

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
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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(b) describes the LSUHSC process for requesting Medicare Coverage Analysis services from third-party vendors and initial development of the in-house budget.

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

Budget: The estimated amount of money that a study team needs to accomplish the goal of a clinical research study or clinical trial.

Medicare Coverage Analysis (MCA): a review to determine if a research study is eligible to receive Medicare coverage and outlines what items and services performed as part of the research study should be billed to Medicare.

4. PROCEDURES

A. Requesting Medicare Coverage Analysis from WCG IRB

When the CTO receives initial study documents from the research team or sponsor, the CTO may request a Medicare Coverage Analysis from WCG.

The CTO will submit to WCG via their [Latitude portal](#), at a minimum, the following documents:

- Protocol
- Draft Agreement or Contract
- Draft Sponsor Budget
- Draft Consent Form

Once submitted, WCG averages 3 to 5 business days to return the finalized MCA via email.

The CTO should provide the MCA to the Principal Investigator for their review and sign-off.

B. Requesting Medicare Coverage Analysis from Kelly Willenberg & Associates

When the CTO receives initial study documents from the research team or sponsor, the CTO may request a Medicare Coverage Analysis from Kelly Willenberg & Associates.

The CTO will submit to Kelly Willenberg and Associates via email (mca@kellywillenberg.com), at a minimum, the following documents:

- Protocol

- Draft Agreement or Contract
- Draft Sponsor Budget
- Draft Consent Form
- [Routing Form – Coverage Analysis](#)

Once submitted, Kelly Willenberg & Associates averages 3 to 5 business days to return the finalized MCA via email.

The CTO should provide the MCA to the Principal Investigator for their review and sign-off.

C. Development of an In-House Budget

Once the MCA has been returned, the CTO should begin drafting the in-house budget using the approved template.

The Timeline on the budget template should be updated to accurately represent the study timeline for each specific budget. Edit the timeline on the Effort-Based tab and it will populate the same information on the Expense-Based tab.

All research activities and procedures should be allocated to either the Effort-Based tab if the cost of the activity will be determined by effort required or the Expense-Based tab if the procedure has a set expense. The CTO will reach out to the research site(s) and to ACS to request pricing for procedures with a CPT code as well as any other activities conducted by the research site's staff.

Fees for activities or procedures that are conducted by LSUHSC personnel should be calculated using anticipated effort times the Study Staff Non-CPT Coded Service Rate listed on the LSU Health Fee Schedule.

On the Expense-Based tab, each item or procedure should include the category of the summary budget where the item will be allocated. For example, ACS fees are allocated to Personnel Costs while research site procedures are allocated to the Subcontract.

Once all fees have been placed on their appropriate tabs, then the summary page will need to be populated.

- I. Personnel Costs: From the effort-based and expense-based tab, add any items that fall into personnel costs. That number will be for a single subject. Divide the number by the current fringe rate; then add a formula into the Salary Requested box $[(\text{single patient fee}/\text{fringe rate}) * D11]$.
- II. Subcontract: From the effort-based and expense-based tab, add any items that fall into Subcontract. That number will be for a single patient. Add a formula into the Subcontract box $[(\text{single patient fee} * D11) + \text{Hospital Start-Up fee}]$
- III. LSUHSC Start-Up Fee: Add start-up fee minus overhead
- IV. IRB Service Fee: Add appropriate fee for IRB review
- V. Patient Incentives: Add a formula to this box $[\text{single patient incentive} * D11]$

The budget should be reviewed and approved by the PI and their Business Manager. Once their approval is received, the in-house budget should be compared to what the Sponsor is offering

to identify a starting place for negotiations. See SOP 1.03(a) for details on the budget negotiation process.

5. APPLICABLE REGULATIONS AND GUIDANCE

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

6. MATERIALS

- 6.1. KW Routing Form – Coverage Analysis
- 6.2. LSUHSC In-House Budget Template