WHICH CLINICAL TRIALS OFFICE DO I WORK WITH?

Work with the LSUHSC CTO When...

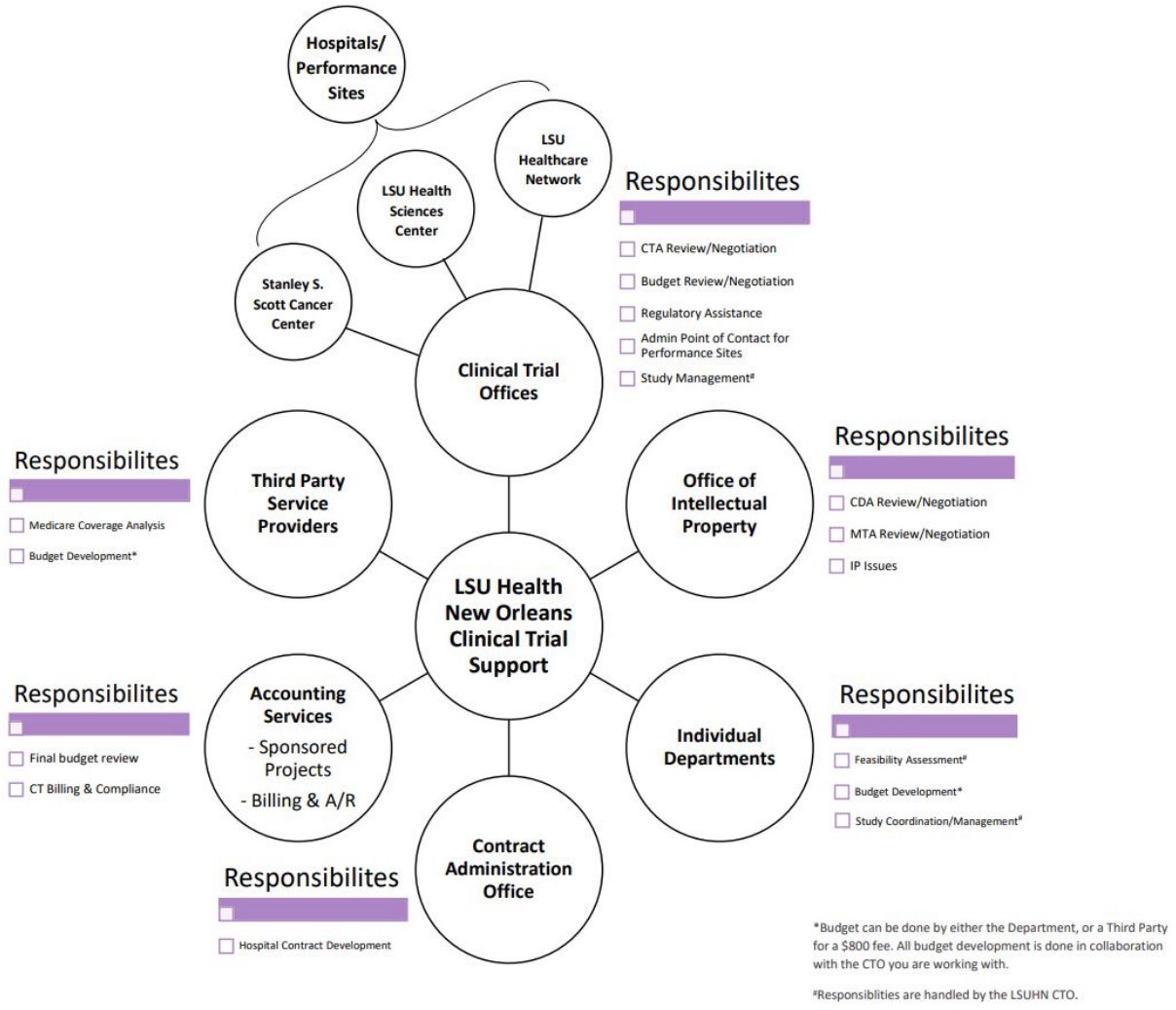
- Any trial that is being conducted on the LSUHSC Campus, affiliated hospitals and/or non-LSUHN clinics
- Documents for Review should be routed through Kuali Negotiations to "Clinical Trials"

Work with the LSU Healthcare Network (LSUHN) CTO When...

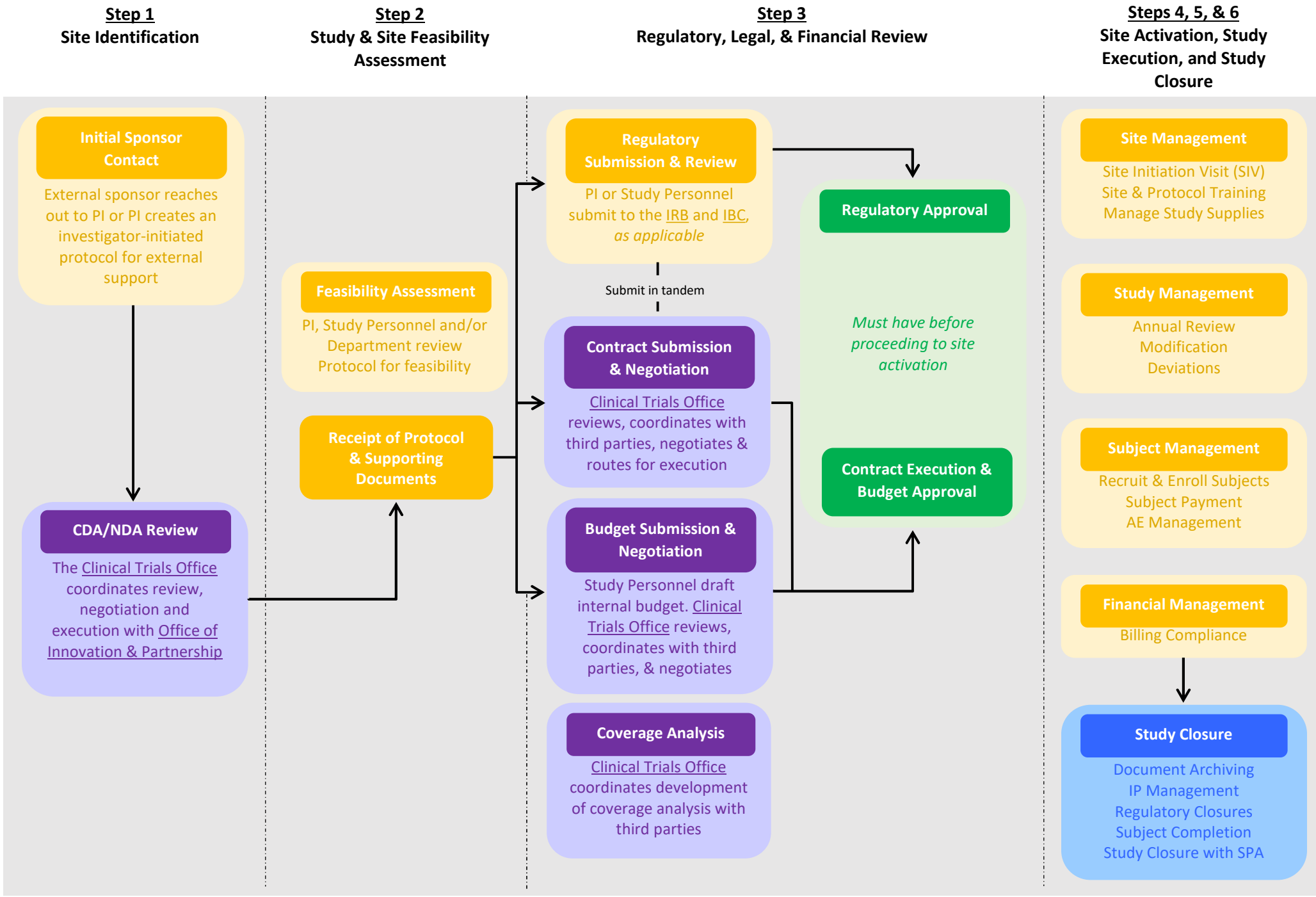
- The trial is being conducted at one or more LSUHN clinics or sites supported by the LSUHN staff and is industry sponsored
- Documents for review should be routed through Kuali Negotiations to "Healthcare Network"
- Please reach out to Stephanie Sonnier for additional information and assistance

Work with the Stanley S. Scott Cancer Center CTO When...

- The oncology trial is being conducted by investigators from the Cancer Center
- Please reach out to David Whaley for additional information and assistance



Lifecycle of Clinical Trials at LSU Health New Orleans



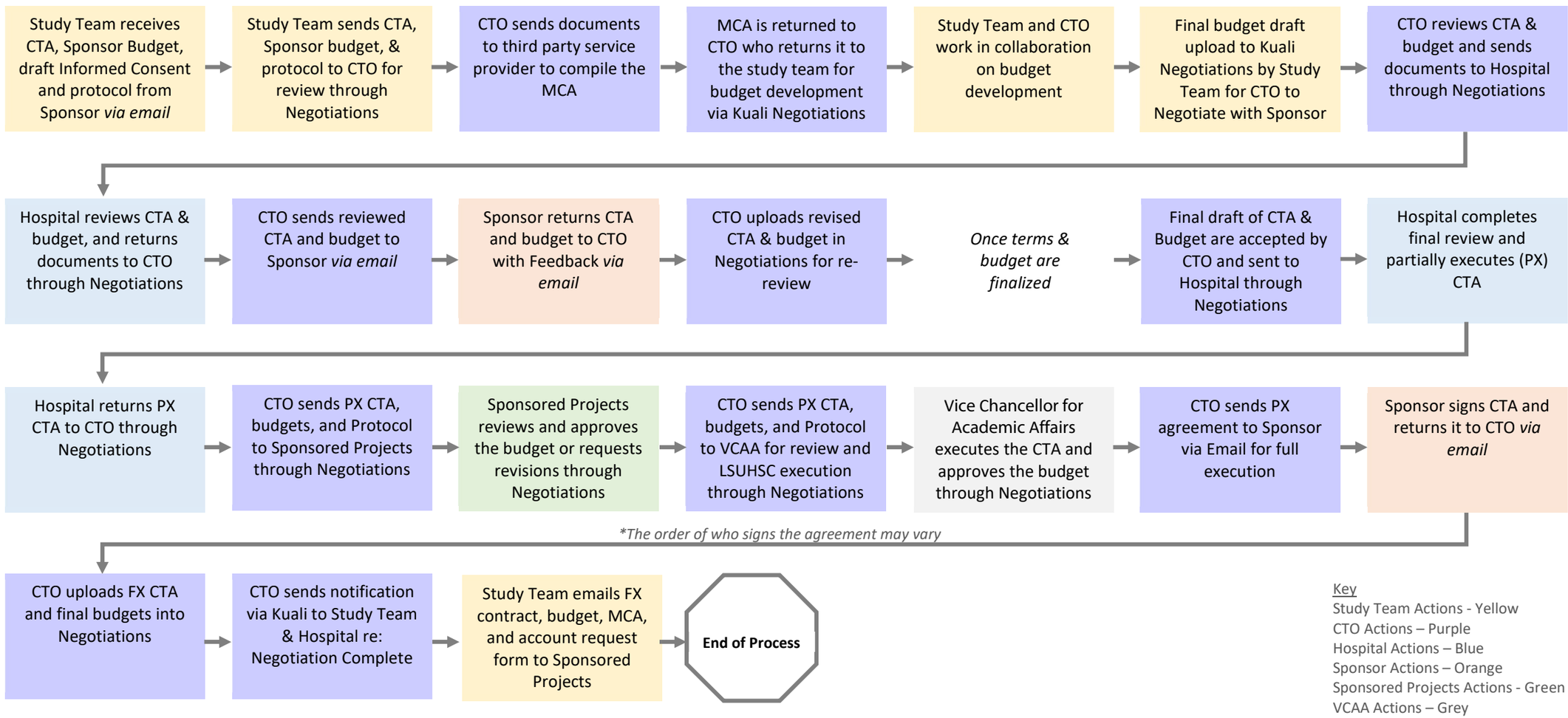
LSU Health NEW ORLEANS
Human Research Protection Program

GUIDANCE

CONTRACT, BUDGET, & MCA REVIEW, NEGOTIATIONS, & ROUTING PROCESS

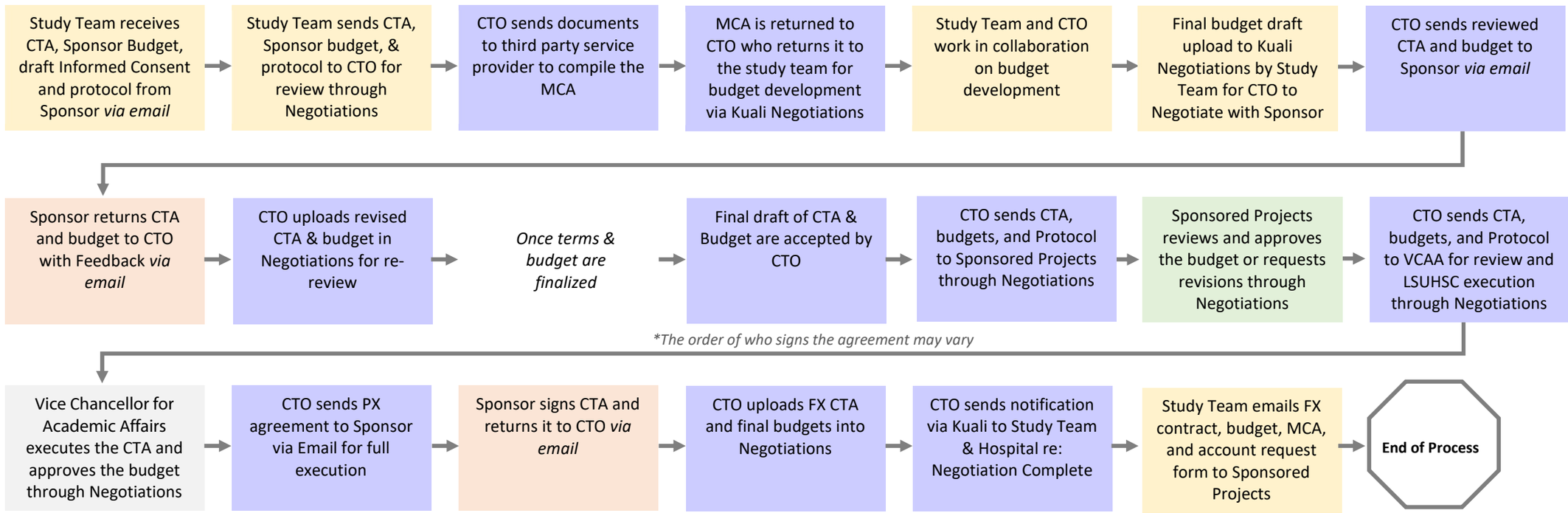
DOCUMENT #	APPROVED BY	EFFECTIVE DATE	PAGE
CTO-1001	Executive Director, ORS	01/26/2022	Page **1** of **2**

CLINICAL TRIALS INVOLVING HOSPITALS



Key
Study Team Actions - Yellow
CTO Actions – Purple
Hospital Actions – Blue
Sponsor Actions – Orange
Sponsored Projects Actions - Green
VCAA Actions – Grey

CLINICAL TRIALS ON CAMPUS ONLY



Key
Study Team Actions - Yellow
CTO Actions – Purple
Sponsor Actions – Orange
Sponsored Projects Actions - Green
VCAA Actions – Grey

Study Start-Up Timeline

The process of being awarded a trial and completing all study start-up elements is highly involved and complicated. The LSUHN Clinical Trials Office provides educational and administrative support as necessary throughout the entire process.

Initial Interest

Principal Investigator (PI) contacts LSUHN Clinical Trial Office (CTO) with trial lead. There will be a conversation on the support needs of the PI, and then the CTO will begin the feasibility process.

CDA/NDA

The CTO coordinates review and signature of the Confidentiality or Non Disclosure Agreement and a trial synopsis is obtained. A trial synopsis contains more information about the trial specifics and can be 1-10 pages in length.

Site Questionnaire

The Sponsor will inquire about feasibility of the study at LSUHN's site. The CTO will provide any necessary support to reach a 1 week turnaround to the Sponsor.

Pre-Study Visit

If Sponsor wants to move forward with our Site, the CTO sets up a Pre-Study Visit. During this PSV, the Sponsor (Clinical Research Associate/CRA) assesses the Site's ability to successfully conduct the trial.

Site Selected/CTA Negotiation

An official letter is received stating that the Sponsor has chosen LSUHN/PI to conduct the trial. At this point, the Sponsor will send a Clinical Trial Agreement that will begin undergoing review by CTO and legal counsel.

Final Feasibility Review

Comprehensive analysis will be conducted by CTO to decide definitively if we should accept the trial. Considerations include business development, available resources, regulatory elements, budgets and contracts, recruitment, and medical.

Budget Negotiation

CTO will spearhead coverage analysis and budget development and ensure maximum reimbursement/payment is received. The trial budget outlining specific payment structure for various trial elements is analyzed and a counter offer returned.

Investigator's Meeting

Protocol and study procedures are reviewed and training conducted. Can require PI to travel to a 1-2 day event, or it can consist of multiple hours of online training. Must be done prior to SIV.

Regulatory

The CTO ensures that all Institutional Review Board (IRB) documents are signed by PI, completed and submitted. PI's timely cooperation is essential. Once IRB has approved, the SIV can be scheduled.

Initiate Recruitment Efforts

Sometime between the Final Feasibility and SIV, the PI and CTO work together to pull a list of patients that may qualify. Screening of patients should begin before enrollment opens.

Site Initiation Visit

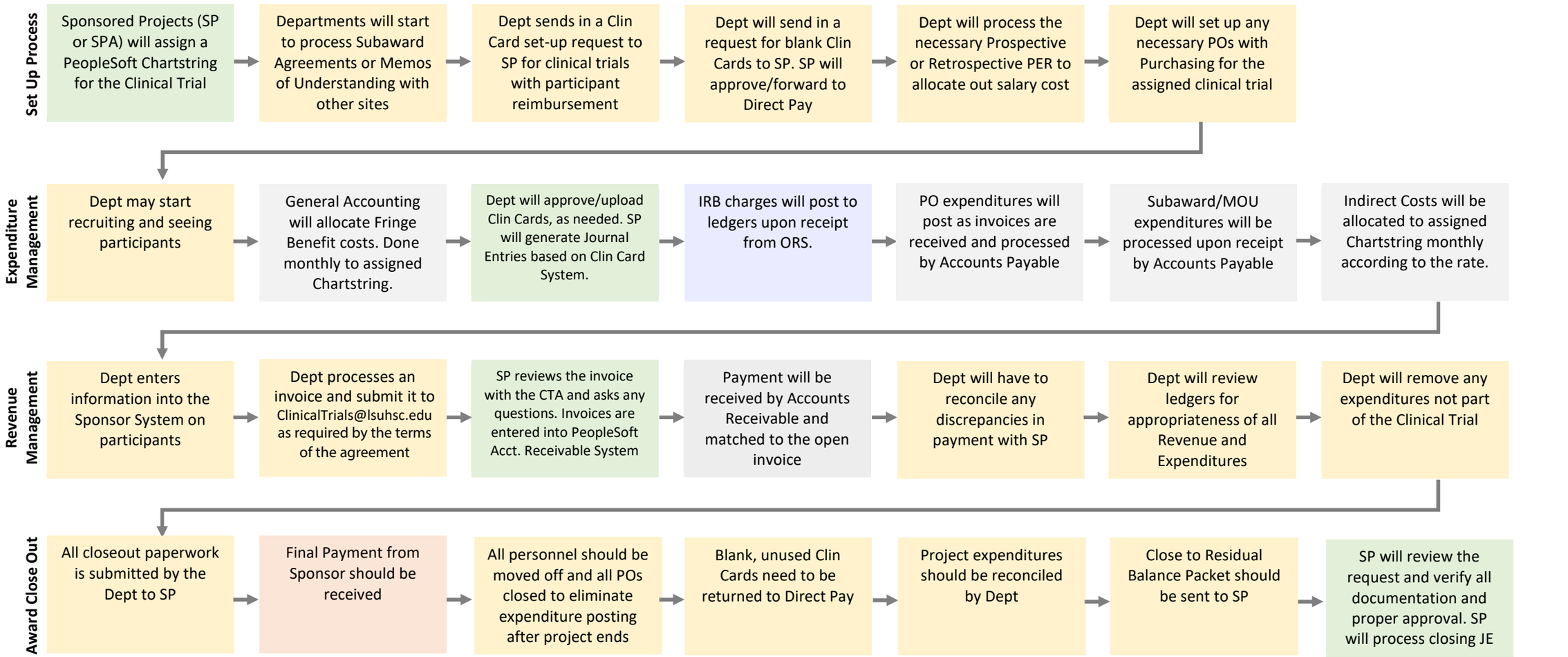
Following agreement on all contracts, the CTO organizes a SIV for the Monitor to visit the LSUHN clinic and ensure that the site has everything needed to conduct every element of the trial protocol.

Enrollment

Enrollment for the study opens. The CTO can provide minimal to full support during the enrollment process.

PHONE: 504-412-1350 **EMAIL:** ssonn7@lsuhsc.edu www.lsuhn.com

SPONSORED PROJECTS CLINICAL TRIALS WORKFLOW



Key
Sponsored Projects Actions - Green
Department Actions - Yellow
Other Accounting Actions – Grey
ORS Actions – Purple
Sponsor Actions – Orange

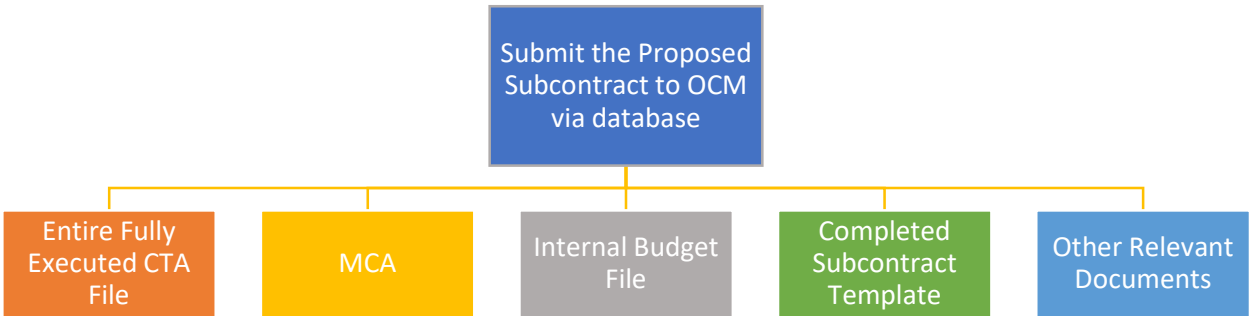
OFFICE OF CONTRACTS MANAGEMENT

You have the clinical trial agreement signed and ready to go… Now what?
Do you need a subcontract with a site for study related services?

Once the:

- ✓ CTA is fully executed; *and,*
- ✓ The Office of Sponsored Projects has assigned a project number…

Departments may proceed with submitting the proposed subcontract to the Office of Contract Management's contracts database (utilizing the appropriate template).



Departments must upload:

- ENTIRE fully executed CTA file (including all referenced attachments/appendices/ exhibits, sponsors budget, etc.);
- MCA;
- OSP "revenue/expenditure" file*;
- Completed subcontract template (including sub-budget in excel);
- If necessary, any other relevant emails/documentation/communications regarding the subcontract (should we need to be aware)

**This file is located on the ORS website -https://www.lsuhsc.edu/administration/academic/ors/ogc_agreements.aspx*

Clinical Trials Contact List

LSU HEALTH SCIENCES CENTER (LSUHSC) CLINICAL TRIALS OFFICE

	Title	Phone	Email
Jawed Alam, PhD, MBA	Executive Director, ORS	(504) 568-4985	jalam@lsuhsc.edu
Gabriela Bonvillain	Supervisor	(504) 680-9070	gdomi1@lsuhsc.edu
Benjamin Davis	Pre-Award Specialist	(504) 568-3214	bdav22@lsuhsc.edu
Central Email	CTO@lsuhsc.edu		
Website	https://www.lsuhsc.edu/administration/academic/ors/clinicaltrials/		

LSU HEALTHCARE NETWORK (LSUHN) CLINICAL TRIALS OFFICE

	Title	Phone	Email
Stephanie Sonnier	Director	(504) 412-1350	ssonn7@lsuhsc.edu
Website			

STANLEY S. SCOTT CANCER CENTER (SSSCC) CLINICAL TRIALS OFFICE

	Title	Phone	Email
David Whaley	Contracts Admin. Officer	(504) 210-2825	dwhal1@lsuhsc.edu

OFFICE OF INNOVATION AND PARTNERSHIPS (OIP)

	Title	Phone	Email
Patrick Reed	Asst. Vice Chancellor	(504) 568-8303	preed3@lsuhsc.edu

SPONSORED PROJECTS ACCOUNTING (SPA)

	Title	Phone	Email
Lynne Tardiff	Asst. Director	(504) 599-0841	ljones9@lsuhsc.edu
Vacant	Manager, CT Billing & Fiscal Operations		
Wendy Roark	Manager, Research & Fiscal Analysis	(504) 568-4867	wroar1@lsuhsc.edu
Angela Han	Manager, Grants Billing & Fiscal Operation	(504) 568-4979	qhan@lsuhsc.edu
Julia Andrews	Sr. Staff Accountant	(504) 568-3674	jand34@lsuhsc.edu
Vacant	Staff Accountant		
Website	https://www.lsuhsc.edu/administration/accounting/sponsored_projects.aspx		
Central Email - SP	Nosponproj@lsuhsc.edu		
Central Email - Invoices	ClinicalTrials@lsuhsc.edu		

CONTRACTS MANAGEMENT

Central Email	lsuhsccmteam@lsuhsc.edu

OFFICE OF RESEARCH SERVICES (ORS)

	Title	Phone	Email
Lynn Arnold	IRB Specialist	(504) 568-3779	larnol@lsuhsc.edu
Kadie Rome	IRB Specialist	(504) 568-4060	krome@lsuhsc.edu
Betsy Dancisak	IRB Specialist	(504) 568-1668	bdanci@lsuhsc.edu
Noel Cal	IRB Coordinator	(504) 568-2491	ncal@lsuhsc.edu
Gabriela Bonvillain	Reliance Liaison	(504) 680-9070	gdomi1@lsuhsc.edu
Taylor Fuselier	IBC Coordinator	(504) 568-4372	tfusel@lsuhsc.edu
Website - IRB	https://www.lsuhsc.edu/administration/academic/ors/irb/		
Central Email - IRB	IRBOffice@lsuhsc.edu		
Website - IBC	https://www.lsuhsc.edu/administration/academic/ors/ibc.aspx		
Central Email - IBC	IBCOffice@lsuhsc.edu		

Updated 3.15.22