Data Collection

Data Collection

Requirements

Blank set of case report forms (CRFs), data collection sheets and or study questionnaires (Case Report Form (CRF) 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: 21 CFR 312

Applicable GCP sections:

- 8.3.14
- 8.3.15
- 4.9.3

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

Drupal.jQueryUiFilter.globalOptions('accordion');