



**Center for Clinical and
Translational Research
Standard Operating Procedure**



Section: **Clinical Research Center**

Date Created: **November 1, 2010**

Title: **Case Report Forms**

Version Date: **January 1, 2023**

SOP Number: **SM39**

PURPOSE: The purpose of this Standard Operating Procedure (SOP) is to establish guidelines and requirements for completing and maintaining case report forms (CRFs) at the site.

SCOPE: This SOP applies to all clinical trials in which University of Nebraska Medical Center (UNMC)/Nebraska Medicine (NM) is responsible for the completion of the CRFs for a clinical research project.

PERSONNEL RESPONSIBLE: The Principal Investigator (PI) is responsible for the data reported to the sponsor in the CRF. The PI may delegate appropriate personnel - Sub-investigators, Study Coordinator, and/or other pertinent staff - to complete this task.

DEFINITIONS:

- **Case report form (CRF or eCRF)** - A printed, optical, or electronic document to record all protocol required information to be reported to the sponsor on each study subject.
- **Source Data** - All information contained in original records and certified.
- **Source Documents** - Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory results, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records) that contain the first recording of pertinent information.
- **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
- **Remote Data Capture** - The process by which investigators and study coordinators use computers at study site to enter clinical data directly into the database without using paper case report forms (CRFs).

PROCEDURES:

- After each research visit and when all necessary information is available, the PI designee will complete applicable CRF pages in a timely manner. This is dictated by the contract, generally 3-5 business days.
- Data reported on the CRF that are derived from source documents will be consistent with source documents. The CRF may be used as an original source document if that form is signed and dated by the individual completing the form.
- Any discrepancies found between source documents and the CRF entries will be corrected on the original CRF and in the electronic record.
- Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e., an audit trail should be maintained); this applies to both written and electronic changes and corrections. Sponsors should provide guidelines to follow for any corrections to data entries. This guidance



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will be followed. NOTE: Sponsor of protocol may require that changes be made on data clarification forms (DCFs) or query forms.

- If changes are made on the source, the person making the changes should sign and date that source as well.
- The PI will sign the required CRF pages only once data is reviewed as complete and accurate.
- The PI-designee will submit completed CRF pages as instructed by the sponsor or sponsor designee as part of the data management process.
- Copies of all sponsor requested data edits will be retained in the subject's file to maintain the data audit trail.
- A legible copy of all CRFs will be maintained at the site or appropriate designated storage facility.
- Electronic CRF's (eCRF) will not be printed.
- The long-term maintenance of the PI's copy of the CRF is the responsibility of that investigator.
- CRFs and all study related material become the PI's or their department's responsibility once data lock is complete. The department should provide boxes that will be used to return all study related documents. Those boxes will be inventoried, and a list provided to the department.

Procedures specific to electronic data capturing systems used for CRFs

- The PI or his/her designee will obtain from the sponsor the following information pertaining to remote data capture for the protocol:
 - Hardware and software necessary to fulfill protocol requirements concerning data capture
 - Names and contact information for support services associated with the system
 - Manual of instructions/operations
 - The source data worksheets (if applicable) and/or eCRF screenshots to assist in developing site source worksheets & data entry personnel requirements
- If a remote data capture device/equipment is used by subjects, specific subject instruction materials for use in the research will be developed or obtained from the sponsor. These materials must be reviewed and approved by the Institutional Review Board.
- Only research staff trained on the system will enter data for the study using their unique and private username and password.
- Training certifications for eCRFs will be filed in the regulatory binder.



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RESOURCES:

- Title 21 CFR 312.62 - Investigator Record Keeping and Record Retention for Clinical Drug or Biological Trials
- Title 21 CFR 812.140 - Investigator Record Keeping and Record Retention for Device Trials
- ICH GCP Consolidated Guideline (E6) - Part 4.9 Records and Reports

Department Approval

Signed Serena Gaines
Research Nurse Manager

Signed: 2/21/2023

Signed [Signature]
Assistant Vice Chancellor for Clinical Research

Signed: 4/3/2023