SM-401– Subject Screening and Enrollment

1. **PURPOSE:**
   This SOP describes the process to be followed for screening and enrolling participants in clinical research at UTRGV.

2. **SCOPE:**
   This SOP applies to investigators and research staff at UTRGV sites who perform screening and enrollment procedures for clinical research studies.

3. **RESPONSIBLE INDIVIDUALS:**

   The investigator has ultimate responsibility for ensuring that all applicable study staff members follow this SOP, and for ensuring that only participants who meet the protocol-specific eligibility criteria are enrolled in the study.

   It is the responsibility of each study staff member who takes part in the screening and enrollment process to fully understand the study eligibility criteria and to only enroll eligible participants.

4. **RELATED TERMS AND DEFINITIONS:**

   Case Report Form (CRF)
   Clinical Trial/Study
   Eligibility Criteria
   Enrollment
   Informed Consent
   Legally Authorized Representative (LAR)
   Screening

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

POLICY STATEMENT:
This SOP must be followed for all screening and enrollment activities at UTRGV.

5. PROCEDURES:

6.1 Pre-Screening Activities:

- After initial IRB approval, the research coordinator or designated research personnel, will develop a Subject Eligibility Checklist that includes all inclusion/exclusion criteria listed in the protocol. If a checklist is provided by the sponsor or CRO, use the one provided.
- Research personnel will prepare a Screening and Enrollment Log, if not provided by the sponsor or CRO, for use at the study site.

6.2 Screening Activities:

- The research team will count the day on which the prospective participant or legally authorized representative (LAR) signs the informed consent document as Day Zero, unless otherwise indicated in the protocol. The screening period for a clinical study may take several days.
- During the screening period, the designated research personnel will assess the prospective participant's eligibility for participation in the study per the inclusion and exclusion criteria detailed in the study protocol.
- Every individual considered as a potential candidate for the study should be entered on the screening and enrollment log**.**
- Designated research personnel will review the Screening Criteria Checklist developed or provided by the sponsor to determine if the participant meets criteria for screening.
- If the potential study participant meets screening criteria, they must be consented and sign the informed consent form **before** any screening procedures are initiated.
    - If the participant agrees to be screened, a participant number will be assigned, and that information will be entered into the Screening and Enrollment log.
    - Screening evaluations and procedures will be followed according to the study protocol.
    - Review the Screening Visit Checklist to ensure all screening procedures have been completed.

- If a prospective study participant is found to be ineligible, the screening evaluations will be stopped. The patient or legally authorized representative will be informed that he/she is not eligible to join the study and any required case report forms (CRF) will be completed.
- Update Screening and Enrollment log with screen fail information.

6.3 Eligibility Determination:

- The Investigator, study coordinator or other designated research personnel is responsible for reviewing all information pertinent to the prospective participant's eligibility status (all chart notes, checklists, laboratory results and information obtained via medical examinations and interview) after all screening evaluations and test results have been completed and received. He/ she will then record on the chart note the prospective participant's current eligibility status.
- The designated research personnel will review all documents as stated above, as well as the screening evaluation documentation to determine if the prospective participant is eligible for the study.
- If the prospective participant is found to be ineligible, the patient or LAR will be informed that he/she is not eligible to join the study and the required case report form (CRF) will be completed.
- If the designated research personnel determines the prospective participant to be eligible, then the study coordinator or other designated research personnel must sign and date the Eligibility checklist along with the treating investigator or PI as the second and final signature. It is ultimately the responsibility of the PI to determine and confirm subject eligibility to participate in the research study.
- The prospective participant or LAR will be informed of his/her status. If they are still interested in becoming a study participant, the study staff may begin the process of enrolling the participant into the study.

6.4 Enrollment Procedures:

- If there are separate screening consents and main study consent forms, designated research personnel will provide informed consent for the main study. This procedure will be performed in accordance with *SOP SM-402: Informed Consent Process*

- After informed consent is signed by the participant or LAR, he/ she will be randomized to a study drug treatment, if applicable, or begin study treatment as described in the protocol.
- The remaining participant information will be entered into the Screening and Enrollment Log.
- Research staff will complete the appropriate case report forms (CRFs).
- Subject Numbering
  - For sponsored research, subject numbering will be developed and determined by the sponsor or CRO.
  - For Investigator-Initiated research, the local PI of the study must have IRB approved procedures for assigning a unique participant numbering system that includes a site number and sequential subject number. The unique identifier may not be derived from any patient identifiers (e.g., subject initials, DOB, SSN, etc.).
  - Once a participant's eligibility to participate in the clinical study has been confirmed, the participant will be assigned the unique subject number according to the predetermined numbering system.
  - All study records that are maintained on each participant will use the unique subject number where possible to protect the participant's confidentiality.

6. REFERENCES:

- 21 CFR 50.20 General Requirements of Informed Consent
- 21 CFR 56.109 IRB Review of Research
- 21 CFR 312.60 General Responsibilities of Investigators
- 21 CFR 312.62 Investigator recordkeeping and record retention
- UTRGV SM-402

7. FORMS OR ATTACHMENTS:

Screening and Enrollment Log