PM-303 Site Initiation Visit

1. **PURPOSE:**
   The purpose of this SOP is to describe activities that will be accomplished by site staff before, during and after the sponsor's Site Initiation Visit (SIV) of a clinical study or trial at UTRGV.

2. **SCOPE:**
   This SOP applies to all clinical research studies conducted at UTRGV requiring a site initiation visit.

3. **RESPONSIBLE INDIVIDUALS:**
   The Principal Investigator (PI), Study Coordinator, Research Nurse, Research Pharmacist, Data Manager, and any other applicable designated research personnel are responsible for attending the SIV.

4. **RELATED TERMS AND DEFINITIONS:**

   Case Report Form (CRF)
   Monitor
   Monitoring Report
   Regulatory Binder
   Site Initiation Visit (SIV)
   Source Documents
   Sponsor

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

5. **POLICY STATEMENT:**
   This SOP should be used as a guide to facilitate site initiation visits for industry sponsored clinical research.

6. **PROCEDURES:**
   6.1 Research personnel will refer to the SIV Checklist for guidance before, during and after the SIV.

6.2 Ensure a fully executed contract is in place between UTRGV and the sponsor of the study **prior** to scheduling the SIV.

6.3 Prior to the scheduled SIV, research personnel will perform the following activities:

- Establish which staff members are essential for attendance.
- Establish a suitable date/time/location for the SIV and ensure sponsor, PI, and other key personnel availability.
- Determine the status of any ancillary contracts (DTA/DTUA, MTA)
- Request an agenda from the monitor conducting the SIV.
  If needed, provide the Monitor with directions and assistance identifying nearby accommodations.
- Assure personnel are familiar with sponsor-provided study materials (e.g.: protocol, Investigator Brochure, CRFs, etc.) in advance of visit.
- Ensure the regulatory binder contains all the necessary documents that have been received. Request any known documents that have not been received.
- Establish the receipt of adequate test article supplies (if applicable) or ensure the location of test article storage is ready for review and meets the sponsor's requirements.
- Identify any sponsor-provided supplies needed once enrollment begins (e.g., eCRF access, lab draw and shipping supplies, etc.).
- Ensure IRB approval and any other applicable committee approval has been obtained.
- UTRGV Office of Clinical Research (OCR) policy uses the SIV to document the initial study training of all of those in attendance.
- UTRGV OCR policy prohibits the addition of any staff member to a Delegation Log prior to their documented training.
- Do not provide a Delegation Log to a sponsor prior to the SIV. If a sponsor is not accepting this policy, they may reach out to clinicalresearch@utrgv.edu.

6.4 During the SIV:

- Assure the PI is present
- Assure all other essential staff are present
- Document the date and the names and roles of all attendees.
- Review details of the protocol, including study operations with the Monitor.
- Discuss with monitor which key personnel are authorized to perform what study-related functions or procedures.

- Document operational questions not covered in the protocol and the answers provided by the sponsor.
- Discuss test article preparation, administration, storage and accountability (if applicable)
- Review instruction on study-specific activities such as diagnostic tests, lab kits or study-required software and any related recordkeeping requirements (e.g., temperature logs, calibration logs, etc.).
- Review directions for source documentation and/or CRF completion.
- Review required source documents and documentation to be provided at future monitoring visits.
- Discuss applicable study-specific training involving protocol execution (e.g., in-service for physician investigator, research nurse).
- Discuss any outside vendor systems, access and training (if applicable).
- Identify important sponsor and/or monitoring body contacts and corresponding timeframes (e.g., enrollment logs, safety reporting).

6.5 Following the SIV:

- File all training documentation in the regulatory binder.
- Ensure completion of Delegation Log
- Document SIV on a Site Visit Log and file in regulatory binder
- Ensure receipt of sponsor/CRO documentation summarizing the SIV.
- Assemble screening/enrollment materials.
- Have a "kick-off" meeting with post-award finance to review the study and all of its financial and billing components.

7. REFERENCES:

- 21 CFR 312.50
- 21 CFR 312.52
- 21 CFR 312.60
- 21 CFR 312.62
- 21 CFR 312.66
- 21 CFR 312.68

8. FORMS OR ATTACHMENTS:

Site Initiation Visit Checklist