SM-403–Study Visits

1. **PURPOSE:**
   The purpose of this SOP is to establish procedures for the research team to perform required study specific visits for research studies conducted at UTRGV.

2. **SCOPE:**
   This SOP applies to research personnel who conduct study visits at UTRGV.

3. **RESPONSIBLE INDIVIDUALS:**
   The investigator and research staff will coordinate and perform the required evaluations in accordance with the protocol guidelines, regulatory authorities, sponsor, and Institutional Review Board (IRB) guidelines and institutional regulations.

4. **RELATED TERMS AND DEFINITIONS:**

   Case Report Form (CRF)
   Concomitant Medications
   Documentation
   Source Data
   Source Documents
   Subject Identification Code

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

5. **POLICY STATEMENT:**
   This SOP applies to all study visits conducted at UTRGV.

6. **PROCEDURES:**
   6.1 The investigator, clinical research coordinator or designee will implement screening and study visit procedures as directed by the IRB approved protocol.

   6.2 Informed Consent: Verify the completion of the informed consent document(s) including correct date and signatures PRIOR to performing any screening procedures. *Refer to Informed Consent Process SOP-402 for details*.

6.3 Perform required clinical evaluations per the protocol.

6.4 Medical History:

- Obtain a medication history per the protocol and for inclusion/exclusion eligibility for all potential study participants.
- Medications may be documented on a visit specific source document if provided or on a subject specific medication log.
- If a medication log is used, original entries and changes should be reviewed, signed, and dated by the Principal Investigator (PI) or a treating investigator who has been delegated to this task. All delegations must be documented.
- If the protocol requires documentation of concomitant medications, the drug start dates, dosage, route, frequency and purpose must be documented.
- The PI and research team will verify that no study exclusionary medications are being used by the subject. If the subject is on an exclusionary medication, the research team will query the provider of the medication and study specific medical monitor to inquire whether an allowable non-exclusionary substitution exists.
- Any medical history obtained verbally must be documented in source documents.

6.5 Research Procedures and Laboratory Analysis:

- Perform all research and laboratory procedures as outlined in the protocol AFTER the subject has provided written informed consent. No research procedures may be performed prior written consent.
- Coordinate with applicable laboratory staff to ensure that specimens are collected and labeled correctly, and that laboratory staff are available to receive and process research specimens.
- All research test results and procedures will be reviewed, signed, and dated by the PI or a treating investigator who has been delegated to this task. All delegations must be documented.
- Abnormal results will be evaluated and graded, if applicable. If clinically significant it must be documented, including action taken.
- The research coordinator or designated research staff member will verify protocol required actions and assure compliance.

6.6 Eligibility checklist:

- Use to verify that all inclusion criteria are met and that no exclusion criteria exist.
- Supporting documentation of all inclusion/exclusion criteria must be contained within the research record.

- The clinical research coordinator and PI will confirm with signature each subject's eligibility prior to randomization and study entry.

6.7 Source Documentation: Complete a protocol-specific flow sheet or other source documentation for the appropriate study visit and submit it to the PI for review and signature.

- All signed source documentation must be filed in the study patient binder or electronic medical record.
- Laboratory or procedure results may be filed in the subject's medical record or the subject research binder but should be consistent throughout the study.

6.8 Case Report Forms (CRF): Complete CRFs as required by the assigned protocol and contract terms (Refer to SOP DM-501: Case Report Form Completion).

6.9 Data Management: Follow protocol specific instructions for enrollment, randomization and all study visit entries.

6.10 Pharmacy (if applicable): Communicate with the pharmacy when a randomization is scheduled for protocols that include study medications.

6.11 Return Visits:

- Schedule a return study visit for each subject as outlined in the protocol.
- Verify that visits occur within the protocol specified time frame (window).
- Notify the study subject and research team, including any supporting departments, of the anticipated study visit date.
- Maintain a schedule of anticipated study visits.
- Document and follow-up on missed study visits

6.12 Missed Study Visits:

- Anticipated study visits that are missed or out of the protocol specified timeframe (window) must be documented as missed study visits.
- The clinical research coordinator (or designee), together with research team will attempt to contact/locate the study participant and bring the study subject back into care.
- If the study participant wishes to discontinue study prematurely it must be documented appropriately and filed as source documentation.
- All attempts and action to locate and bring the study participant back into care or for study discontinuation must be documented and filed as source documentation.

6.13 Study Discontinuation:

- Subjects should not be discontinued as lost to follow-up until all efforts to locate and bring the subject back into care have been exhausted and properly documented.
- If the study subject chooses to discontinue prematurely the study team, including supporting departments and the sponsor, must be notified of the premature discontinuation visit.
- For protocols that are using IP, the clinical research coordinator must record the return of all study medications in the source document flow sheet, clinic/study visit note, or appropriate medication log at the discontinuation visit. Ensure all investigational drug is returned to the pharmacy for documentation and destruction or return to sponsor.
- If the study participant does not return all previously dispensed study product, the clinical research coordinator (or designee) must attempt to determine if the participant has any study product in his/her possession or if this was discarded and document these findings.
- For research subjects who possess additional study product(s), the clinical research coordinator (or designee) must counsel, and document attempts to have that remaining study product returned.
- The research coordinator (or designee) will notify the research pharmacy of study product disposition.

REFERENCES:

- 21 CFR 312.59 Disposition of Unused Supply of Investigational Drug
- 21 CFR 312.60 General Responsibilities of Investigators
- 21 CFR 312.62 Investigator Recordkeeping and Record Retention
- UTRGV DM-501
- UTRGV DM-502
- UTRGV SM-401
- UTRGV SM-402

FORMS OR ATTACHMENTS:

None