1 PURPOSE

The purpose of this SOP is to describe the procedures to be followed for data entry into an electronic data capture (EDC) system and/or clinical trials management system (CTMS) and discrepancy/query resolution for studies conducted in the CRU.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Version 1.0, 19Sept2024: Initiation of new SOP

3 POLICY

N/A

4 RESPONSIBILITIES

4.1 CRU Director or Assistant Director

- 4.1.1 Ensure that the data collection systems used in the CRU have an audit trail to track changes made to the data once entered into the system.
- 4.1.2 Create or manage the creation of all new studies in CRU-administered data collection systems.
- 4.1.3 Work with the principal investigator to ensure that all study personnel receive the training necessary to accurately enter data into the EDC and/or CTMS.
- 4.1.4 Manage the granting and removal of access privileges to CRU-administered data collection systems for study staff for each study.
- 4.1.5 Ensure that electronic data files stored on the CRU shared drive are only accessible to personnel involved with study conduct.
- 4.1.6 Ensure that there is locked cabinet space available for the storage of paper study records for CRU-coordinated studies.
- 4.1.7 For studies without a data monitoring component, perform periodic data checks to ensure the accuracy and completeness of data entry.
- 4.1.8 After the completion of the study, ensure that records are archived according to IRB, sponsor, and Federal requirements.

4.2 CRU Research Coordinator and/or Laboratory Manager

- 4.2.1 Ensure that any documents received from or samples taken from participants are labeled with the participant's unique study number; biological samples should also be labeled with the sample number, visit number, and the date and time of sample collection, as applicable.
- 4.2.2 Ensure that no information that identifies study participants is entered into the electronic data capture system or transmitted outside of the institution; identifying information will be entered

into the CTMS, but this data will not be transmitted outside of the institution.

4.3.3 Enter the data from the source documents into the CTMS and EDC systems within 5 business days, or within sponsor-provided timelines, of the study participant visit or another event.

4.3.4 Ensure that any corrections made to the data are documented, with the initials of the person making the corrections, the date of the corrections, and the reason for the corrections.

4.3.5 Once the study data is entered into the EDC and CTMS, properly file the participant's source documents in the participant study binder under the appropriate visit tab and store in locked, limited access area.

4.3.6 Check data against available source documents and respond to data correction requests and make corrections to data within 7 business days, or within sponsor-provided timeline.

4.3 Principal Investigator

4.3.1 Ensure that all personnel granted access to the EDC and/or CTMS have received the necessary training on the protocol and EDC system(s), including any electronic assessment tools being used to collect data in the study.

4.3.2 Assign a unique study ID to each participant and maintain the list linking study participant IDs and participant identifying information in a locked storage area with access limited to personnel involved in study conduct.

4.3.3 Oversee the collection, entry, and correction of all data for the study.

4.3.4 Ensure that the data is valid and entered accurately into data management systems.

5 PROCEDURE

5.1 Ensure that data entry systems used in the CRU have audit trail capability.

5.2 Create case report forms in the EDC and build the study in the CTMS.

5.3 Train all study team members who will be entering data on proper use of the EDC and CTMS.

5.4 Grant access privileges to all personnel who have been trained and will be entering study data.

5.5 As participants are enrolled in the study, assign the next available study identification number as their unique study identifier.

5.6 Label all study data forms with unique study participant identifier.

5.7 When source documents are received, enter participant visit data into the EDC and CTMS within 5 business days or other time frame specified by the study sponsor. Do not enter any information that could identify the participant in the EDC.

5.8 When the mistake is found during data entrance, correct the mistake on paper first before entering the data to the EDC and CTMS. All the corrections should be made with a black ink pen with single line through the incorrect text. Initials of the person making the correction along with the date of the correction should be written by the strikethrough.

5.9 Document corrections to data with initials of person making the correction, date correction made, and reason for correction.

5.10 When data entry is complete, file the participant's source documents in the participant study binder under the appropriate visit tab.

5.11 Store all study documents in a locked, limited access area.

5.12 Perform periodic data checks to ensure the accuracy and completeness of data entry.

5.13 Respond to data correction requests within 7 business days or within sponsor-provided timeline, checking data against available source documents.

5.14 As studies end or when study team members terminate employment or transfer to another department, remove their access from data collection systems.

5.15 Archive records according to IRB, sponsor, and Federal requirements.

6. REFERENCES

6.1 International Conference on Harmonisation (ICH) Guidelines – https://www.ich.org/page/ich-guidelines

7 SIGNATURES

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Approved by: _____ Date: 05 Nov 2024

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