LSU HEALTH COORDINATOR COMPETENCIES

X 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.

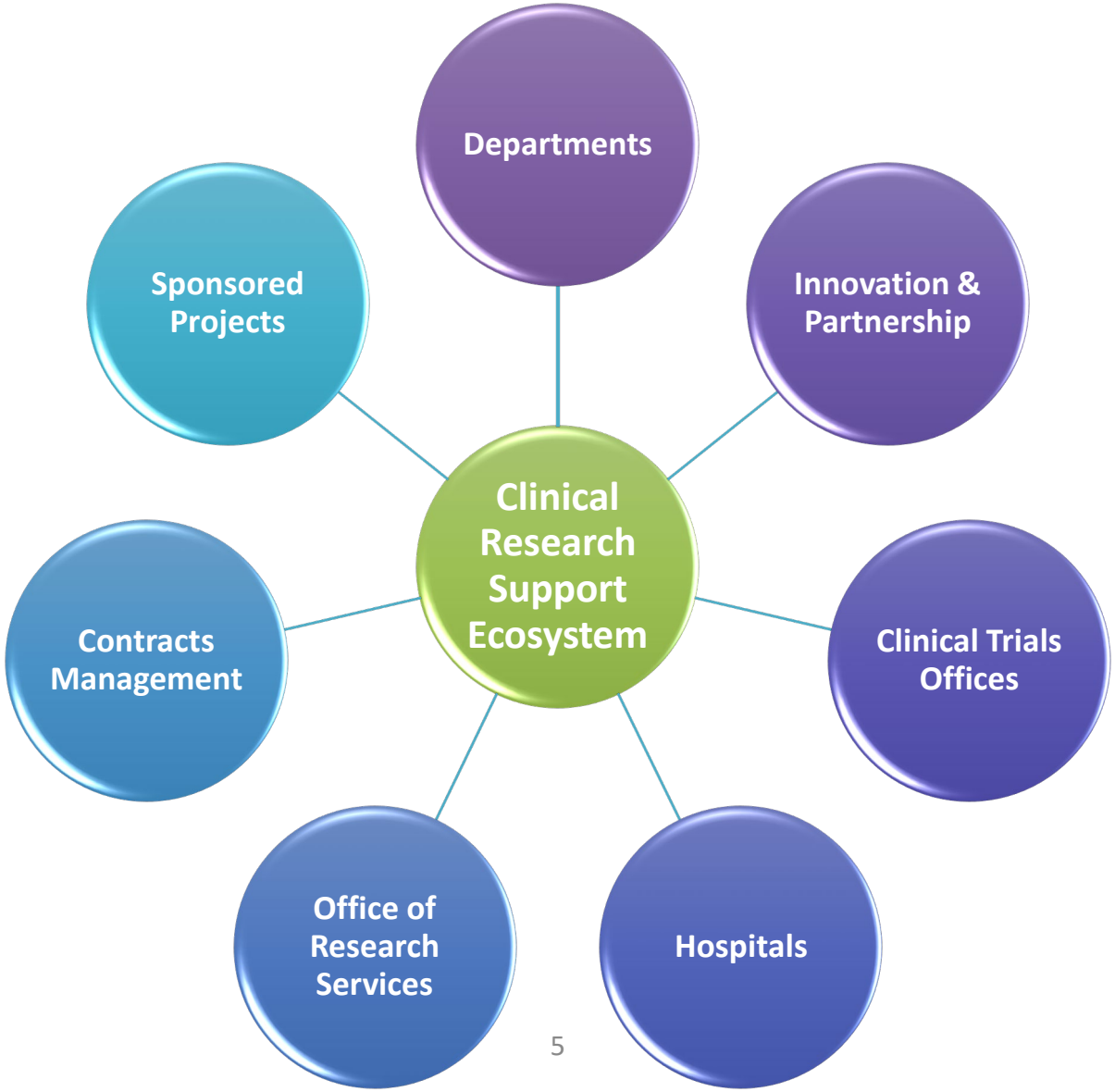
Coordinator Responsibilities May Include:

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

Study Start-Up	Regulatory Management	Other
• Prepare & submit initial IRB application • Prepare & submit regulatory documentation • Prepare & organize regulatory binder	• Maintain regulatory binder • Assist in preparation and coordination of monitoring or auditing visits • Prepare & submit post-approval IRB applications & regulatory documents	• Maintain working knowledge of current regulations, regulatory guidance and local policies • Assist team with regulatory-based training

As you gain more experience, you will be able to take on more responsibilities.

LSU Health Research Offices



LSU Health NEW ORLEANS
Office of Research Services

LSU Health Research Offices

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 NEW ORLEANS
Office of Research Services

LSU Health Research Offices

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

LSU Health NEW ORLEANS
Office of Research Services

LSU Health Research Offices

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

LSU Health NEW ORLEANS
Office of Research Services

LSU Health Research Offices

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

LSU Health NEW ORLEANS
Office of Research Services

LSU Health Research Offices

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

LSU Health NEW ORLEANS
Office of Research Services

LSU 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

LSU Health NEW ORLEANS
Office of Research Services

LSU Health Research Offices

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

LSU Health NEW ORLEANS
Office of Research Services

LSU Health Research Offices

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

LSU Health NEW ORLEANS
Office of Research Services

LSU Health Research Offices

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

LSU Health NEW ORLEANS
Office of Research Services

Clinical Research Systems at LSU Health

System Purpose	System Name
Protocol Development	Protocol Builder (SSO)
Contract Negotiations	Kuali Negotiations (SSO)
Regulatory Oversight	Kuali Protocols (SSO)
eRegulatory Binder	Veeva Vault
CTMS (LSUHN Only)	SignalPath
EMR (LSUHN, Hospitals Only)	EPIC

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

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