Clinical Research
STANDARD OPERATING PROCEDURE

DM-501– Case Report Form Completion

1. **PURPOSE:**
   To describe the standard procedures to be followed for the collection, transcription, and management of clinical research data to Case Report Forms (CRFs) at UTRGV.

2. **SCOPE:**
   This SOP applies to all data management for all clinical research involving human subjects at UTRGV.
   A sponsor-provided eCRF/CRF manual should be followed, when available, for each study.

3. **RESPONSIBLE INDIVIDUALS:**
   CRF completion should only be carried out by the Principal Investigator (PI) or research personnel delegated by the PI. All delegations must be documented on a study specific delegation log.

4. **RELATED TERMS AND DEFINITIONS:**
   Case Report Form (CRF)
   Data Clarification Form (DCF)
   Documentation
   Electronic Case Report Form (eCRF)
   Quality Assurance (QA)
   Query
   Source Data
   Source Documents

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

5. **POLICY STATEMENT:**
   UTRGV requires all clinical research CRFs be completed in a timely manner. Refer to the Clinical Trial Agreement, when applicable, for exact time frames for individual studies.

6. **PROCEDURES:**
   6.1 An eCRF or CRF manual, if available, should be provided by the study sponsor.

6.2 Research staff members who complete CRFs and eCRFs must receive prior training conducted by the sponsor, PI or research designee. Proof of individual staff training for physical CRFs must be documented in the study training log.

6.3 For eCRFs, only research staff trained to use remote data capture system will enter data for the study using their unique and private username and password. Training certifications for eCRFs must be filed in the regulatory binder.

6.4 For physical CRFs, record all documentation in black ballpoint pen. Do not use pencils.

6.5 Ensure that all entries are accurate, legible, and verifiable with appropriate source documents.

6.6 As required by the protocol, remove patient identifiers from the source document copies and the CRF. Label these documents with the subject identification code as defined by the sponsor.

6.7 Complete all fields on the CRF according to sponsor specifications. If data are not available then write 'unknown', 'not applicable', or 'missing' on the CRF. Do not leave blank spaces.

6.8 Do not create additional fields on the CRF. Provide only requested information.

6.9 Correct an error by striking through the error one time without obliterating the original entry, dating, and initialing it. Explain the correction in a Note-to-File if necessary. Never use correction fluid or obliterate entries made on the CRF.

6.10 Ensure that the data for the CRFs are transcribed promptly and accurately from the source documentation after each subject visit. Institute quality assurance measures such as "double checking" entries to maximize efficiency and eliminate unnecessary data clarifications.

6.11 Physical CRFs should be stored in a secure location during the course of the study and archived when the study has finished.

6.12 When all entries and corrections are deemed to be complete, the CRF/eCRF must be signed by the PI to assert that he/she believes it to be complete and correct.

7. **REFERENCES:**
    - 21 CFR 11 Electronic Records
    - 21 CFR 312.60 General responsibilities of investigators
    - 21 CFR 312.62 Investigator record keeping and record retention
    - FDA Information Sheets, October 1995 Recordkeeping in Clinical Investigations
    - UTRGV DM-502

8. **FORMS OR ATTACHMENTS:**
    None