SM-404– Protection of Confidential Information

1. **PURPOSE:**
   The purpose of this SOP is to establish guidelines for ensuring the confidentiality of study subjects who participate in clinical research at UTRGV.

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

3. **RESPONSIBLE INDIVIDUALS:**
   The investigator and study staff are responsible for ensuring the protection of confidential information for all study participants.

4. **RELATED TERMS AND DEFINITIONS:**

   Case Report Form (CRF)
   Certificate of Confidentiality (CoC)
   Confidentiality
   Direct Access
   Electronic Protected Health Information (ePHI)
   Personal Identifying Information (PII)
   Protected Health Information (PHI)

   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 personnel engaged in research at UTRGV.

6. **PROCEDURES:**
   6.1 Study staff must only discuss data, material, or study subject information with those associated with the research or involved in the related care of the study subject.
   6.2 Study staff may describe the study to a potential participant during subject recruitment and answer questions to the person's satisfaction within the limits of protecting the confidential information as defined above.

6.3 Designated research personnel will store all study related documents, including regulatory and subject records, in a secure location with access limited to appropriate study personnel.
6.4 All study staff will maintain confidentiality of Protected Health Information (PHI) for each subject.
6.5 Study personnel asked to transmit data will identify subject specific data only with initials and study subject number.
6.6 All study staff will be compliant with HIPAA regulations, when applicable.
6.7 Study team will keep any hard copy materials with Personal Identifying Information (PII) in locked cabinets, offices or suites when not being used in project activities. Electronic source must be password protected.
6.8 After data entry, any materials with PII will be stored or destroyed according to the plan submitted to and approved by the IRB of record.
6.9 Any hard copy materials with PII that are to be discarded will be placed in appropriate receptacle to be shredded. *See UTRGV ADM-10-102*.
6.10 The PI and study staff will ensure that all computer files will be password protected.
6.11 The PI will not include identifying information in publications.
6.12 Any external electronic storage device (e.g. thumb drive) with PII that are to be discarded will be placed in receptacle for proper destruction.
6.13 PII will not be sent via email unless required for the sponsor and/or a federal auditor. Communication must be sent in an encrypted, password protected file.
6.14 Authorization from the PI is needed prior to giving data sets and analysis results to anyone outside the project.
6.15 If working with sensitive or stigmatizing activities, a Certificate of Confidentiality may be obtained from the National Institutes of Health for federally funded studies.

REFERENCES:

- NIH: Clinical Research and the HIPAA Privacy Rule
- FDA 21 CFR Part 56: Institutional Review Boards
- DHHS 45 CFR Part 46 Protection of Human Subjects
- UTRGV DM-502
- UTRGV DM-504
- UTRGV ADM-10-102

FORMS OR ATTACHMENTS:

None