Clinical Research Enterprise (CRE)

Standard Operating Procedures

Source Documentation

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Approval: **Approved By** **Date**

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Purpose

The purpose of this SOP is to discuss how source documentation is completed and maintained in the CRE. Study information and findings are recorded initially in a variety of primary records created by the coordinator or sponsor conducting the study or by the person conducting each specific procedure. The documents are referred to as source documentation and must be retained even after CRF entries have been made. The documents are used by the monitor to verify CRF entries. The primary source documents may also be inspected if the FDA audits the site. CRE uses a chart order to maintain consistency among source documentation. Standardization makes the occasional necessity of seeing another coordinator's patients easier.

References

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Scope

This SOP applies to all members of the CRE staff.

Allowable Exceptions

This SOP is meant to be followed without deviation

I. Creating source documents

a. Standard forms used for source documentation have been created for the CRE. These forms are located on shared network folder. The form is reviewed for format, accuracy, and completeness. The form is presented to the staff for comments and suggestion.

   i. Each form will be dated and given a version number

   ii. Forms can be developed or changed by the coordinator for a specific study. Forms should follow the established format as closely as possible.

b. When a new study is assigned to a coordinator, she/he studies the protocol and

begins to develop source documents specific to the trial if the sponsor is not providing source.

II. Format for standardized chart

a. Charts contain a divide which provides a total of 9 sections for separation of different types of source documentation. Each chart is arranged as follows

   i. Section 1 & 2 (inside from cover)

      1. Original Informed Consents
      2. Demographics, including W-9 and medical release forms

   ii. Section 3 (front side of divider)

      1. Correspondence, including any telephone contact, progress notes, prescription refills

   iii. Section 4 (Back side of divider)

      1. Adverse Events
      2. Concomitant Medications

   iv. Section 5 (front of middle divider)

      1. Study visits, including sources documents, physical exams, disease assessments

   v. Section 6 & 7 (back of middle divider)

      1. Medical History
      2. Procedures, including any diagnostic tests performed for the study

   vi. Section 8 (inside back cover)

      1. Labs

Training