LSU HEALTH COORDINATOR COMPETENCIES

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PROTOCOL COMPLIANCE

# Sponsor Monitoring

# Objectives

- Discuss what is the purpose of Sponsor Monitoring
- Outline steps for scheduling and preparing for a Monitoring visit
- Discuss what happens during a Monitoring visit
- Discuss what happens after a Monitoring visit

# Sponsor Monitoring

Because part of the responsibilities of a Sponsor are to oversee an investigator's performance related to quality data and human subject protections, sponsors may provide monitoring capabilities for a study.

There are two main purposes for a Sponsor to monitor:

1. Ensure that the investigator is complying with the Federal regulations and the protocol.
2. Identify issues and correct them when there is evidence that the site is out of compliance

A Sponsor Monitoring Visit may be in person (on-site) or remote.

# Scheduling a Monitoring Visit

A Sponsor's right to monitor a site is based both on the regulations and the contract between the Sponsor and LSUHSC.

**Example Contract Language**:
*The Sponsor and its representatives, upon reasonable advance notice, and at mutually agreed upon dates and times during regular business hours, will be provided access to the premises, facilities, Study records, and Study Team as required to accomplish research site monitoring activities. Monitoring by the Sponsor does not relieve the Institution of any of its regulatory obligations under this Agreement.*

# Preparing for a Monitoring Visit

- Schedule a room for the monitor to use, if on-site
- Schedule any meetings with key personnel if requested by the monitor
- Make available direct access to all requested clinical research study-related records
- Refer to performance site SOPs for any additional requirements when scheduling a monitoring visit

# Preparing for a Monitoring Visit: General Site Review

- Verify PI is still in good standing (e.g., qualifications, time)
- Verify labs and equipment are still in good standing (e.g., certified, calibrated)
- Verify staff is up to date with protocol training
- Verify staff is abiding by the protocol and delegation log

# Preparing for a Monitoring Visit: Study Document Review

**Informed Consent**

- ❑ Confirm each subject was consented
- ❑ Verify the informed consent document is complete
- ❑ Confirm all enrolled subjects met enrollment criteria

**Other Documents**

- ❑ Verify source documentation, CRF entries, and other records are complete and maintained
- ❑ Verify all required reports are complete, submitted, and maintained
- ❑ Verify essential documents are being maintained in accordance with sponsor and institutional requirements

# Preparing for a Monitoring Visit: Investigational Product

- Verify the storage conditions are appropriate
- Verify the IP was only provided to eligible subjects
- Verify subjects were provided with instructions for use of the IP
- Verify receipt, use, and return of IP is properly documented
- Verify disposition of unused IP complies with Sponsor and regulatory requirements

# During the Monitoring Visit

**On-Site Monitoring**

When the monitor arrives, have them sigh the monitor visit log. Orient the Monitor to the investigational site facilities. Provide the Monitor with all study documents requested

**Remote Monitoring**

Document on the monitor visit log the dates and times of the Monitor arrival and exit. Provide the Monitor with all study documents requested via a secure method.

**Tips**

- Check in throughout the day to address any questions
- Expect to discuss deviations from the protocol, SOPs, GCP, and other applicable regulatory requirements

# After the Monitoring Visit

The monitor is expected to provide the investigational site, within a reasonable amount of time, a monitoring report that includes a summary of what the monitor reviewed, including:

- significant findings/facts
- deviations and deficiencies
- conclusions
- actions taken or to be taken and/or actions recommended to secure compliance

The PI and research team member should address all findings presented by the monitor within a specified timeline that is acceptable to the sponsor and the investigational site.

# 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