PM-304 Study Monitoring and Auditing Visits

1. **PURPOSE:**
   The purpose of this SOP is to describe the procedures followed by key research personnel engaged in clinical research at UTRGV during a periodic monitoring visit from the sponsor representative.

2. **SCOPE:**
   This SOP applies to all clinical research studies conducted at UTRGV. The Principal Investigator (PI) will designate appropriate research team members to facilitate monitoring visits. Ensuring high standards of data collection and source data verification are maintained at all times.

3. **RESPONSIBLE INDIVIDUALS:** The PI and key research personnel are responsible for arranging, managing, participating in, and resolving any outstanding items resulting from the monitoring visit.

4. **RELATED TERMS AND DEFINITIONS:**

   Case Report Form (CRF)
   Electronic Medical Records (EMR)
   Monitoring
   Monitoring Report
   Regulatory Binder
   Sponsor
   Test Article- Also referred to as investigational product (IP)
   Investigational Product (IP)- Also referred to as test article.

   Please reference the Standard Operating Procedures Glossary of Terms for complete definitions of terms in this SOP.

5. **POLICY STATEMENT:**
   This SOP will be used as a guide to facilitate study monitoring visits.

6. **PROCEDURES:** The primary research personnel assigned to the study will do the following activities before, during, and after a monitoring visit:

6.1 Preparing for a Site Monitoring Visit:

- Schedule all monitor visits in advance. When possible, the next monitor visit should be scheduled at the conclusion of the current visit. The monitor visits will be conducted per the specified frequency documented in the Clinical Trial Agreement (CTA).
- The monitor must confirm whether the visit will be in person or remote. If in person, they must specify the number of people visiting the site and any specific needs they require during the visit (phone lines, projector, etc.)
- The monitor must specify if they need to visit any other specific personnel or space during their time onsite/remote visit. And if so, which departments (Investigational Pharmacy, Lab, regulatory etc.).
- If a monitor confirms they must speak to or visit anyone other than the coordinator and PI, there are two options:
    A. The study coordinator provides the contact information for those personnel. The monitor contacts the above-mentioned personnel to schedule, keeping the study coordinator copied on all correspondence. **OR**
    B. The study coordinator acts as a middleman to schedule the visits with the above-mentioned personnel.
- Designated site staff will reserve space according to the requirements of the building in which the space is being reserved.
- Most buildings on campus can use the Ad Astra app on the myUTRGV page to reserve space. (See reference section for link)
- If the Ad Astra app does not work for your department or building, please contact your building administrator to determine the process.
- Designated site staff will enter confirmed monitor visit date and time in Outlook calendar and share the invitation with all relevant research team members, including any support services, with the agenda and time of meeting.
- Upon scheduling monitor visit, designated staff member will request binder access from administrator of Florence eBinders™. See Appendix A for instructions on how to request Florence eBinders™ monitor access.
- Study staff must receive a notice or letter from the monitor at least two weeks prior to arrival, unless an exception is granted. The notice of the monitoring visit must also include the focus of the visit, any special preparations/documents requested, and a list of required participants during the visit.

6.1.1 Ensure all regulatory documentation, shadow charts and case report forms (CRFs) are complete and available for review.

6.1.2 Ensure all unanticipated problems, adverse events (as defined in the protocol) and protocol deviations have been reported to the sponsor and the IRB.

6.1.3 Ensure all queries received to date have been resolved to the extent possible.

6.1.4 All test articles are to be stored in the Investigational Pharmacy. Investigational pharmacy staff must be prepared to show Investigational Product (IP) is being securely stored according to the instructions in the protocol (e.g., temperature or light specifications) and all accountability records are updated. Pharmacy staff must be able to provide the status of all IP and required documentation prior to the monitoring visit upon request of the PI or designee.

6.1.5 Ensure the appropriate study participant medical records will be available for review at the time of the monitoring visit.

- If the department conducting the research uses an Electronic Medical Records system capable of guest access, a designated research staff member will request the applicable source data from medical records at least seven (7) days in advance of visit. It is up to the PI and study coordinator to determine the steps for obtaining this access, to document the steps and make them available to appropriate study staff.
- The monitor should never be allowed to navigate through the EMR using an employee's login information.
- If the department conducting the research uses an EMR that is not capable of guest access they may choose **one** of the following options:
  - Use Florence eBinders™ to import patient records, creating electronic patient shadow charts. This option allows for remote monitoring visits. **OR**
  - Print records from the EMR to create a paper shadow chart. If this option is used, monitoring of patient data must always be done in person.

  Both options may require prompt the monitor to request additional proof of source document verification (e.g., SOPs, EMR HITECH Compliance Certification, 21 CFR Part 11 Compliance Certification, Non-Repudiation Letter, etc.).

6.1.6 Prepare any questions or discuss any concerns you may have about communications or operations of the study.

6.2 <u>During the Monitoring Visit</u>:

6.2.1 Ensure the monitor signs the site visit log within the regulatory binder.

6.2.2 Assure the study monitor has all documents required to complete the monitoring visit.

6.2.3 Provide the monitor with an update on any study-related issues**.**

6.2.4 Throughout the visit, check periodically with the monitor and provide information or documents as needed.

6.2.5 At visit conclusion, the monitor will identify any outstanding items requiring attention (e.g., protocol adherence, source document verification, etc.).

6.2.6 Key study personnel managing the monitor visit will address any outstanding items.

6.2.7 The monitor may request to speak with the PI, who should be available during the visit.

6.3 Follow-up after the Monitoring Visit:

6.3.1 Ensure any outstanding items are addressed in a timely manner (within two (2) weeks) and the necessary information is provided to the PI, sponsor and/or monitor.

6.3.2 Provide outstanding item resolution to the sponsor and/or monitor and document resolution in the study files (e.g., fax/scan additional source documentation for an adverse event to the sponsor and/or monitor and file the fax with confirmation in the AE section of the regulatory binder(s)).

6.3.3 Forward the PI a copy of the monitor visit report, if not already done so by the monitor, and inform them of the plans to address any outstanding issues identified during the visit.

6.3.4 File the monitor visit letter(s) in the regulatory binder. If you are not using Florence for regulatory, please send a copy of the monitoring letter(s) to OCR at clinicalresearch@utrgv.edu.

7. REFERENCES:

- 21 CFR 312.50
- 21 CFR 312.56
- 21CFR 312.59
- 21CFR 312.60
- 21CFR 312.62
- 21CFR 312.64
- 21CFR 312.66
- 21CFR 312.68
- UTRGV RA-206

8. FORMS OR ATTACHMENTS:

- **Appendix A**

- At least seven (7) days before a scheduled monitoring visit, a study team member will send an email to clinicalresearch@utrgv.edu with "Florence Monitor Access Request" in the subject line. The email must include the following information:
  - Monitor Name
  - Monitor Email
  - Study Department
  - Study PI
  - Full Study Title
  - Short Title/Study Number, if applicable
  - Date(s) monitor access is needed
  - Specify if the monitor should have access to the full study or if there are only specific folders and documents being reviewed during the visit. For example, while most visits are for everything, some visits are only for regulatory or only for patient data.

- If access is needed in less than seven (7) days, include "Urgent" in the subject line. Provide a justification for why the request is urgent.

- If this is the monitor's first time using Florence, the Florence administrator will send an invitation for the monitor to join the team in a training environment. The invitation will come via email. The monitor will follow the instructions in the email to create their account for the training environment.

- First time monitors will also be sent links to training modules as well as a signature request for an attestation within Florence.

- After the monitor has sent their training certificate to clinicalresearch@utrgv.edu **and** signed the attestation within Florence, the Florence administrator will send them an invitation to join the production environment (real Florence). The invitation will come via email. The monitor will follow the instructions in the email to create their account for the production environment.

- It is important to note that while the training environment and production environment look similar, they are a different URL. Therefore, encourage the monitor to save the production environment URL after they've gained access to it.

- If a first-time monitor fails to complete those actions, it is the monitor's responsibility to reschedule the visit.

- Once a monitor has access to the production environment, view-only permissions will be assigned to the monitor for the appropriate binders/folders/documents during the access dates requested.

- Monitors may contact the Florence helpdesk for technical assistance at 1-888-829-0896 or support@florencehc.com.

- Monitors may also contact clinicalresearch@utrgv.edu for assistance with access.