Electronic Data Capture Systems

VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES

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1. PURPOSE

This Standard Operating Procedure describes the generally accepted procedures for completing, correcting, and signing clinical research data in sponsor-provided electronic data capture (EDC) systems, including the procedures for quality control and data query resolution. In addition, this SOP describes how data in an EDC system should be archived.

2. REQUIREMENTS

The clinical research sponsor may provide commercially developed or self-programmed EDC systems for a specific study to the study site. A high-standard EDC system is not only efficient in operation, but it also has full support to enable compliance with GCP and applicable regulatory requirements. For instance, regulation 21 CFR Part 11 is applicable to electronic data capture.

VCU also facilitates data collection through electronic Case Report Forms (eCRFs). For investigator-initiated studies, data collection can be done either on a paper case report form or within a university available system (e.g., Redcap). Only staff who have been delegated the responsibility by the Principal Investigator (PI) may enter data into an EDC. Ensure that access permissions granted to investigator site staff are in accordance with delegations by the investigator and visible to the investigator.

3. DEFINITIONS

Case Report Form (CRF) - A data acquisition tool (paper or electronic (eCRF)) designed to record protocol-required information to be reported by the investigator to the sponsor on each trial participant.

Data Acquisition Tool (DAT) - A paper or electronic tool designed to collect data and associated metadata from a data originator in a clinical trial according to the protocol and to report the data to the sponsor. The data originator may be a human (e.g., the participant or trial staff), a machine (e.g.,wearables and sensors) or a computer system from which the electronic transfer of data from one system to another has been undertaken (e.g., extraction of data from an electronic health record or laboratory system).

Examples of DATs include but are not limited to CRFs/eCRFs, interactive response technologies (IRTs), clinical outcome assessments (COAs), including patient-reported outcomes (PROs) and wearable devices, irrespective of the media used.

Electronic Data Capture System (EDC)- An Electronic Data Capture (EDC) system is a software application designed to electronically collect, manage and store research study data.

4. PROCESS

For clinical research that utilizes an EDC system, it will be sponsor or university-provided. Therefore, different EDC systems and the EDC system of each study will be unique. The study site staff should follow the specific procedures required for each study by the sponsor in using EDC. The generally accepted procedures are detailed below.

A. Training and practice on the use of EDC: Before the start of the study, the study site staff designated for the completion of eCRFs must be properly trained to use the EDC system. The training may be self-guided web-based learning, or training by the monitor or a delegated staff member.
Document completion of the training on the staff training record. Some training programs are coupled with certification for the EDC user who completes the training, whereby the EDC user must obtain a certificate after completion of the training. For self-guided web-based training, it is common practice to print the certificate as instructed after completion of the training process.

- During the training or practice rounds of the EDC system prior to study initiation, assess the adaptability of the EDC system to the routine workflow and any non-user-friendly navigation problems, which may lead to a potentially higher error rate. If necessary, the EDC user should communicate their concerns to the sponsor or service provider immediately to determine if modifications are possible.

B. General procedures for logging in and logging out of the EDC system:

- A unique, confidential user ID and password will be issued by the sponsor or system service provider to each designated EDC user. The EDC user must ensure they have received a user ID and password before the study starts.
- The EDC user logs into the EDC system with a unique user ID and password.
- For security reasons, the EDC users should not disclose their user IDs/passwords to anyone else for any purpose.
- The EDC users should not use anyone else's unique user ID/password.
- The EDC users should log out of the system when computer data entry or other data management activities are completed.

C. General procedures for data entry in eCRFs

- Only study site staff designated for eCRF completion by the PI are permitted to perform data entry in eCRFs.
- Data entered by study site staff in eCRFs is derived from source documents such as medical records, laboratory reports, and prescriptions.
- Electronic CRFs will be completed for all study participants who sign the informed consent form.
- Enter data in the eCRF as soon as possible in accordance with any timeline set by the sponsor. Do not use abbreviations for text data.
- A warning message or error note may appear when non-logical data is entered in the eCRF. Read the message carefully and make the necessary changes when appropriate.
- Always double-check data entered in eCRFs to ensure correctness before submission via the EDC. Some sponsors require the investigator to check and approve the data entered and to provide a signature before submission.
- Data may only be changed by designated study site staff appointed by the PI. A reason for the change must be entered in the appropriate data field.
- Refer to the eCRF completion guidelines/user manual, which contains quick tips and navigation. Contact the monitor or help desk for assistance.
- If the EDC system reports the number of queries generated to the PI of each study site, the PI or designated personnel may elect to benchmark query rates between sites as a way to evaluate the quality of data entries and set up a plan for improvement if necessary.

D. General procedures in query resolution in EDC

- Only study site staff designated for data query resolution by the PI are permitted to perform query resolution duties.
- Designated personnel should check frequently for queries generated in the eCRF. The query should be resolved promptly in accordance with any defined timelines by the sponsor.

F. General procedures in signing off eCRFs

- If required by the sponsor, the designated co-investigators or PI reviews and approves the entered data by signing a specific signature field in the eCRF, usually done by entering one's user ID and password as an electronic signature.

- Once a request is made to lock the patient data by data management, the PI provides a final electronic signature in the eCRF.

G. General procedures in archiving study data

- If required by the sponsor, upon completion of the study, a hard copy of the data in the eCRF should be printed out and sent to the PI for a written signature. A copy of the completed CRFs should be archived in the investigator site file at the end of the study in compliance with all applicable federal regulations, clinical trial agreements, and GCP. Study data may also be archived in a secure digital format when applicable according to local regulations and if agreed upon with the sponsor.

5. REFERENCES

A. US Code of Federal Regulations
- 21 CFR Part 11 – Electronic Records; Electronic Signatures

B. Good Clinical Practice
- ICH Harmonised Guideline Guideline For Good Clinical Practice E6(R3)

C. VCU/VCU Health Standard Operating Procedures
- Clinical research management system

Review/Revision History CR-CO-530		
Version No.	**Effective Date**	**Description**
CR-CO-530.3	08/04/2025	● Clarifies what type of data collection can be done for investigator-initiated studies ● Removed signed hard copy requirement; archived completed CRFs instead. ● Updated all definitions ● Aligned with ICH E6(R3) ● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-530.2	06-01-2021	● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-530.1	06-01-2018	● Original