.

Routing for Authorized Official Signature

Once the agreement/amendment is signed by the PI, the partially executed agreement and the in-house budget will be sent via an electronic signature portal (i.e. AdobeSign) unless wet ink is required.

This event, regardless of signature method, will be documented as a new activity in the associated Kuali Negotiation, with the documents uploaded as attachments to that activity. A notification from Kuali should still be sent to the VCAA altering her that the electronic signature portal packet email is associated with the negotiation.

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 LSU Health signatures have been obtained, the executable version of the agreement/amendment will be sent to the hospital for execution via email. This event will be documented as a new activity in the associated Kuali Negotiation with the agreement/amendment uploaded as attachments to that activity.

Returning to Sponsor for Countersignature

Once executed by local parties, the agreement will be returned to the sponsor for countersignature. This event will be documented as a new activity in the associated Kuali 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 will be uploaded as an attachment to a new activity in the associated Kuali Negotiation documenting this receipt. At this point, the Negotiation will be marked complete.

Routing When the Sponsor Wants to Use Their Own Electronic Signature Portal

LSUHSC will agree to allow a sponsor to use their own electronic signature portal; however, the final CTA or amendment must first go through our institutional routing process and the hospital routing process, if applicable. No signatures would be obtained during the internal process and all parties will be alerted to the change in how signatures are being obtained. When allowed, the CTO will ask that a member of the staff be included in the routing process for informational purposes only.

F. After Execution

Account Setup Request

The CTO Staff member will complete the Sponsored Projects Project Number Request form. This form, along with the final documents, will 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 will draft an invoice for the start-up fee and/or the IRB initial review fee. The invoice will be sent to the Business

Manager. Once the Business Manager signs the invoice and sends it to the sponsor, the Business Manager should return the signed invoice to CTO.

The CTO will then draft the journal entry for these fees. The invoice will 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 will 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:

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Michael Hagensee, MD, PhD
Executive Director, Office of Research Services

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6.7. Workflow: Routing when Hospitals ARE NOT Involved

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Michael Hagensee, MD, PhD
Executive Director, Office of Research Services