

Data Collection

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Requirements

Blank set of case report forms (CRFs), data collection sheets and or study questionnaires (<u>Case Report Form (CRF)</u> resource from NINDS)

Refer to attached guidance to ensure appropriate source documentation

Tips / Additional Information

- Source documents are original recordings of subject or study data.
- Data collection sheets can act as source documentation. For instance, during study visits, subject information is written directly onto worksheets.
- If documents are filed electronically, write a signed and dated note to file indicating the location.
- An industry sponsor will usually provide CRFs to sites. All protocol-required information is transferred from source documents onto CRFs.
- Annotated CRFs or data collection sheets should be monitored.
- Regulations/Guidelines: <u>21 CFR 312</u>

Applicable GCP sections:

- <u>8.3.14</u>
- <u>8.3.15</u>
 <u>4.9.3</u>
- 4.9.3

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Source URL: https://www.researchgo.ucla.edu/regulatory-binder-data-collection

Drupal.jQueryUiFilter.globalOptions('accordion');