1. OBJECTIVE

To ensure that the Clinical Trials Office (CTO) Staff are informed about their obligations and responsibilities as they pertain to applicable regulations, guidance, and institutional policies. This Standard Operating Procedure (SOP) applies to the written procedures followed by all members of a CTO staff at LSU Health Sciences Center.

SOP 3.03 describes the process for allocating time and effort of central clinical trials coordinators and research coordinators, and how their time and effort is allocated to the appropriate study accounts for CTO reimbursement.

2. RESPONSIBILITY

The HSC, SSSCC and HN Clinical Trials Offices develop, implement, and maintain SOPs. The need to write a new or revise an existing SOP is based upon changes to federal regulations, guidelines, institutional policies, or procedures. These documents will be provided to staff of the HSC CTO.

The supervisor of the CTO is ultimately accountable for all CTO activities and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks.

3. DEFINITIONS

Clinical Research Coordinator (CRC): Oversees and coordinates the daily activities of clinical research studies. S/he works closely with the clinical teams and investigators to ensure that all protocol required procedures and visits occur according to protocol specified guidelines. S/he typically manages participant enrollment including obtaining informed consent.

Clinical Research Nurse Coordinator (CRNC): Carries out some of the same responsibilities as the Research Coordinator while fulfilling nursing tasks as required by the research study.

Regulatory Coordinator (RC): Typically drafts or edits the protocol document and submits new protocols, amendments, continuing reviews and safety reports to the appropriate IRB for review. S/he is also responsible for maintaining data integrity, reviewing records, assisting with preparation of internal audits, resolving problems associated with noncompliance, tracking study activity, and ensuring that all clinical research proceeds in compliance with institutional and governmental policies and regulations

4. PROCEDURES

A. Request for Coordinator Support

The CTO will be offering clinical trial coordinator and nurse coordinator support to PIs who need additional assistance with research activities and coordination on funded clinical research.

The CTO will also be offering regulatory coordinator support to PIs who need additional assistance with regulatory activities on funded and unfunded clinical research.

When a study team identifies the need for additional coordinator support, they should reach out to the HSC CTO requesting resources. The study team should provide the following information:

- PI Name
- Department
- Study Title
- Funding
- Sponsor
- Resources Needed
- Anticipated Monthly Effort (hours)
- Anticipated Start Date
- Anticipated End Date

The supervisor of the CTO will review the request and determine if resources are available for allocation to the project. If available, a coordinator will be allocated to the study site to assist with the project.

The CTO aims to allocate 85% effort per coordinator.

B. Working with CTO Coordinators

Scope of Work

When a coordinator is allocated to a study, the supervisor will provide the PI with a copy of the coordinator's job description, clearly outlining what activities are within his/her scope of work.

Any additional activities that a PI may want to assign to a coordinator outside of their scope of work must first be approved by the supervisor of the CTO.

Supervisory Responsibilities

For administrative matters, the coordinators should contact the supervisor of the CTO, who is ultimately responsible for supervising the coordinators.

For scientific matters related to a specific study s/he is working on, the coordinator should contact the PI of the study, who has responsibility to supervise coordinator conduct on their specific study.

Professional Conduct

If there are concerns related to coordinator conduct on a specific study, the PI should first speak with the coordinator about his/her concerns, documenting the discussion for the supervisor of the CTO. If issues continue or escalate, the PI should contact the supervisor of the CTO for further assistance.

C. Tracking of Coordinator Time & Effort

Each coordinator is responsible for tracking hourly time and effort dedicated to each project. At least quarterly, the tracked information should be shared with the supervisor of the CTO who will handle reimbursement from the study's specific project account.

Annual or Sick Leave

Each coordinator is responsible for communicating with the supervisor of the CTO and their PI(s) when they plan to take annual leave or when out on sick leave. The supervisor of the CTO is responsible for approving leave.

The coordinator should work with the PI and study team(s) to ensure there is someone else on the team able to cover for any tasks the coordinator would normally be responsible for handling.

D. Reimbursement for Time & Effort

At least quarterly, the supervisor of the CTO will submit an Electronic Change in Source Funds (ecsof) via PeopleSoft for each coordinator to move funds from the specific project into the CTO account in support of coordinator salaries. The amount requested for transfer will be calculated using the coordinator's hourly rate multiplied by the actual number of hours worked per month on the project.

5. APPLICABLE REGULATIONS AND GUIDANCE

LSU Health Guidance/Policy	Title
None	

6. MATERIALS

6.1. CTO Resources Request/Allocation Tracking REDCap Survey

Approved by:

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