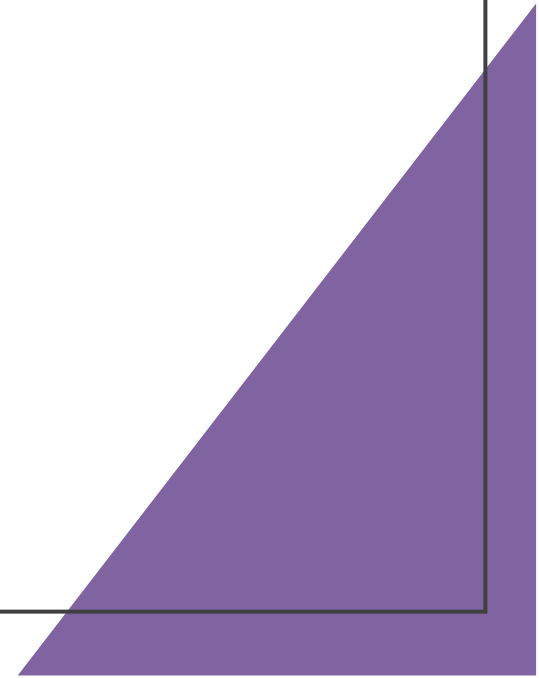


LSU HEALTH COORDINATOR COMPETENCIES



ONBOARDING

**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:

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.

Study Start-Up

- Protocol Review
- Assist with Feasibility Assessment and Budget Review
- Regulatory Prep
- Study Material Prep

Subject Management

- Communication with Subjects
- Recruitment
- Screening & Enrollment

Site Management

- Communication with Sponsor
- Site Initiation Visit (SIV)
- Site & Protocol Training

Financial Management

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

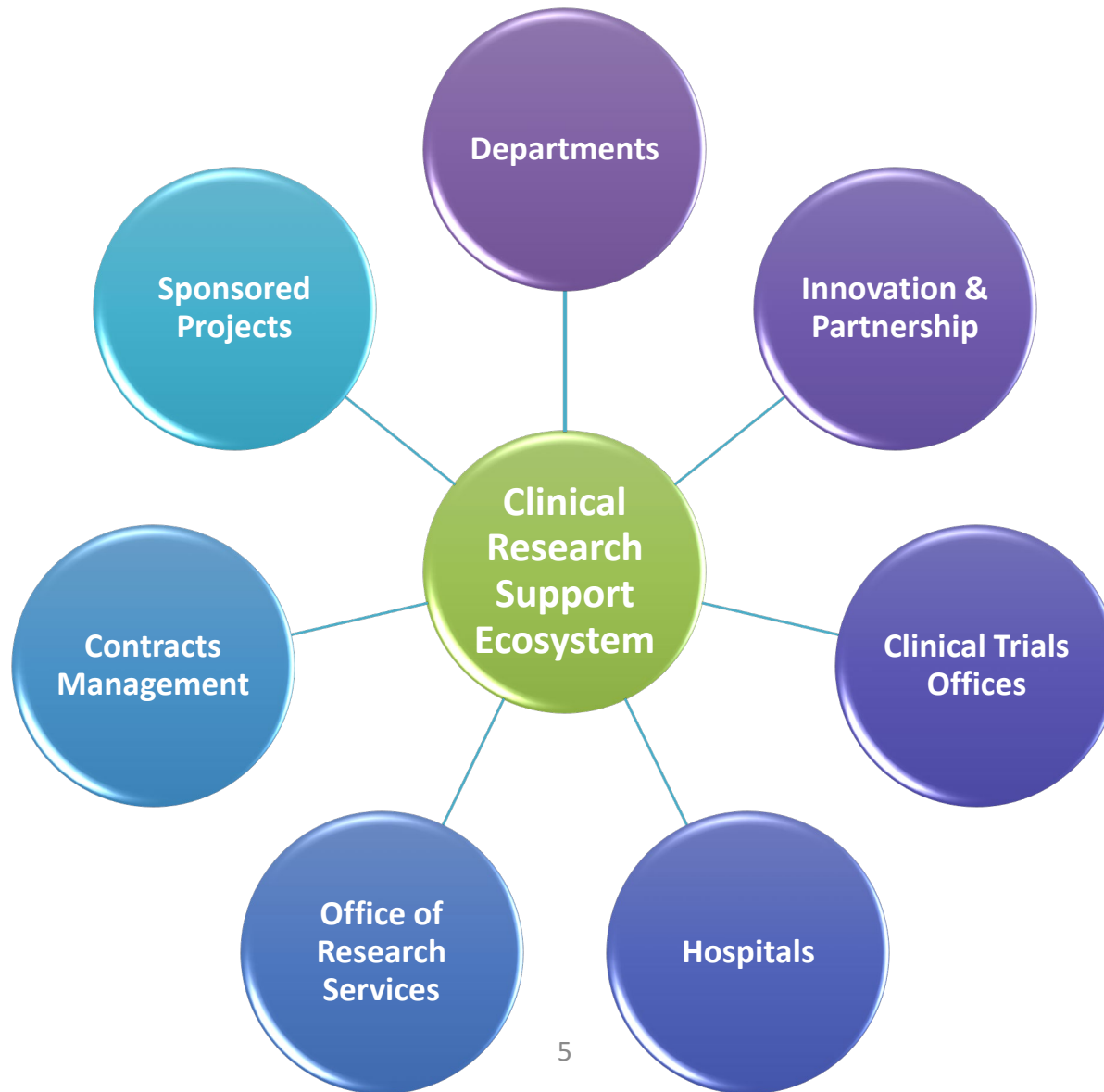
Study Management

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

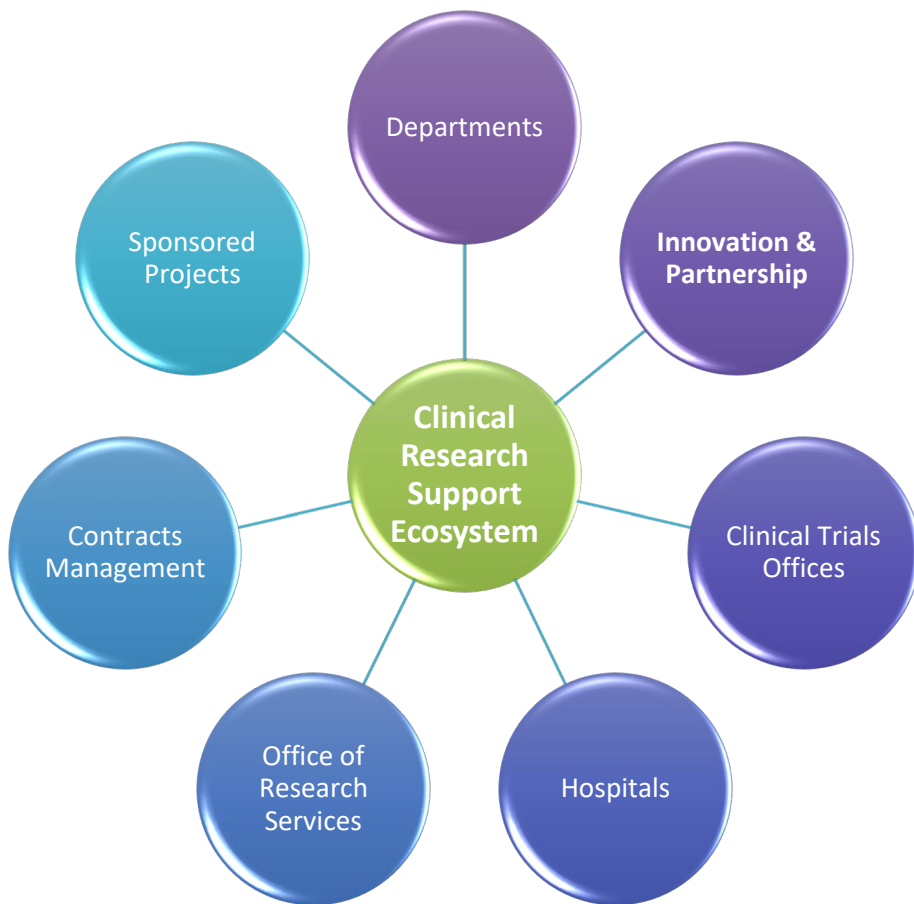
Study Closeout

- Submission of Closure Documents
- Secure Storage for Study Files

LSU Health Research Offices



LSU Health Research Offices



Innovation & Partnership

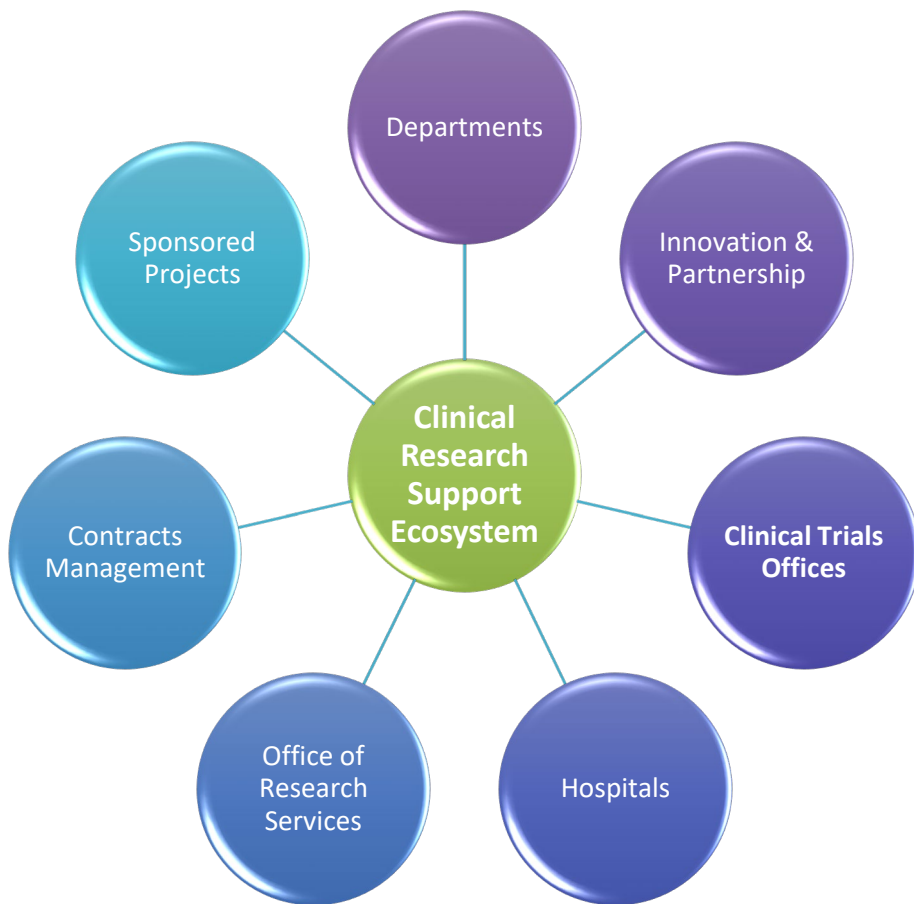
Responsible for the review, negotiation, and execution of Confidentiality/Non-Disclosure Agreements (CDAs, NDAs) and Material Transfer Agreements (MTAs)

Who Can I Contact?

Patrick Reed

preed3@lsuhsc.edu or 568-8303

LSU Health 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

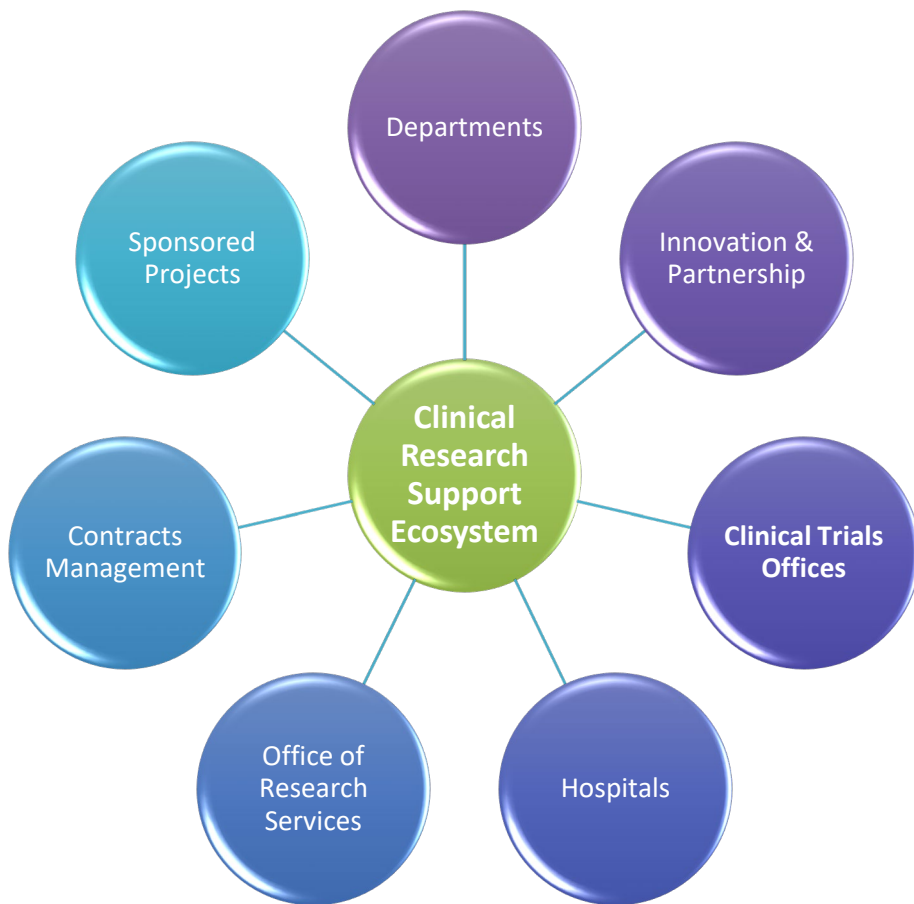
Work with HN when...

An industry-Sponsored study is conducted at a Healthcare Network Clinic

Work with SSSCC when...

An oncology trial is being conducted

LSU Health 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).

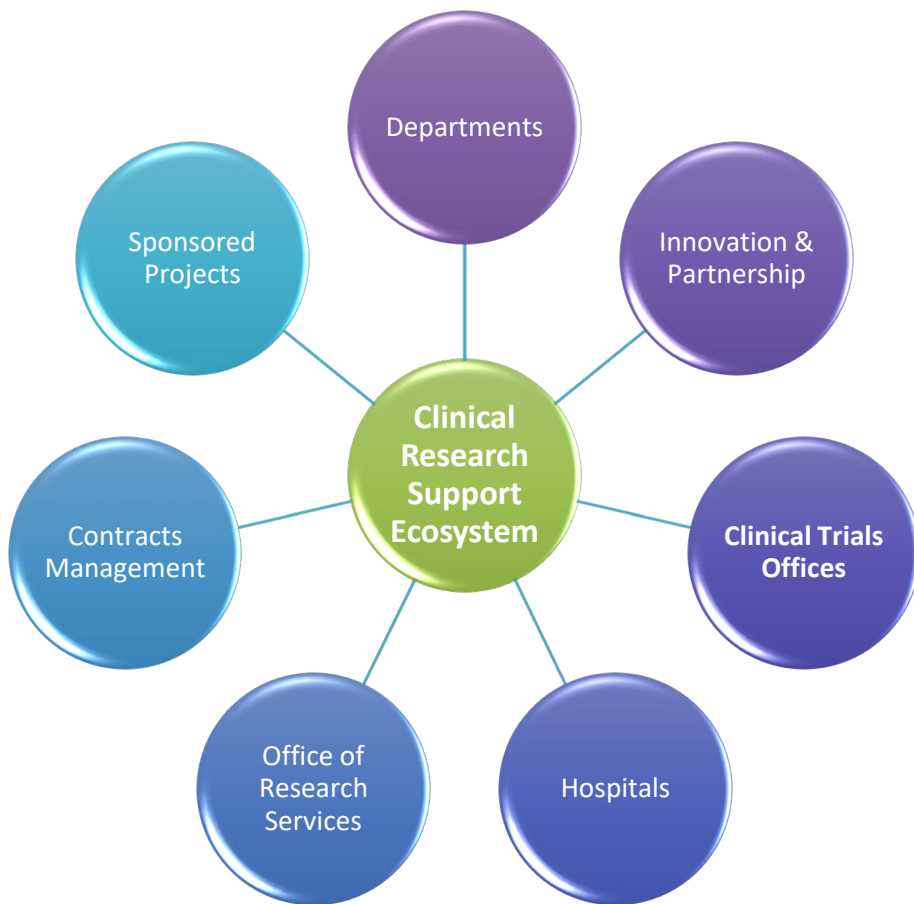
Also offers coordinator resources and standard SOPs.

Who Can I Contact?

Gabi Bonvillain, Ben Davis

CTO@lsuhsc.edu or 680-9070

LSU Health Research Offices



Clinical Trials Office – HN

Responsible for the review, negotiation, and execution of all research-related contracts & budgets.

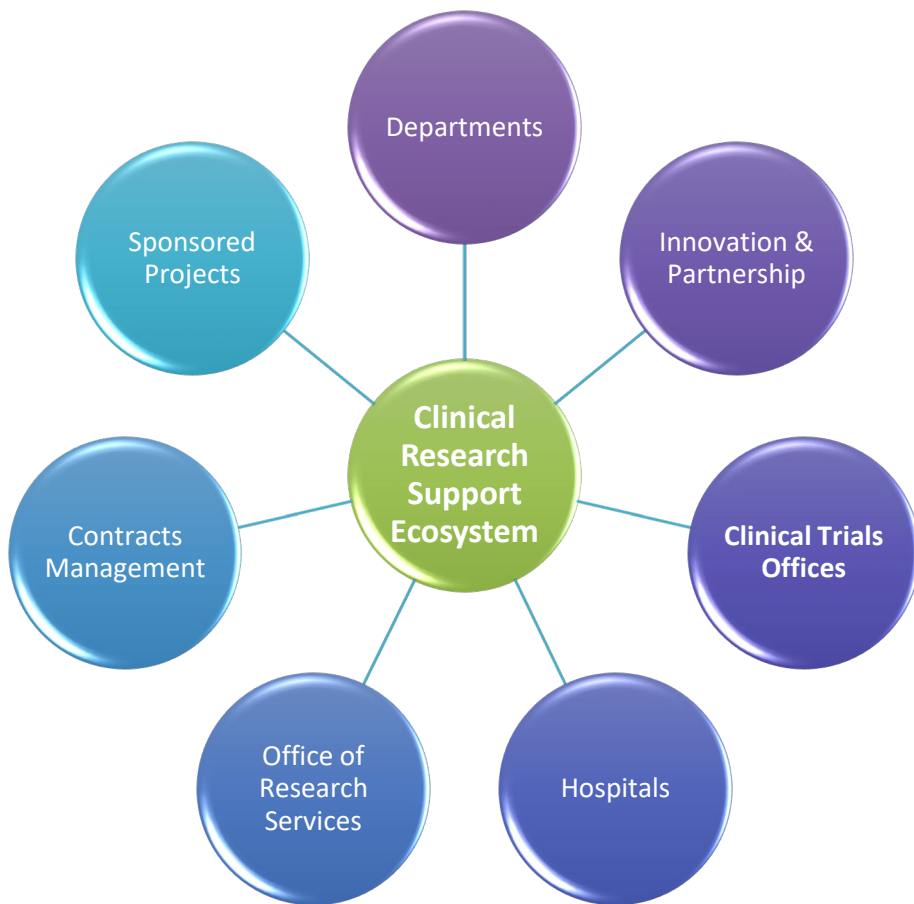
Also offers coordinator resources and standard SOPs.

Who Can I Contact?

Stephanie Sonnier

ssonn7@lsuhsc.edu or 412-1350

LSU Health 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*)
emed1@lsuhsc.edu or 210-3539

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

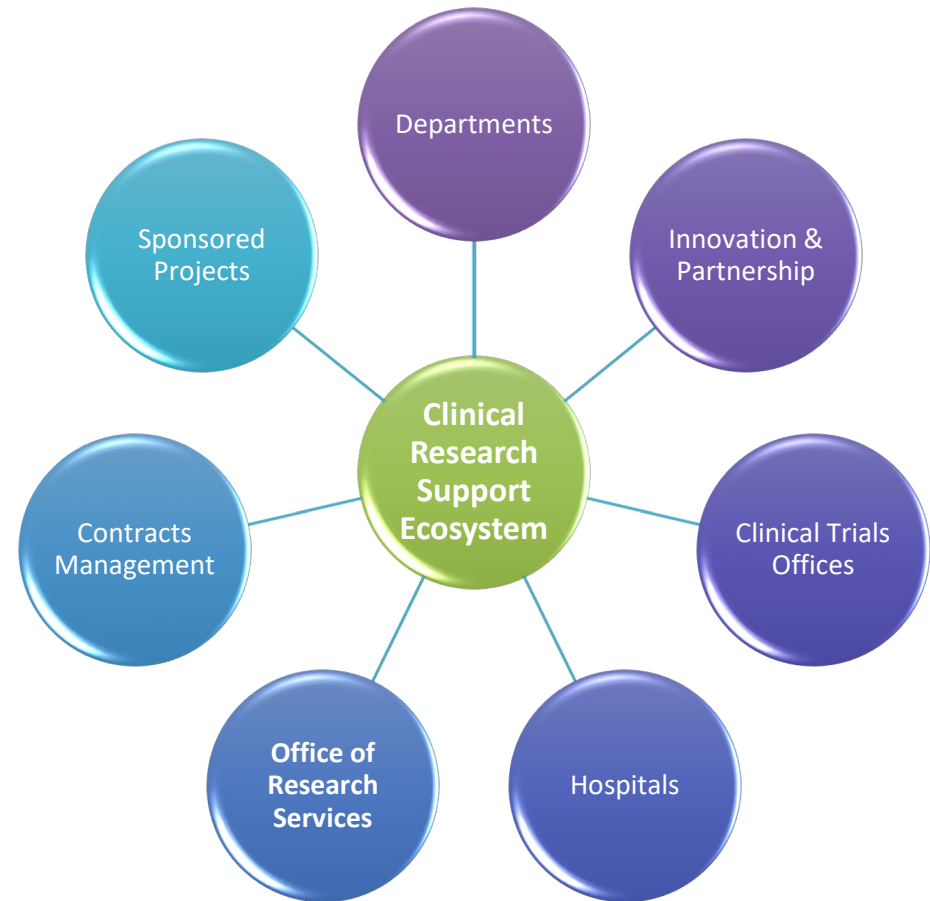
LSU Health Research Offices

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 Research Offices

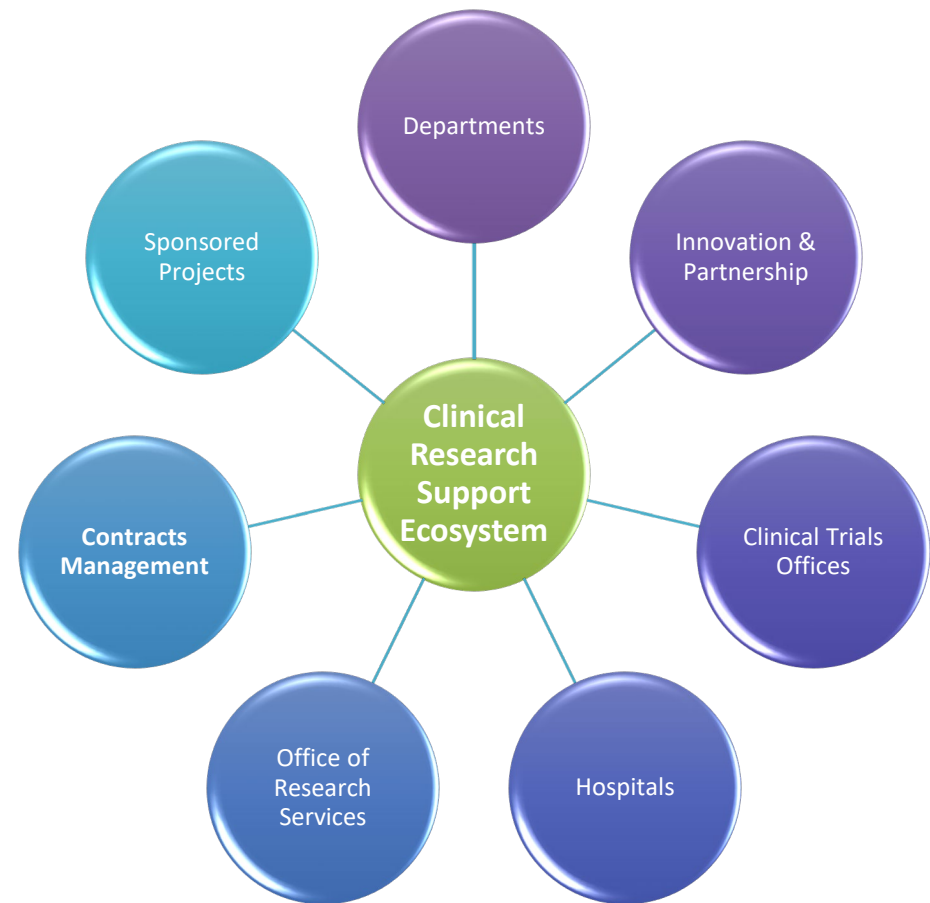
Contracts Management

Responsible for review, negotiation, and execution of subcontracts with an external entity for study related services

Who Can I Contact?

Mary Lapworth

lsuhscmteam@lsuhsc.edu



LSU Health Research Offices

Sponsored Projects

Responsible for Account Setup, Expenditure Management, Revenue Management, and Award Close-Out.

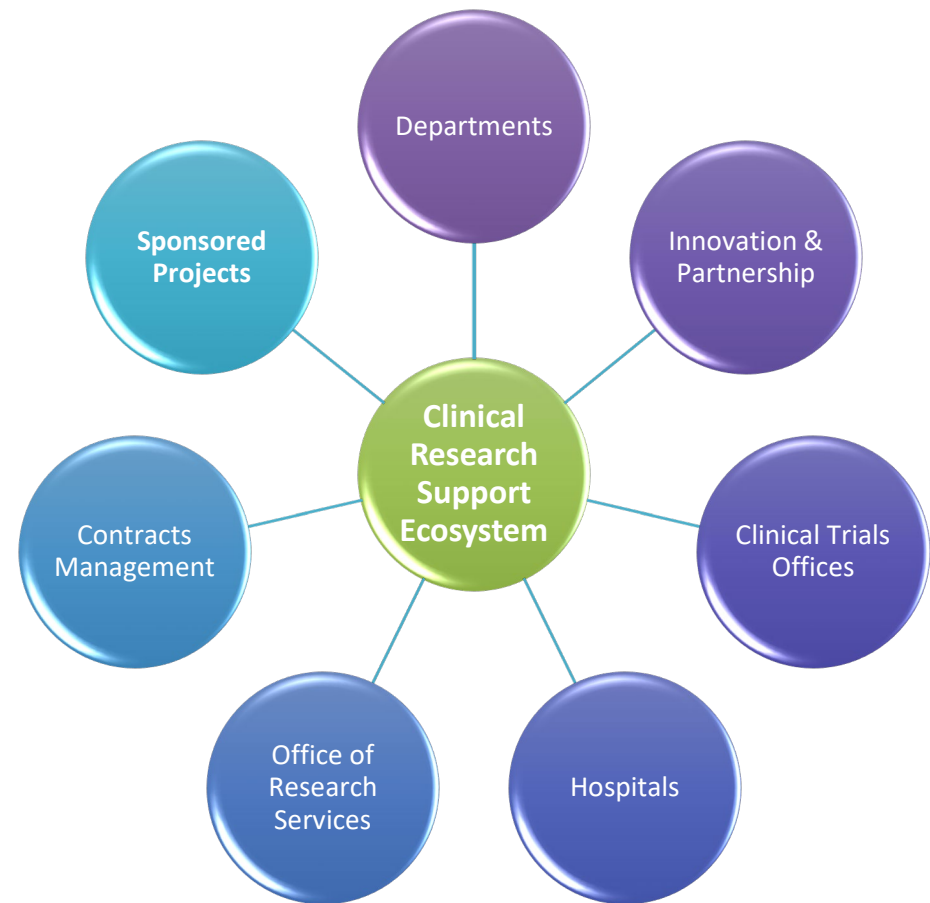
Who Can I Contact?

Central Email

Nosponproj@lsuhsc.edu

Invoice Email

ClinicalTrials@lsuhsc.edu



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)*
- 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

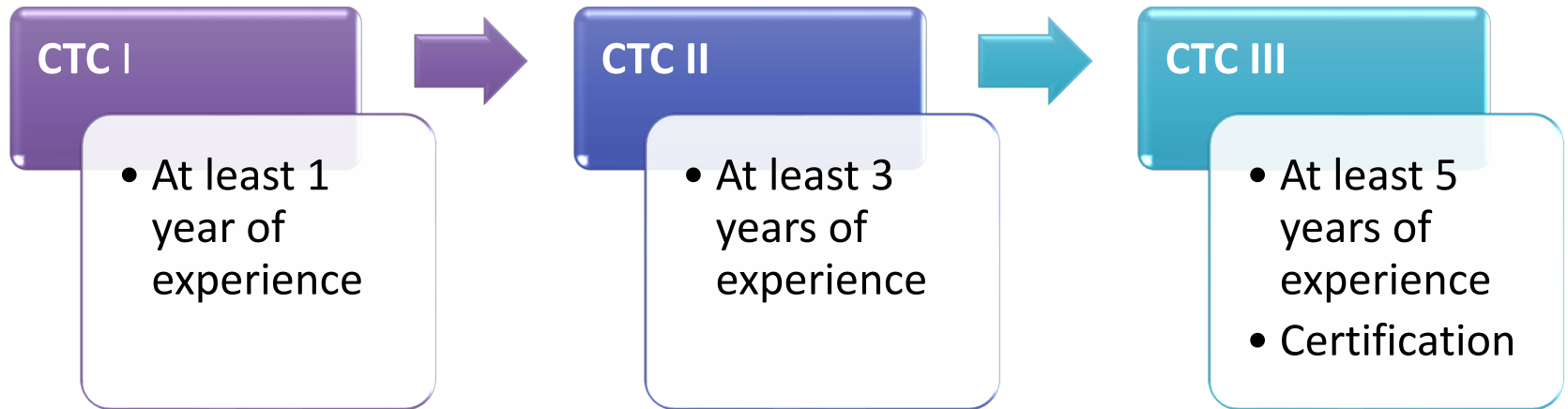
- Are you credentialed at the study sites?
- Do you have clean copies of consents & HIPAA?
- Are all regulatory approvals up to date?
- Do you have access to all the appropriate Research systems (EDC, EMR)?
- Do you have the supplies/equipment needed to conduct the study (i.e., lab kits, iPads)? Confirm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

Financials

- Who is your department's business manager?
- Do you have each study's account number?

CRC Career Progression

LSU Health New Orleans Career Ladder



Nationally Recognized Certifications



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