UNIVERSITY OF SOUTH ALABAMA

CT 305 MONITORING VISITS

EFFECTIVE DATE: March 2024

Purpose

To describe the activities associated with periodic site visits by Sponsor monitors. This standard operating procedure supports industry standards and Good Clinical Practice.

Scope

This document applies to all clinical studies using human subjects conducted by USA staff or using USA facilities. The Principal Investigator (PI) may appoint research staff to coordinate and interact with study monitors.

Definitions

Monitoring: The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

Monitor: Also referred to as a Clinical Research Associate (CRA). An individual appointed by the Sponsor/Grantor, as applicable, responsible for assuring the protection of Human Subjects, the accuracy and completeness of reported trial data, and the compliance of the trial with the protocol, good clinical practices and applicable regulations

Policy

FDA requires the Sponsor or sponsor representative to oversee the accuracy and integrity of study data. As a result, the Clinical Trial Office must allow monitors access to the study data. Access can be granted via the Electronic Medical Records and/or by viewing the paper shadow chart. A

Confidentiality Agreement needs to be signed by the monitor prior to gaining access to the Electronic Medical Record. If access to the EMR is not required then the individual Confidentiality Agreement is not required as the monitor is covered under the Clinical Trial Agreement.

Procedure

1. Monitoring visits should be scheduled at least four weeks in advance and during normal operating hours unless approved by the Principal Investigator (PI) and/or CTO Director.

2. If the monitor requires access to the electronic medical records, an account will need to be set up for each new monitor. This should be done at least four weeks prior to the first monitoring visit.

    2.1. The monitor will require a J#. To obtain a J# the monitor must complete the "Non-Employee Access Request" form located https://forms.office.com/r/WGKqt2JXCt

    2.2. Once a J# is obtained, the monitor should complete the Confidentiality and Security Agreement form. This form should be sent to IT to request access.

3. Monitors should receive access to the RealTime CTMS. Access can be granted by a member of the Clinical Trial Office and should be limited to the study the monitor is working on.

4. Prior to a monitor visit:

    4.1. Ensure all original signed informed consent documents are available.

    4.2. Ensure all case report forms (CRFs) are complete.

    4.3. Ensure the appropriate documents are filed in the Regulatory Documents binder.

    4.4. Ensure specific CRFs and source documents that will be reviewed are available on the visit date.

    4.5. Set up appointments for the monitor to meet with the pharmacist, as appropriate, and the PI.

    4.6. Request the monitor's access to appropriate patient list in the Electronic Medical Record (EMR) and RealTime.

    4.7. Check to see if the monitor has signed a Confidentiality and Security Agreement.

5. During the site visit:
    5.1. Ensure that the monitor signs the Monitoring log if applicable.
    5.2. Interact with the monitor to help validate data in the CRFs; answer questions about the data or regulatory documents.
    5.3. Follow-up on data clarifications.
    5.4. Meet with the Monitor to discuss findings.

6. Following a monitor visit:
    6.1. Resolve the monitor's findings.

6.2. File the follow-up letter and any other applicable communications pertaining to the monitor visit in the Regulatory Binder.

Additional Resources

RELATED SOPS:

- **CT 104 CONFIDENTIAL INFORMATION**

RELATED FORMS:

- **CONFIDENTIALITY AND SECURITY AGREEMENT**

History

N/A

Next Review Date

March 2027

Responsible Party

Director, Clinical Trial Office