PM-302 Site Qualification Visit

1. **PURPOSE:**
   The purpose of this SOP is to outline the activities required to facilitate the clinical site selection process. A visit is conducted to determine if the site has the ability to conduct a study with adequate staff, training, education, experience, and resources.

2. **SCOPE:**
   This SOP applies to all site personnel involved in the implementation and coordination of clinical research at UTRGV.

3. **RESPONSIBLE INDIVIDUALS:** The qualified Investigator and Research Personnel are responsible for providing the required information to the sponsor.

4. **RELATED TERMS AND DEFINITIONS:**

   Feasibility Assessment
   Monitoring
   Site Qualification Visit (SQV)
   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 for Site Qualification Activities for sponsored research.

6. **PROCEDURES:**
   6.1 The Investigator or research personnel will be contacted by the sponsor representative to schedule an SQV.
   6.2 Research personnel will schedule the visit with the sponsor on a mutually agreed upon date, during regular business hours, to ensure that as many study members as possible can attend.

6.3 Research personnel will request an agenda from the sponsor representative at least 2 weeks in advance of the visit.
6.4 Research personnel will ensure that all research staff have copies of any available related materials prior to the visit.
6.5 Research personnel and investigator will conduct the visit with the sponsor representative, review departmental procedures, and answer any questions the sponsor may have.
6.6 Research personnel and investigator will demonstrate the site's ability to recruit the appropriate number of subjects within the protocol-specified time frame.
6.7 Research personnel will take the representative on a tour of the facility where the research will occur to view exam rooms, equipment, and sample preparation areas.
6.8 The Investigator may be present for the duration of the visit or meet with the sponsor representative for a portion of the visit.
6.9 If the tour will include the Investigational Research Pharmacy, the research pharmacist and/or research technician will be notified in advance to schedule the tour.
6.10 The sponsor representative will discuss and review the items that need to be completed or addressed; usually documented on a checklist provided by the sponsor representative.
6.11 A completed site qualification checklist, or any other documentation provided by the sponsor representative, will be completed and a copy filed in the site's files.
6.12 The sponsor representative should give the site a time estimate of when they will be notified of their selection status.

7. REFERENCES:

- 21 CFR 312 Subpart D: Selecting Investigators and Monitors

8. FORMS OR ATTACHMENTS:

None