LSU Health Coordinator Competencies

ONBOARDING

Clinical Research Nurse Coordinators
Objectives

- Describe the roles and responsibilities of a Clinical Research Nurse 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 nurse professions
Clinical Research Nurse Coordinator Role

- A nurse acting as 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 Management</th>
<th>Study Closeout</th>
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</thead>
<tbody>
<tr>
<td>• Protocol Review</td>
<td>• Communication with Sponsor</td>
<td>• Maintain study documents &amp; regulatory binder</td>
<td>• Submission of Closure Documents</td>
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<tr>
<td>• Assist with Feasibility Assessment and Budget Review</td>
<td>• Site Initiation Visit (SIV)</td>
<td>• Reporting to regulatory bodies &amp; Sponsor</td>
<td>• Secure Storage for Study Files</td>
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<tr>
<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 & Eligibility
- Screening & Enrollment
- Ordering labs & procedures

**Financial Management**

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

**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.
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
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
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
lsuhscmteam@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>
</tr>
<tr>
<td>CTMS (LSUHN Only)</td>
<td>SignalPath</td>
</tr>
<tr>
<td>EMR (LSUHN, Hospitals Only)</td>
<td>EPIC</td>
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</tbody>
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**Coming Soon:**
- CTMS *(LSUHSC, Hospitals)*
- eConsenting 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 trails* (*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 know where to go to conduct as research activities at the site?
- Are you familiar with the eligibility criteria? Do you have clean copies of the eligibility checklist?
- 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 know how to order labs, procedures, and how to review physician schedules?
- Do you have the supplies/equipment needed to conduct the study (i.e., lab kits, iPads, dry ice)? Confirm they are not expired.

Financials
- Who is your department’s business manager?
- Do you have each study’s account number?
CRNC Career Progression

LSU Health New Orleans Career Ladder

CRNC I
• At least 1 year of experience

CRNC II
• At least 3 years of experience

CRNC III
• At least 5 years of experience

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