Clinical Trials Coordinators
Objectives

- Describe the roles and responsibilities of a Clinical Research Coordinator
- Identify the clinical research offices and resources within LSU Health New Orleans
- Identify the clinical research systems used at LSU Health New Orleans and understand how they interact with one another
- Discuss the studies that make up your research portfolio
- Describe the career progression within clinical research professions
Clinical Trials Coordinator Role

- A research professional working with and under the direction of the LSU Health Principal Investigator (PI).
- Supports, facilitates and coordinates the daily clinical trial activities and plays a critical role in the conduct of the study.
Coordinator Responsibilities May Include:

<table>
<thead>
<tr>
<th>Study Start-Up</th>
<th>Site Management</th>
<th>Study Closeout</th>
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<tbody>
<tr>
<td>• Protocol Review</td>
<td>• Communication with Sponsor</td>
<td>• Submission of Closure Documents</td>
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<td>• Assist with Feasibility Assessment and Budget Review</td>
<td>• Site Initiation Visit (SIV)</td>
<td>• Secure Storage for Study Files</td>
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<td>• Regulatory Prep</td>
<td>• Site &amp; Protocol Training</td>
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<td>• Study Material Prep</td>
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**Subject Management**

- Communication with Subjects
- Recruitment
- Screening & Enrollment

**Financial Management**

- Subject Compensation
- Coordinate with Department Business Manager or Appropriate Person

**Study Closeout**

- Maintain study documents & regulatory binder
- Reporting to regulatory bodies & Sponsor

Speak with your study PI and team to determine what your responsibilities will include.

As you gain more experience, you will be able to take on more responsibilities.
LSU Health Research Offices

Clinical Research Support Ecosystem

- Departments
- Innovation & Partnership
- Clinical Trials Offices
- Hospitals
- Office of Research Services
- Contracts Management
- Sponsored Projects
Innovation & Partnership
Responsible for the review, negotiation, and execution of Confidentiality/Non-Disclosure Agreements (CDAs, NDAs) and Material Transfer Agreements (MTAs)

Who Can I Contact?
Patrick Reed
preed3@lsuhsc.edu or 568-8303
Clinical Trials Offices

*LSU Health currently has three Clinical Trials Offices: one at the Health Sciences Center, one at the Healthcare Network, and one at the Cancer Center.*

**Work with HSC when...**
A study is conducted at LSUHSC, an affiliated hospital and/or a non-HN Clinic

**Work with HN when...**
An industry-Sponsored study is conducted at a Healthcare Network Clinic

**Work with SSSCC when...**
An oncology trial is being conducted
Clinical Trials Office – HSC
Responsible for the review, negotiation, and execution of all research-related contracts & budgets (except for NDA, CDA, or MTA).
Also offers coordinator resources and standard SOPs.

Who Can I Contact?
Gabi Bonvillain, Ben Davis
CTO@lsuhsc.edu or 680-9070
Clinical Trials Office – HN
Responsible for the review, negotiation, and execution of all research-related contracts & budgets.
Also offers coordinator resources and standard SOPs.

Who Can I Contact?
Stephanie Sonnier
ssonn7@lsuhsc.edu or 412-1350
Clinical Trials Office – SSSCC
Responsible for Business Operations Including: CDAs, CTAs, Coverage Analyses, Budgets, Subcontracts and Invoicing.

Who Can I Contact?
David Whaley (Contracts, Financials) dwhal1@lsuhsc.edu or 210-2825

Eileen Mederos (Study Conduct) emede1@lsuhsc.edu or 210-3539
HSU Health Research Offices

**Hospitals**
Sites where most research activities are conducted, including University Medical Center, East Jefferson General Hospital, West Jefferson Medical Center, Children’s Hospital, Touro Infirmary, and Ochsner Kenner

**Who Can I Contact?**
Visit this [webpage](#) for Hospital-specific contacts
Office of Research Services
Houses research compliance and regulatory offices, including the Institutional Review Board (human subjects), Institutional Biosafety Committee (biologics), Conflicts of Interest Office, & Grants Office

Who Can I Contact?
Visit this [webpage](#) for specific contacts
Contracts Management
Responsible for review, negotiation, and execution of subcontracts with an external entity for study related services

Who Can I Contact?
Mary Lapworth
lsuhsccmteam@lsuhsc.edu
Sponsored Projects
Responsible for Account Setup, Expenditure Management, Revenue Management, and Award Close-Out.

Who Can I Contact?
Central Email
Nosponproj@lsuhsc.edu
Invoice Email
ClinicalTrials@lsuhsc.edu
Clinical Research Systems at LSU Health

<table>
<thead>
<tr>
<th>System Purpose</th>
<th>System Name</th>
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<tbody>
<tr>
<td>Protocol Development</td>
<td>Protocol Builder (SSO)</td>
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<tr>
<td>Contract Negotiations</td>
<td>Kuali Negotiations (SSO)</td>
</tr>
<tr>
<td>Regulatory Oversight</td>
<td>Kuali Protocols (SSO)</td>
</tr>
<tr>
<td>eRegulatory Binder</td>
<td>Veeva Vault</td>
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<tr>
<td>CTMS (LSUHN Only)</td>
<td>SignalPath</td>
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<tr>
<td>EMR (LSUHN, Hospitals Only)</td>
<td>EPIC</td>
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**Coming Soon:**
CTMS (LSUHSC, Hospitals)
eConsent Platform
Required Research Training

**LSU Health-Specific Training**

- CATS Bloodborne Pathogens – High Risk *(every 3 years)*
- CATS Conflicts of Interest in Research *(every 3 years)*
- CATS HIPAA Privacy – Research *(every year)*
- CATS Biosafety Training, *personnel shipping samples only* *(every 3 years)*

**CITI Program Training**

- Biomedical Research – Basic/Refresher *(every 3 years)*
- GCP Drug Development – Basic/Refresher, *drug trials only* *(every 3 years)*
- GCP Device Development – Basic/Refresher, *device trials only* *(every 3 years)*
- GCP for Clinical Trials with Investigational Drugs & Medical Devices (U.S. FDA Focus), *drug or device trials* *(every 3 years)*
- CRC Foundation/Advanced, *optional*

**Other Training**

- Site-Specific Training
- Protocol-Specific Training
- IATA Shipping of Dangerous Goods Training *(every 2 years)*
Review Your Research Portfolio

**General Study Information**
- What studies are you responsible for?
- Who is the PI of each study?
- Who is your Sponsor point of contact?
- Where is the regulatory binder stored?
- Where are patient binders stored?

**Study Conduct**
- Are you credentialed at the study sites?
- Do you have clean copies of consents & HIPAA?
- Are all regulatory approvals up to date?
- Do you have access to all the appropriate Research systems (EDC, EMR)?
- Do you have the supplies/equipment needed to conduct the study (i.e., lab kits, iPads)? Confirm they are not expired.

**Financials**
- Who is your department’s business manager?
- Do you have each study’s account number?
LSU Health New Orleans Career Ladder

**CTC I**
- At least 1 year of experience

**CTC II**
- At least 3 years of experience

**CTC III**
- At least 5 years of experience
  - Certification

Nationally Recognized Certifications

**SoCRA**
- Certified Clinical Research Professional

**ACRP**
- Certified Clinical Research Associate
- Certified Clinical Research Coordinator
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
Links to Resources:

- LSU Health SOPs for Conduct of Clinical Research
- Clinical Research Coordinator Resource Guide
- LSU Health Coordinator Master List
- LSUHSC Clinical Trials Office
- Institutional Review Board
- Commercial IRBs: WCG or ADVARRA
- Institutional Biosafety Committee
- GCP Website
- SoCRA
- ACRP
- ClinicalTrials.gov
- MAGI