LSU HEALTH COORDINATOR COMPETENCIES

REALITY CHECK

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

<table>
<thead>
<tr>
<th>Type</th>
<th>Also Known As</th>
<th>Description</th>
<th>Negotiator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trial Agreement (CTA)</td>
<td>• Clinical Study Agreement</td>
<td>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.</td>
<td>Clinical Trials Office</td>
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<tr>
<td></td>
<td>• Clinical Services Agreement</td>
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<td></td>
</tr>
<tr>
<td>Confidential Disclosure Agreement (CDA)</td>
<td>• Confidentiality Agreement</td>
<td>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.</td>
<td>Office of Innovation and Partnership</td>
</tr>
<tr>
<td></td>
<td>• Nondisclosure Agreement</td>
<td></td>
<td></td>
</tr>
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<td>Description</td>
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<tr>
<td>Material Transfer Agreement</td>
<td>Uniform Biological Materials Transfer Agreement (UBMTA)</td>
<td>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.</td>
<td>Office of Innovation and Partnership</td>
</tr>
<tr>
<td>Data Transfer and Use Agreement (DTUA)</td>
<td>Data Use Agreement</td>
<td>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.</td>
<td>Clinical Trials Office</td>
</tr>
<tr>
<td>Subcontract</td>
<td>Subaward Agreement</td>
<td>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.</td>
<td>Contract Management Office</td>
</tr>
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<td>Research Agreement</td>
<td>• Collaborative Agreement</td>
<td>Like Clinical Trial Agreement except that typically, human subjects are not involved.</td>
<td>Clinical Trials Office</td>
</tr>
<tr>
<td></td>
<td>• Scientific Services Agreement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grant Award Agreement</td>
<td></td>
<td>Differs from a Notice of Grant Award in that an agreement must be signed and returned to the sponsor</td>
<td>Office of Grants &amp; Contracts</td>
</tr>
<tr>
<td>Purchased Services Agreement</td>
<td></td>
<td>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.</td>
<td>Contract Management Office</td>
</tr>
<tr>
<td>Professional Services</td>
<td></td>
<td>Provides unique, technical, and/or infrequent functions performed by an independent contractor qualified by education, experience, and/or technical ability to provide services</td>
<td>Contract Management Office</td>
</tr>
<tr>
<td>Agreements</td>
<td></td>
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</table>
Lifecycle of a Clinical Trial

**Step 1: Site Identification**
- **Initial Sponsor Contact**
  - External sponsor reaches out to PI or PI creates an investigator-initiated protocol for external support

**Step 2: Study & Site Feasibility Assessment**
- **Feasibility Assessment**
  - PI, Study Personnel, and/or Department review protocol for feasibility
- **Receipt of Protocol & Supporting Documents**

**Step 3: Regulatory, Legal, & Financial Review**
- **Regulatory Submission & Review**
  - PI or Study Personnel submit to the IRB and IBC as applicable
  - Must have before proceeding to site activation
- **Contract Submission & Negotiation**
  - Clinical Trials Office reviews, coordinates with third parties, negotiates & routes for execution
- **Budget Submission & Negotiation**
  - Study Personnel draft internal budget, Clinical Trials Office reviews, coordinates with third parties, & negotiates
- **Coverage Analysis**
  - Clinical Trials Office coordinates development of coverage analysis with third parties

**Steps 4, 5, & 6: Site Activation, Study Execution, & Study Closure**
- **Contract Execution & Budget Approval**
- **Regulatory Approval**
- **Site Management**
  - Site Initiation Visit (SIV)
  - Site & Protocol Training
  - Manage Study Supplies
- **Study Management**
  - Annual Review
  - Modification
  - Deviations
- **Subject Management**
  - Recruit & Enroll Subjects
  - Subject Payment
  - AE Management
- **Financial Management**
  - Billing Compliance
- **Study Closure**
  - Document Archiving
  - IP Management
  - Regulatory Closures
  - Subject Completion
  - Study Closure with SPA

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*LDS Health NEW ORLEANS*  
*Office of Research Services*
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

**GUIDANCE**

**DOCUMENT #** | **APPROVED BY** | **EFFECTIVE DATE** | **PAGE**
--- | --- | --- | ---
CTO-1001 | Executive Director, ORS | 09/09/2022 | Page 1 of 1

**Study approved. Study Team receives CTA, Sponsor Budget, and protocol from Sponsor via email.**

**CTO sends reviewed CTA and budget to Sponsor via email.**

**Sponsor returns CTA and budget to CTO with Feedback via email.**

**CTBO completes the MCA with P.I. input or sends to third party vendor.**

**MCA is reviewed by P.I. if approved signed by P.I. CTBO uses for budget development.**

**Study Team and CTBO work in collaboration on budget development.**

**CTBO negotiates with Sponsor with help of Hospital to create a budget acceptable to all parties.**

**Hospital reviews CTA & budget and returns documents CTBO via email.**

**CTO sends reviewed CTA and budget to Sponsor via email.**

**Sponsor returns CTA and budget to CTBO with Feedback via email.**

**CTBO completes the MCA with P.I. input or sends to third party vendor.**

**MCA is reviewed by P.I. if approved signed by P.I. CTBO uses for budget development.**

**Study Team and CTBO work in collaboration on budget development.**

**CTBO negotiates with Sponsor with help of Hospital to create a budget acceptable to all parties.**

**Hospital returns PX CTA to CTBO via email.**

**CTBO sends PX CTA, budget, and protocol to Sponsored Projects through Negotiations.**

**Sponsored Projects reviews and approves the budget or requests revisions through Negotiations.**

**CTO sends PX CTA, budget, and protocol to VCAA for review and LSUHSC execution through Proposals.**

**VCAA executes the CTA and approves the budget through Proposals.**

**CTBO sends PX agreement to Sponsor via Email for full execution.**

**Sponsor signs CTA and returns it to CTBO via email.**

**End of Process**

*The order of who signs the agreement may vary*
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.
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...

Submit the Proposed Subcontract to OCM via database

- Entire Fully Executed CTA File
- MCA
- Internal Budget File
- Completed Subcontract Template
- Other Relevant Documents

Reach out to lsuhscmtteam@lsuhsc.edu with questions.
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
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