LSU HEALTH COORDINATOR COMPETENCIES

ONBOARDING

Regulatory Coordinators
Objectives

- Describe the roles and responsibilities of a Regulatory 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 regulatory coordinator profession
Regulatory Coordinator Role

- A research professional working with and under the direction of the LSU Health Principal Investigator (PI).

- Coordinates aspects of protocol submissions, prepares and submits regulatory documents, and maintains records on assigned studies to ensure regulatory compliance with DFCI and DF/HCC policies as well as federal regulation and ICH/GCP guidelines.
Coordinator Responsibilities May Include:

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

<table>
<thead>
<tr>
<th>Study Start-Up</th>
<th>Regulatory Management</th>
<th>Other</th>
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<tbody>
<tr>
<td>• Prepare &amp; submit initial IRB application</td>
<td>• Maintain regulatory binder</td>
<td>• Maintain working knowledge of current regulations, regulatory guidance and local policies</td>
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<tr>
<td>• Prepare &amp; submit regulatory documentation</td>
<td>• Assist in preparation and coordination of monitoring or auditing visits</td>
<td>• Assist team with regulatory-based training</td>
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<tr>
<td>• Prepare &amp; organize regulatory binder</td>
<td>• Prepare &amp; submit post-approval IRB applications &amp; regulatory documents</td>
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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
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>
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<tr>
<td>eRegulatory Binder</td>
<td>Veeva Vault</td>
</tr>
<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)*
- 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)

Other Training

• Site-Specific Training
• Protocol-Specific Training
Review Your Research Portfolio

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

Study Conduct
- Do you have clean copies of consents & HIPAA?
- Do you have access to the study record in Kuali Protocols?
- Are all regulatory approvals up to date?
CRC Career Progression

Nationally Recognized Certifications

SoCRA
- Certified Clinical Research Professional

ACRP
- Certified Professional
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
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