PURPOSE: This SOP describes the standard procedures to be followed for the collection, transcription, and management of clinical research data to Case Report Forms (CRFs) at the CRC.

SCOPE: This SOP applies to data management for all clinical trials involving human subjects at the CRC.

RESPONSIBILITY: The delegation of responsibility for CRF completion by the investigator should be documented on the appropriate delegation log. CRF completion should only be carried out by the investigator or individuals listed on this form.

DEFINITIONS:

Case Report Form (CRF): A paper or electronic questionnaire specifically used in clinical trial research. The Case Report Form is the tool used by the sponsor of the clinical trial to collect data from each participating site. All data on each patient participating in a clinical trial are held and/or documented in the CRF, including adverse events.

Data clarification form (DCF): A document that requests additional information and/or clarification of data entered on a specific case report form and with its completion with dated signature(s) serves as confirmation, clarification and/or correction of the original data entry.

Documentation: All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

Electronic Case Report Form (eCRF): Auditable electronic record designed to capture information required by the clinical trial protocol to be reported to the sponsor on each trial subject. A CRF in which related data items and their associated comments, notes, and signatures are linked electronically.

Quality Assurance (QA): All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s).

Query: Any question raised during the review of a particular entry on a case report form which is open to different interpretations including various data errors.

Source Data: All information contained in original records and certified copies of results, observations or other facets required for the reconstruction and evaluation of the research that is contained in source documents.

Definitions (cont.):

Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

PROCEDURE:

1. Research staff members who complete CRFs and eCRFs must receive prior training either by the sponsor or research designee. Proof of individual staff training should be documented in training log.

2. Only research staff trained on the 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.

3. Record all documentation in black ballpoint pen. Do not use pencils.

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

5. 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. Complete all fields on the case report forms (CRF's) according to sponsor specifications. If data are unavailable then write 'unknown', 'not applicable' or 'missing' on the CRF. Do not leave blank spaces.

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

8. Correct an error by striking through the error without obliterating the original entry, dating and initialing it, and explaining the correction. Never use correction fluid or obliterate entries made on the CRF.

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

10. If the sponsor uses an eCRF system, ensure that data is entered promptly and accurately from the source documentation, according to sponsor specifications.

PROCEDURE (cont):

11. If the sponsor or CRO utilizes a DCF as the primary data clarification tool, the research coordinator or designee is responsible for clarifying discrepancies and documenting on the form accordingly.

12. CRFs should be stored in a secure location during the course of the study and archived when the study has finished. See SOP 504: Archiving Study Records.

13. When all entries and corrections are deemed to be complete, the CRF must be signed by the principal investigator and/ or designee to assert that he/she believes it to be complete and correct.

REFERENCES:	21 CFR 11 Electronic Records 21 CFR 312.60 General responsibilities of investigators 21 CFR 312.62 Investigator recordkeeping and record retention FDA Information Sheets, October 1995 Recordkeeping in Clinical Investigations Guidelines for the Monitoring of Clinical Investigations, January 1988 International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline, May 1997 USF HRPP Policy and Procedure Manual: Research Record Retention and Accessibility
RELATED POLICIES:	SOP 102: Training Clinical Research Staff SOP 103: Responsibilities of the Research Team SOP 502: Source Documentation SOP 504: Archiving Study Records
APPENDICES:	None
REVISION HISTORY: Keep a running history of all revision dates.	

Approval Date	Effective Date	Review/Revision Date
01/01/2015	**01/01/2015**	