

Section Clinical Research Center

Date Created: November 1, 2010

Title: Case Report Forms

Date Reviewed/Modified: July 21, 2021

SOP Number: SOP- 4

Version Number: 5

**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 of protocol required information to be reported to the sponsor on each study subject.
- **Source Data**-All information contained in original records.
- **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 Entry**- 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 will not be used as an original source document unless indicated in the protocol.
- Any discrepancies found between the source document and the CRF entries will be corrected on the original CRF and in the electronic record.
- Any change or correction to a printed CRF should have one line drawn through the error, be dated, initialed, and explained (if necessary) and should not obscure the original entry; electronic changes and corrections will have an audit trail. Sponsors should provide guidelines to follow for any corrections to data entries. This guidance will be followed.

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

- 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 paper 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.
- In some cases, the final electronic CRFs for the study will be provided to the investigator in an electronic format (USB, CD, etc.). If this is the case the investigator will verify that the information is complete. This should be stored with all other study related documents keeping in mind this contains subject's Protected Health Information (PHI)
- 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 use 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

### **Staff Accountability:**

Developed By: Director of Clinical Research Operations, Clinical Research Center  
Associate Vice Chancellor for Clinical Research, Clinical Research Center

Reviewed By: Research Nurse, Clinical Research Center

### **Department Approval**

Signed *LuAnn Larson*  
Director of Clinical Research Operations

Date: Jul 21, 2021

Signed *Matt Lunning*  
Medical Director of Clinical Research Center

Date: Aug 2, 2021









# SOP-4 Case Report Forms- Final Edits

Final Audit Report

2021-08-02

Created:	2021-07-21
By:	Charles Miller (charles.miller@unmc.edu)
Status:	Signed
Transaction ID:	CBJCHBCAABAAUhN_rRCs7ltgddPkKv6lpP4faOzXS6Z1

## "SOP-4 Case Report Forms- Final Edits" History

-  Document created by Charles Miller (charles.miller@unmc.edu)  
2021-07-21 - 8:26:40 PM GMT- IP address: 192.94.102.5
-  Document emailed to LuAnn Larson (llarson@unmc.edu) for signature  
2021-07-21 - 8:27:31 PM GMT
-  Email viewed by LuAnn Larson (llarson@unmc.edu)  
2021-07-21 - 8:31:43 PM GMT- IP address: 35.230.6.182
-  Document e-signed by LuAnn Larson (llarson@unmc.edu)  
Signature Date: 2021-07-21 - 8:32:05 PM GMT - Time Source: server- IP address: 35.247.116.78
-  Document emailed to Matt Lunning (mlunning@unmc.edu) for signature  
2021-07-21 - 8:32:07 PM GMT
-  Email viewed by Matt Lunning (mlunning@unmc.edu)  
2021-07-21 - 9:04:44 PM GMT- IP address: 192.94.102.11
-  Document e-signed by Matt Lunning (mlunning@unmc.edu)  
Signature Date: 2021-08-02 - 4:07:26 PM GMT - Time Source: server- IP address: 35.230.6.182
-  Agreement completed.  
2021-08-02 - 4:07:26 PM GMT