SM-402– Informed Consent Process

1. **PURPOSE:**
   To describe the processes followed for informed consent development, review, and documentation, including requests to waive the informed consent process or informed consent documentation based on federal criteria. This SOP ensures that adequate and legal informed consent has been properly obtained and documented for each study subject participating in a clinical study at UTRGV.

2. **SCOPE:**
   This SOP applies to the Principal Investigator (PI) and all key research personnel who obtain informed consent for human subjects' research at UTRGV.

3. **RESPONSIBLE INDIVIDUAL:**
   PI retains overall responsibility for the development, implementation, and evaluation of the informed consent process. Designated research personnel are responsible for implementation of this SOP in accordance with Federal, State, and local Institutional Review Board (IRB) requirements.

4. **RELATED TERMS AND DEFINITIONS:**

   Assent
   Coercion
   Health Insurance Portability and Accountability Act of 1996 (HIPAA)
   Informed Consent
   Key Personnel
   Legally Authorized Representative (LAR)
   Minimal Risk
   Undue Influence
   Voluntary

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

5. POLICY STATEMENT:

This SOP must be followed by all research personnel consenting subjects to a clinical research study at URTGV.

6. PROCEDURES:

6.1 The regulatory coordinator, or other designated research personnel, will obtain an informed consent template from the UTRGV IRB, UTRGV relied-upon IRB, or the sponsor, if provided. He/she will perform the following activities in compliance:

- Add any required institutional or IRB mandated elements into the clean version of informed consent template.
- All consent documents must be translated into the preferred language of the subject. The translated documents must also be approved by the IRB.
- If the person performing the informed consent does not speak the preferred language of the subject, an interpreter must be present during the consent.
- Ensure the consent is written at no higher than an eighth-grade level, using lay language relevant to the study.
- Ensure the information in the informed consent does not conflict with the protocol in any way. If there are conflicts, resolve them so both documents contain the same information. If the documents are generated by a sponsor or Clinical Research Organization (CRO), bring the conflicting information to their attention to resolve.
- For applicable clinical trials, include a specific statement that refers to the trial's description on www.clinicaltrials.gov.
- Ensure that all key research personnel listed on the informed consent form have current approved Human Subjects Research Protection Training.
- Prepare all study documents including the informed consent form, final protocol, study manuals, questionnaires, all recruitment materials and any other applicable study documents for critical review by the PI prior to IRB submission.
- If the consent form has been provided by a sponsor or CRO, send any revisions made to the consent form back to the sponsor or CRO for their approval.
- Submit the informed consent form with supporting documents referenced above for IRB review after PI approval (and sponsor approval, if applicable) is obtained.
- Ensure that the informed consent form is not used prior to IRB approval.
- Ensure that the IRB approved informed consent form is documented with a valid version date and stamp on it.
- Retain a copy of the IRB approval letter for the protocol and the IRB stamped informed consent form in the study regulatory file.

6.2 The PI and/or other key personnel obtaining informed consent will:

- Possess current UTRGV IRB-approved Human Subjects Research protection training. The PI must be listed on the informed consent form, however other research staff can act on behalf of the PI as long as they have been delegated by the PI to do so. All delegations must be documented.
- Ascertain that the most current IRB stamped informed consent form is used prior to discussion with the potential subject.
- Ensure that the informed consent process is conducted in a quiet, comfortable, and private setting.
- Properly discuss/inform potential subjects regarding study events, risks/benefits, voluntariness of participation, and other information detailed in elements of the informed consent form to ensure that subjects understand the content and meaning of the research related information.
- Ensure that the subject can provide voluntary consent free from coercion or other undue influence.
- Provide the potential subject sufficient time to consider all options. Allow them ample time to read, review, ask questions and, if applicable, take home the informed consent document to discuss the research with family, friends, and/or others.
- If participant chooses to consent, ensure there are no blank spaces or unchecked boxes.
- Ensure that the potential subject signs and dates the form using legal name prior to initiation of any study related activities.
- If consent is being obtained by physical signature, the signature must be in black ink. Ensure that the PI and/or key research personnel obtaining consent signs and dates the form in ink as soon as possible after the study participant has signed.
- If consent is being obtained electronically, an IRB approved method of obtaining compliant electronic signatures must be used.
- Document the consent process in source documents.
- Provide the study subject with a copy of the signed consent form. File the original signed informed consent form in the study subject's source documents or in a separate binder where it will be available upon IRB, sponsor monitor and/or auditor request.
- Since the informed consent process continues throughout the subject's participation in the study, consent should be verified on an ongoing basis.
- Any and all consent changes must be approved by the IRB prior to use.

- Significant new information must be given to the subject and continuing consent/reconsent documented (e.g. consent addendum, amended consent form, or verbal communication otherwise documented).
- Ensure that amended informed consent forms and addendums to consent are signed by all study subjects, if applicable, per the sponsor or IRB directions, and that subjects receive a copy of the signed form. These forms are to be treated as the original informed consent and should be filed with the original.

6.3 An IRB waiver of informed consent for non-FDA studies may be obtained provided the research satisfies all the required criteria from 45 CFR 46.116(d):

- The research involves no more than minimal risk to the subjects.
- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- The research could not practicably be carried out without the waiver or alteration.
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- For more information on determining whether a research study qualifies for a waiver or partial waiver of the authorization requirement, refer to the UTRGV IRB website and handbook.
- The waiver determination is made by the IRB.

6.4 If your study collects or has access to Protected Health Information (PHI), a Research HIPAA Authorization Form must be signed by the subject at the time of informed consent.

6.5 An IRB waiver of Authorization for Use and Disclosure of PHI may be obtained provided the research satisfies all the required criteria from 45 CFR 164.512:

- The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based at least on the presence of the following elements:
  - an adequate plan to protect the identifiers from improper use and disclosure;
  - an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
  - adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized

oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by this subpart;

- The research could not practicably be conducted without the waiver or alteration; and
- The research could not practicably be conducted without access to and use of the PHI.
- The waiver determination is made by the IRB.

7 REFERENCES:

- 21 CFR 50.25 Elements of Informed Consent
- 21 CFR 56.109 IRB Review of Research
- 21 CFR 312.60 General Responsibilities of Investigators
- 45 CFR 46.116 General Requirements for Informed Consent
- 45 CFR 46.117 Documentation of informed consent
- 45 CFR 164.512
- AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research
- UTRGV GA-105
- UTRGV IRB Website Link

8 FORMS OR ATTACHMENTS:

Research HIPAA Authorization Form