LSU HEALTH COORDINATOR COMPETENCIES

X

DOCUMENTATION & DOCUMENT MANAGEMENT

Research-Related Agreements

Objectives

- Identify typical contracts and agreements used in research
- Describe processes for putting agreements in place
- Identify notable clauses and language that are specific to LSUHSC contracts and agreements

Types of Contracts/Agreements

Type	Also Known As	Description	Negotiator
Clinical Trial Agreement (CTA)	• Clinical Study Agreement • Clinical Services Agreement	Typically, between LSUHSC-NO and a pharmaceutical company, with the intent of the study being to test how well a new medical approach or treatment works, or to test the use of an established treatment for a new purpose.	Clinical Trials Office
Confidential Disclosure Agreement (CDA)	• Confidentiality Agreement • Nondisclosure Agreement	Outlines confidential material, knowledge, or information that the parties wish to share with one another for certain purposes but wish to restrict access to or by third parties. The parties agree not to disclose information covered by the agreement. Protects nonpublic business information.	Office of Innovation and Partnership

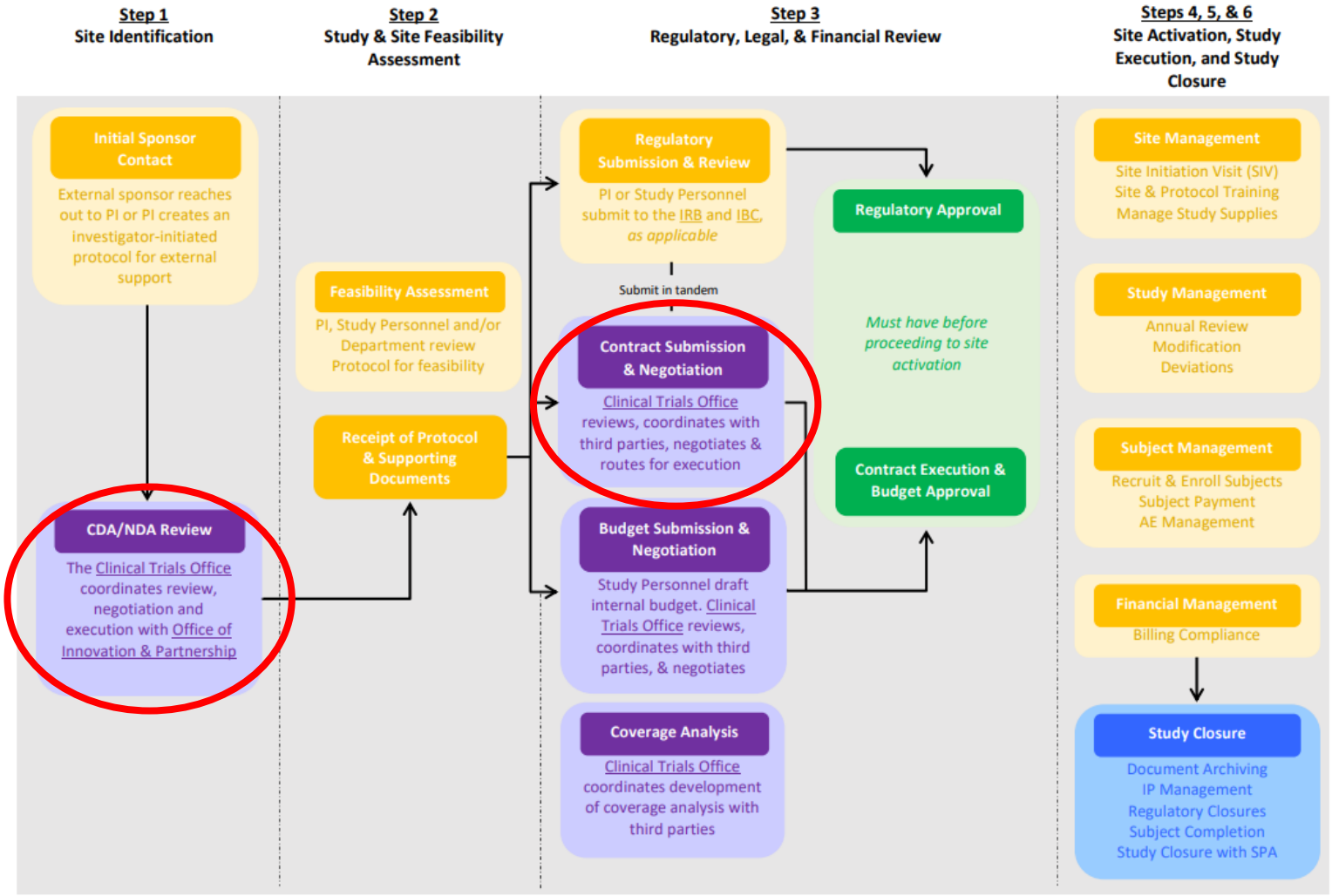
Types of Contracts/Agreements

Type	Also Known As	Description	Negotiator
Material Transfer Agreement (MTA)	• Uniform Biological Materials Transfer Agreement (UBMTA)	Governs the transfer of tangible research materials between two organizations, when the recipient intends to use the material for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives.	Office of Innovation and Partnership
Data Transfer and Use Agreement (DTUA)	• Data Use Agreement	Governs the sharing of research data between two organizations, either when the recipient is collaborating with LSUHSC (and not other agreement in is place) or when the recipient intends to use the data for their own research purpose.	Clinical Trials Office
Subcontract	• Subaward Agreement • Subrecipient Agreement	Between a party to an original contract and a third party to provide all or a specified part of the work or materials required in the original contract.	Contract Management Office

Types of Contracts/Agreements

Type	Also Known As	Description	Negotiator
Research Agreement	• Collaborative Agreement • Scientific Services Agreement	Like Clinical Trial Agreement except that typically, human subjects are not involved.	Clinical Trials Office
Grant Award Agreement		Differs from a Notice of Grant Award in that an agreement must be signed and returned to the sponsor	Office of Grants & Contracts
Purchased Services Agreement		Sometimes used in lieu of a subcontract; typically, between a party to an original contract or grant award and a third party to provide award-specific services.	Contract Management Office
Professional Services Agreements		Provides unique, technical, and/or infrequent functions performed by an independent contractor qualified by education, experience, and/or technical ability to provide services	Contract Management Office

Lifecycle of a Clinical Trial



LSU Health NEW ORLEANS
Office of Research Services

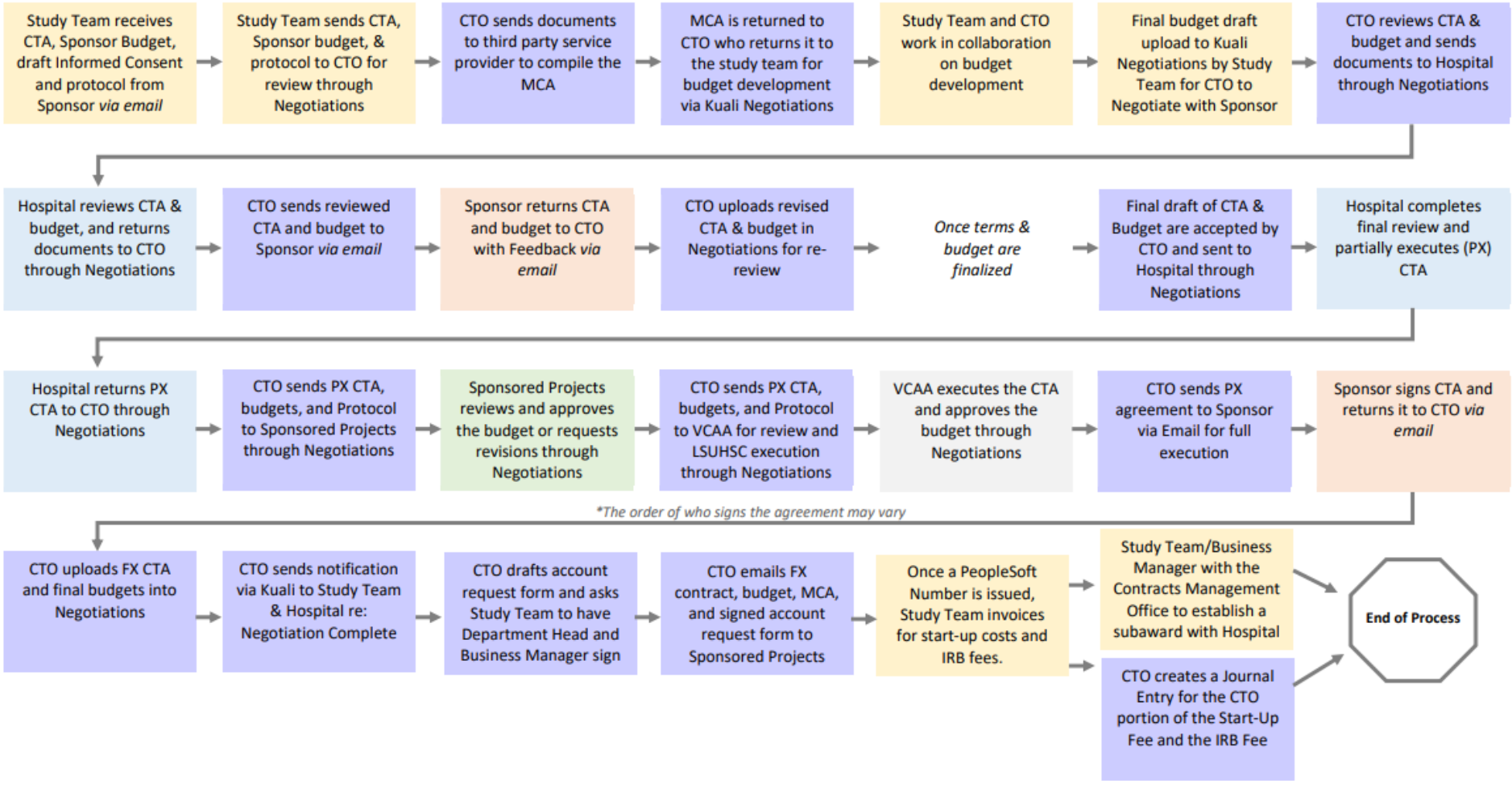
LSUHSC CTO Contract/Agreement Workflow

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

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	09/09/2022	Page **1** of **1**

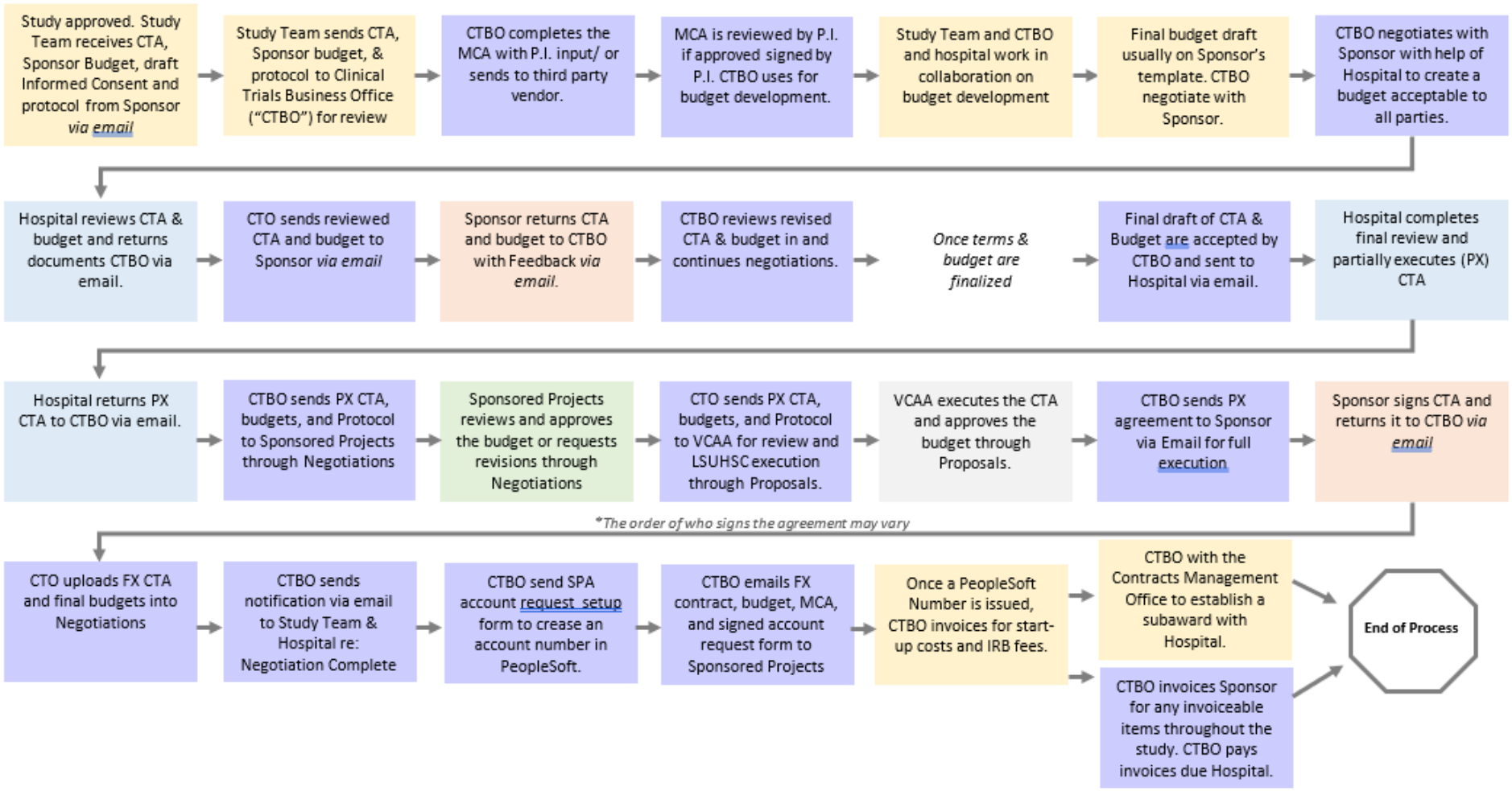


SSSCC CTO Contract/Agreement Workflow

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

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	09/09/2022	Page 1 of 1



LSUHN CTO Contract/Agreement Workflow

LSU Health Healthcare Network

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.

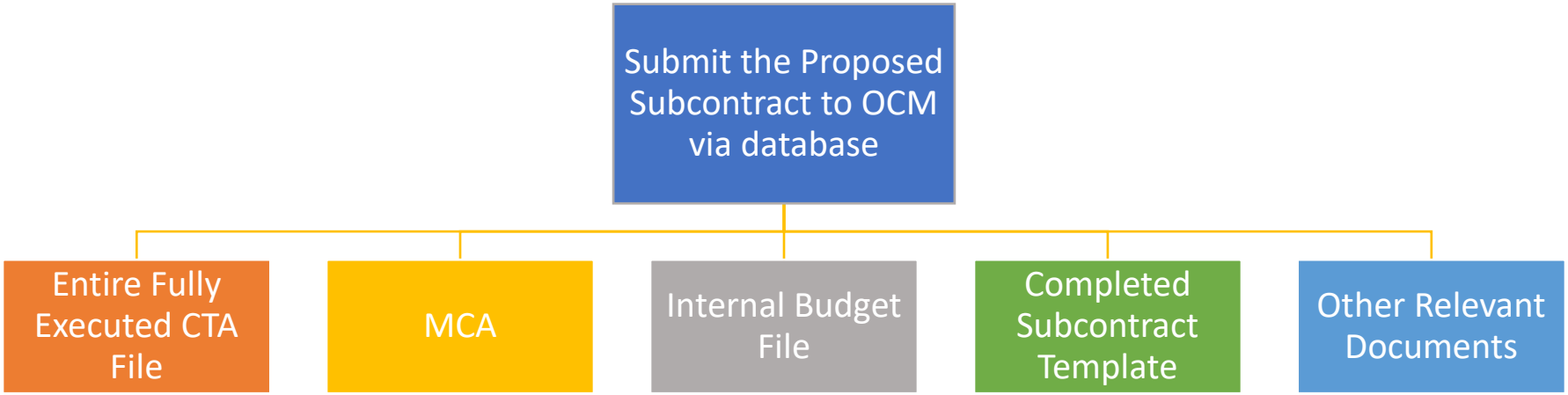
Initial Interest	Principal Investigator (PI) contacts LSUHN Clinical Trial Office (CTO) with trial lead. There will be a conversation on the support needs of the PI, and then the CTO will begin the feasibility process.
CDA/NDA	The CTO coordinates review and signature of the Confidentiality or Non-Disclosure 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

Contracts Management Contract/Agreement Workflow

Do you need a subcontract with a site for study related services?

- ✓ Once the CTA is fully executed; and
- ✓ Once Sponsored Projects has assigned a project number…



Reach out to lsuhsccmteam@lsuhsc.edu with questions.

LSU Health NEW ORLEANS
Office of Research Services

Notable Clauses & Language

- Legal Name
- Parties to the Agreement
- Amendments
- Arbitration
- Assignment
- Attorney's Fees
- Confidentiality
- Conflict Between Protocol & Contract
- Control of Defense
- Export Control
- Force Majeure
- Governing Law
- HIPAA
- Indemnification
- Insurance
- Intellectual Property
- March-In Rights
- Monitoring & Audits
- Ownership
- Payment Terms
- Publication
- Publicity
- Severability
- Subject Injury
- Term
- Termination
- Travel Expenses
- Warranties

Notable Clauses & Language: Data Management

- While LSU Health has set standard expectations for data management (i.e., eCRF data entry timelines, monitoring expectations, etc.) as it relates to research, each sponsor may have their own data management expectations. The CTO will negotiate with the Sponsor to set data management expectations that align closely with our institutional expectations, but it is likely that expectations can change from sponsor to sponsor.
- The CTO will ensure the study team is aware of study-specific data management language.

LSU Health Coordinator Competencies

- ✓ Onboarding
- ✓ Ethical Standards
- ✓ Protocol Compliance
- ✓ Informed Consent
- ✓ Patient Recruitment & Retention
- ✓ Management of Patients
- ✓ Documentation & Document Management
- ❑ Data Management & Information Technology
- ❑ Financial Stewardship
- ❑ Leadership & Professional Development