Data Clarification		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-CO-515.3	Status: Final	Version Date: 07/22/2025 Effective Date: 08/04/2025

1. PURPOSE

This Standard Operating Procedure defines the generally accepted processes to be followed in relation to data clarification for paper case report forms (CRF) and electronic data capture systems (EDC).

2. REQUIREMENTS

Data clarification is usually carried out through the generation of data queries by the data manager (usually the sponsor) to the principal investigator (PI), whereby the PI or designee clarifies or corrects data discrepancies. All queries raised must be addressed in a timely manner consistent with sponsor requirements.

3. DEFINITIONS

Data Clarification

Data clarification is one of the data validation steps for clarification of discrepancies found in the data submitted by the study team. It is an important step in dataset cleaning by the sponsor or contract research organization (CRO) data manager for subsequent statistical analyses of the study.

4. PROCESS

Each study has a unique set of procedures for the PI to complete data clarification or data query resolution. The generally accepted procedures are detailed below.

A. Prior to data clarification, the PI:

- Designates study personnel to perform data clarification duties for each study (reference VCU/VCU Health Standard Operating Procedure (SOP) CR-CO-525: Delegation of Authority).
- Ensures standard operating procedures and/or written guidance documents for data clarification or data query resolution are in place. The designated study personnel should review and understand the procedures before the study starts.
- Identifies and communicates with delegated study personnel the designated timelines for query resolution defined by the sponsor.

B. For paper-based CRF studies:
- Once the data queries have been received from the data manager or the monitor, the study team should respond to the query as soon as possible within the scheduled time frame, if any.
- All queries generated by the monitor or sponsor should be documented on data clarification forms (DCFs). The designated study personnel must review the forms and identify the data in the CRF for each query on the DCF.
- Each query should be checked against the data in the source documents by study personnel.
- When corrections to CRF entries are required, the delegated study personnel should follow the sponsor's established correction procedures.
- The delegated study personnel responsible for responding to queries should sign and date the DCF. The PI may need to verify and sign off the data query form depending on study requirements.
- For reasons of confidentiality, the study participants' full names should never appear on the DCF.
- A copy of the completed DCF should be filed in the appropriate location designated by the sponsor.

C. For an electronic data capture-based study:
- Data queries will appear in the designated EDC system. The delegated study personnel should check and respond to pop-up queries or query icons frequently within the required timelines, if any.
- Check each of the queries against the data in the source documents.
- Change incorrect data by entering the correct information in the EDC according to EDC system specifications.
- The PI may need to verify and sign the data query depending on the sponsor's requirement.
- Facilitate the monitor in performing source data verification on the corrected data by making the relevant hospital records and/or other source documents available during monitoring visits.
    - Remote monitor access must follow current VCU Health processes which are available through VCU Health intranet, SOP "Clinical Research Sponsor/Contract Research Organization Representative Electronic Health Record & Facility Access."

5. REFERENCES

A. ICH Harmonised Guideline Guideline For Good Clinical Practice E6(R3)
B. VCU/VCU Health Standard Operating Procedure (SOP)
- CR-CO-525: Delegation of Authority

C. VCU Health Standard Operating Procedures

- Clinical Research Sponsor/Contract Research Organization Representative Electronic Health Record & Facility Access

Review/Revision History CR-CO-515		
Version No.	**Effective Date**	**Description**
CR-CO-515.3	08/04/2025	● Added information about data queries ● Aligned with ICH E6(R3) ● Aligned with HRPP toolkit ● Updated references ● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-515.2	06-01-2021	● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-515.1	08-10-2018	● Original