Case Report Form Compliance

VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES

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1. PURPOSE

This Standard Operating Procedure describes the minimally required procedures for collecting and transcribing data to paper or electronic case report forms (CRF), and managing research project-specific CRFs for clinical research projects conducted at VCU/VCU Health institutions, affiliates, and participating sites.

2. REQUIREMENTS

The collection of complete, accurate, and verifiable data is essential to meet the objectives of a research study. To that end, key research personnel should collect and manage research participant data in a responsible manner that is compliant with study requirements and all federal, state, and local regulations. CRFs should be protocol-specific and designed in such a way as to facilitate the collection of specific data elements required by the study protocol.

To ensure the integrity of data collected in the course of a clinical trial, the electronic systems involved in clinical trial data management at VCU/VCU Health will have strict controls on system set-up, access, and secured use.

3. DEFINITIONS

Case Report Forms (CRFs)- CRFs are the official clinical data recording document or tool for both sponsors and regulatory authorities and may take the form of paper documents, electronic systems, or a combination of both.

4. PROCESS

To deliver the highest quality research data, data collection should adhere to the following standards and procedures:

- Each research project should have CRFs based on the study protocol and approved by the investigator or sponsor.
- CRFs may be electronic, paper, or a combination, as determined by the sponsor or sponsor-investigator of the study.

- Prior to the initiation of research-project activities, the study-specific CRFs and data collection instructions should be available to key research personnel for review. The instructions should provide requirements for data collection, storage, and transmission.
- At or before the site initiation visit or the initiation of study activities, key research personnel should be trained on the proper completion, retention, correction, and transmission of CRFs as required by the sponsor. For studies utilizing EDC (electronic data collection) systems, set-up, oversight, and training of personnel on the electronic data management system are the responsibility of the sponsor or sponsor-investigator throughout the contracted period.
- Only the Principal Investigator (PI) or the delegated study site staff may make entries, corrections, or comments on the CRF pages/electronic forms. The final verification and signing off of CRFs can only be done by the PI or designated study staff.
- All data entered on CRFs must be legible, complete, and verifiable from source documents. Data inconsistent with source documents should be resolved, explained, and documented by the PI or designated member of the research team.
- For paper CRFs, only indelible ink should be used, unless otherwise instructed by the sponsor of the study.
- For paper CRFs, errors should be corrected by striking through the error with a single line, making the correction, and dating and initialing the correction. White out should never be used on source documentation or paper CRFs. The original entry should not be obliterated by the correction. If necessary, note an explanation or clarification in the margin of the CRF.
- In the source document or laboratory report, the investigator should comment on and document any clinically significant abnormalities noted from the laboratory values that are outside the reference range to avoid the generation of data queries.
- All data fields should be complete per sponsor or sponsor-investigator instructions.
- Personal Health Information (PHI) should be removed and not included on any photocopies or printed copies of source documents and CRFs, electronically or with indelible ink, and replaced with the participant study-specific identifier when the document is being sent externally to non-VCU/ VCU Health systems. Exceptions to this requirement must be approved by the Institutional Review Board.
- All data should be entered onto study-specific CRFs. CRFs should be completed in a timely manner following a participant visit or contact and, in a timeframe consistent with sponsor or sponsor-investigator requirements.
- Data queries and/or clarifications should be addressed in a timely manner consistent with sponsor or sponsor-investigator requirements and should be kept with the participant study files.

- When modifications to the CRFs are required, appropriate personnel must be trained on the changes.

5. REFERENCES

A. US Code of Federal Regulations
   - 21 CFR 312.62(b): Case Histories (Drugs/Biologics)
   - 21 CFR 812.140(a)(3): Investigator Records

B. Good Clinical Practice
   - ICH Harmonised Guideline Guideline For Good Clinical Practice E6(R3)
     - Section 4 – Investigator
       - Section 4.5 – Compliance with Protocol
       - Section 4.9 – Investigator Records and Reports

Review/Revision History CR-CO-505

Version No.	Effective Date	Description
CR-CO-505.3	08/05/2025	● Aligned with HRPP toolkit ● Aligned with ICH E6(R3) ● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-505.2	06-01-2021	● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-505.1	06-01-2018	● Original