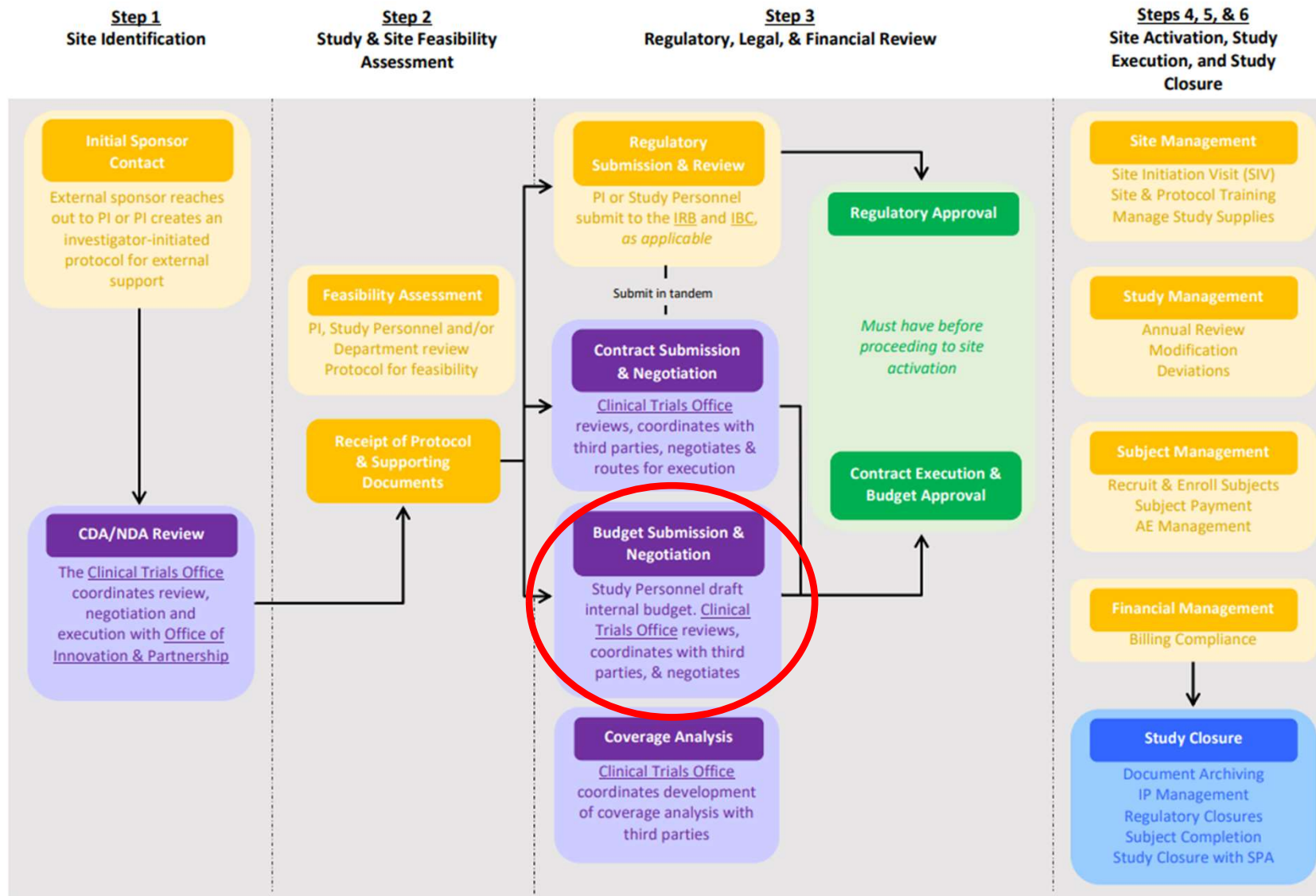


Budget Development for Clinical Trials

Office of Research Services
Professional Development Knowledge Base

Clinical Trial Start-Up



What Do You Need to Draft a Budget?

✓ **Study Protocol**

- Provides us with a list of procedures as well as the schedule of events

✓ **Medicare Coverage Analysis**

- Tells us what can be covered by Medicare and what is a research cost

✓ **Site Fee Schedule** (*CTO will obtain from site*)

- Tells us how much each procedure will cost at the site

✓ **Sponsor Budget**

- Needed to compare actual costs to Sponsor offer

Budget Template

While the Sponsor will likely provide their budget on their own template, HSC builds an internal budget on an in-house template for routing

Tabs within the In-House Template:

- Budget Summary
- Start-Up and Invoiceable Costs
- Effort-Based Costs
- Expense-Based Costs

Start-Up & IRB Fees

LSUHSC Start-Up Fees

- \$10,800
- Split between CTO and Department
- *Nephrology, Dental, and HSC Baton Rouge use a different start-up fee*

Hospital Start-Up Fees

- Differs between each site

LSUHSC IRB Fees

- Local Review: Between \$1,000 and \$2,500 depending on type of review
- Reliance Review: \$2,000

Timeline

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.

Examples:

Timeline																
Baseline/ Screening	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12	Visit 13	Visit 14	Visit 15	Closeout Visit

Timeline																
Visit 1, Week -2 (Screening)	Visit 2, Week 0	Visit 3, Week 4	Visit 4, Week 8	Visit 5, Week 12	Visit 6, Week 16	Visit 7, Week 20	Visit 8, Week 24	Visit 9, Week 28	Visit 10, Week 32	Visit 11, Week 36	Visit 12, Week 40	Visit 13, Week 44	Visit 14, Week 48	Visit 15, Week 52	Visit 16, Week 60	12 Weeks Post Virtual Visit

Timeline																												
Screening	Treatment Cycles (4 Cycles @ 56 days)																								Long term Follow-up			
Screening @ 21 Days	C1D1*	C1D7	C1D14	C1D28	C1D42	C1D56*	C2D1*	C2D7	C2D14	C2D28	C2D42	C2D56*	C3D1*	C3D7	C3D14	C3D28	C3D42	C3D56*	C4D1*	C4D7	C4D14	C4D28	C4D42	C4D56/ EoT	3 Month	6 Month	9 Month	12 Month

Effort-Based Costs

Research activities that do not have a CPT-code or do not have a set expense per item should be considered effort-based costs. These are allocated to a responsible party and budgeted as increments of an hour.

Examples:

- Informed Consent
- Inclusion/Exclusion
- Demographics
- Medical History
- Phone Call
- Questionnaires
- Hourly Fee

Responsible Parties:

- PI
- Study Coord.
- Co-Investigator
- Hospital Personnel
- Pharmacist

Hourly Increments:

- 1-6 min = 0.1
- 7-12 min = 0.2
- 13-18 min = 0.3
- 19-24 min = 0.4
- 25-30 min = 0.5
- 31-36 min = 0.6
- 37-42 min = 0.7
- 43-48 min = 0.8
- 49-54 min = 0.9
- 55-60 min = 1.0

Study Staff Rates

LSU Health has set standard Study Staff Non-CPT Coded Service Rates that include fringe.

Study Staff Service Rates	
	Hourly Fee
Principal Investigator, Co-Investigator(s)	<i>AAMC Rate or Higher</i>
Clinical Research Nurse Coordinator	\$ 100
Clinical Research Coordinator	\$ 75

Expense-Based Costs

Each item or procedure should be listed on its own line and 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.

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.

Example:

Category	EXPENSE-BASED Item or Procedure	CPT Code	Timeline										Total
			Screening (Visit 0)	D1 (Visit 1)	D2	D3	D4 (Visit 2)	D7 (Visit 3)	D10 (Visit 4)	D15 (Visit 5)	D29 (Visit 6)	D61 (Visit 7)	
Personnel	Physical Exam/Vital Signs/BMI/Facility	99221-99239	260	235			235	235	235	235	235	235	1905.00
Subcontract - WJ	ECG -	93000-93010	275.00										275.00
Personnel	ECG - Professional Fee	93000-93010	33.00										
Subcontract - WJ	CT/Chest X-Ray (if not previously performed) - Technical	71250-71270/ 71045-71048	2630										2630.00
Personnel	CT/Chest X-Ray (if not previously performed) - Professional	71250-71270/ 71045-71048	140										

Invoiceable Costs

Invoiceable Costs are expenses that may or may not occur during the conduct of a study. If the activity or procedure occurs, the study team would invoice the sponsor. The invoiceable fees are not included in the total expected Sponsor contribution because they may or may not occur. LSU Health has developed a standard set of invoiceable fees which should be included in the budget for all industry-sponsored clinical trials, as applicable.

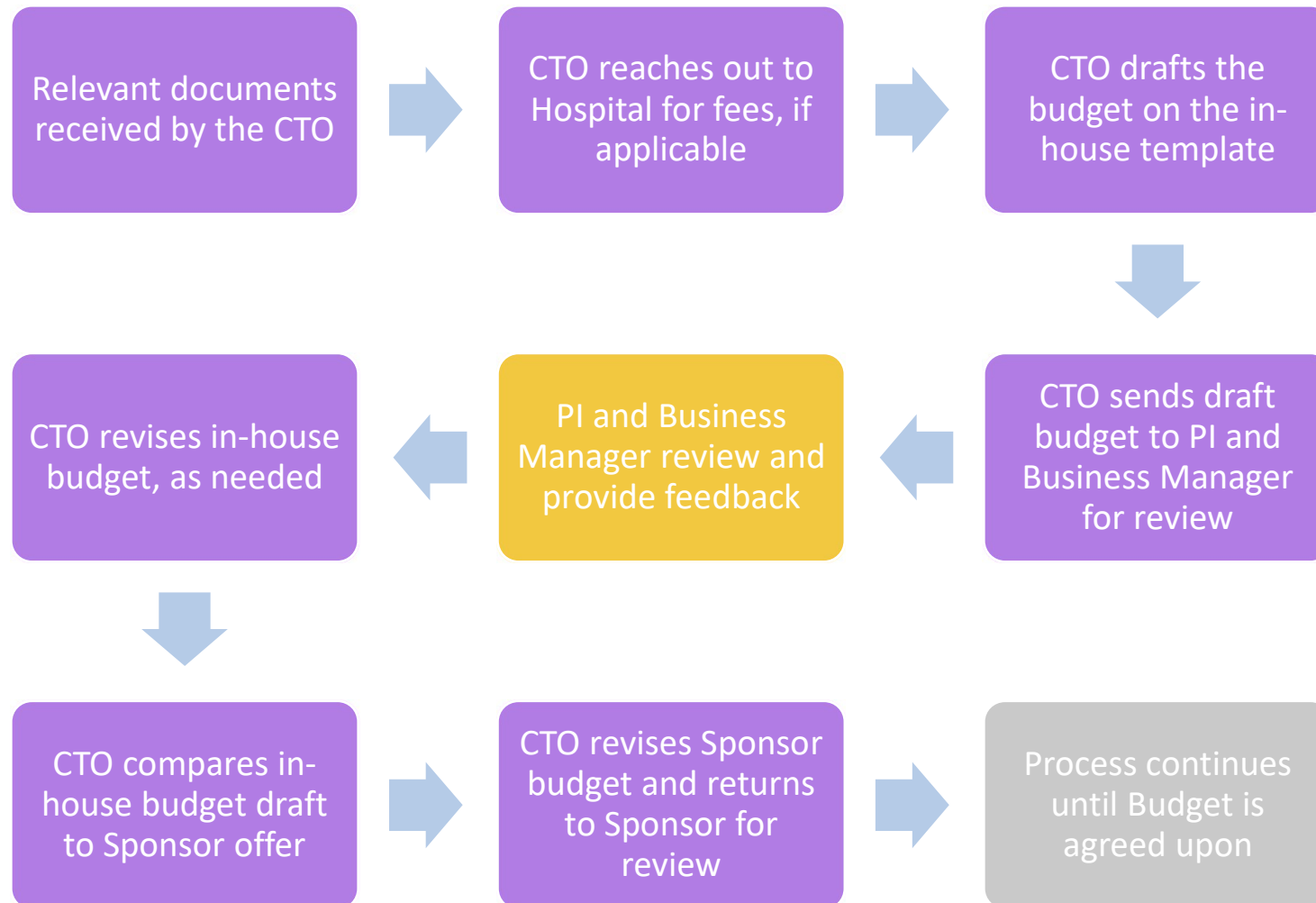
Invoiceable	Fee
Protocol Amendment with Consent Changes	\$500
Protocol Amendment without Consent Changes	\$250
Budget or Contract Amendment	\$450
LSUHSC IRB Amendment Review	See IRB Fee Schedule
LSUHSC IRB Renewal/Continuing Review	See IRB Fee Schedule
LSUHSC IBC Renewal/Continuing Review	\$300
Monitoring Visit (Remote or On Site), Half Day	\$500
Monitoring Visit (Remote or On Site), Full Day	\$1,000
Monitor Change Fee	\$500
Sponsor-Directed Audit, per day	\$1,000
FDA-Directed Audit, per day	\$2,000
SAE Reporting, per event	\$250
Document Storage Fee	\$750
Administrative Close-Out and Visit	\$1,000
Reconsent	\$100
Lab Set-Up/Specimen Storage Fee	\$750
Clinical Trial Management System (LSUHN Only)	\$1,000
eRegulatory System (LSUHN Only)	\$500
LSUHN Clinic Room Rate, per visit	\$130

Budget Summary

The budget summary outlines the total costs of the project and allocates those costs into categories need for account setup. This is a high-level overview of what the actual costs of project are expected to be as compared to the funds provided by the Sponsor.

SPONSORED PROJECTS ACCOUNT BREAKDOWN					
PERSONNEL COSTS					
Position	Name	% Effort	Salary Requested 500001	Fringe Requested 510000	Total
PI		0%			
Clinical Research Coordinitor		0%			
Co-Investigator		0%			
Subtotal Personnel Costs			\$	\$	\$
OPERATING SERVICES COSTS					
540000	Supplies				\$0.00
520000	Travel				\$0.00
530000	Consultants				\$0.00
560000	Other				\$0.00
570000	Equipment				\$0.00
530000	Operating Services				\$0.00
550000	Subcontract [Hospital/Clinic]				\$0.00
550000	Subcontract [Hospital/Clinic]				\$0.00
Subtotal Operating Services					\$0.00
LSUHSC TOTAL					
	Modified TOTAL Direct Costs				\$0.00
510000	LSUHSC Start-Up Fee				\$0.00
590000	TOTAL Indirect Costs				\$0.00
530000	IRB Service Charge				\$0.00
530000	Patient Incentives				\$0.00
	TOTAL ANTICIPATED STUDY COSTS				\$0.00
REVENUE FROM SPONSOR					
	Subtotal Per Patient Cost				\$0.00
	Site Start-Up Fee				\$0.00
	LSUHSC IRB Fee				\$0.00
	Study Closeout Fee				\$0.00
	ANTICIPATED FUNDING BY SPONSOR				\$0.00
	ANTICIPATED STUDY				
	SURPLUS/DEFICIT				\$0.00
COMMENTS:					

Review of Budgets



Questions?

Appendix