|  |  |  |
| --- | --- | --- |
| **C:\Users\wrighei306\Desktop\images.jpg** | ***STUDY LOGO*** | ***UoG LOGO, if applicable*** |

**SOURCE DATA PLAN DOCUMENT. GUIDANCE AND TEMPLATE.**

|  |  |
| --- | --- |
| Protocol Number: |  |
| Protocol title: |  |
| Principal Investigator: |  |
| Site Number/address: |  |
| Applicable from Date: |  |

**Introduction**: Auditors, monitors and inspectors expect investigators to be aware of the location of the source data and to be consistent in recording them. The precise location of the documentation of the original record is essential to the possibility of reconstructing the clinical trial and allowing for the verification of data to be collected for the trial. The location of source data should be clearly defined prior to subject recruitment.

It is acceptable to add additional columns or lines of information to this plan to properly reflect the source data requirements for each trial with the provision it is deemed acceptable and signed off by those named below.

**What are source documents?**

Source documents are documents which contain source data. Source data is: "All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.” [*Section 1.51, Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)*].

In order to comply with these requirements, the Sponsor of the study is requesting that a source data index be prepared by the site and signed and dated by the principal investigator prior to screening any subjects. This source data index will serve as a tool for monitors, auditors and inspectors in their work of verifying data obtained for the trial and will assist in verifying the trial is obtained in compliance with current legislation and guidelines, and the trial protocol.

**Instructions**:

* The original Source Data Plan is to be completed as part of the site set up process. The type and location of all source data will be collected on the Source Data Plan for the clinical trial noted above. If during the course of the study, any changes to source data type or location occur (e.g. in the event of protocol amendment), an updated REVISED Source Data Plan should be completed only indicating the change (i.e. different from original source data plan).
  + Please be as specific as possible when identifying source data location. E.g., instead of writing “medical records”, which is the collective name covering different document types and locations, write “patient record: dispensing and administration chart”, medical record: continuation”, “medical record: Nurses notes” “ diary card”, etc
  + The original source data document is the first place where the data is recorded: it could be the nurse’s charts or a local lab report. Other examples of source documents are: certified print outs from electronic medical records, study specific work sheets, investigational Product dispensing Log. NOTE: the CRF cannot be used as the source unless it is identified in the protocol as the source
  + Please note in the instance that Source Data is stored in a worksheet that may impact on the care of a patient, it must be made available, in a timely manner, in their medical notes and any originals also retained.

**SOURCE DATA PLAN – ORIGINAL / REVISED (Please delete as appropriate)**

|  |  |
| --- | --- |
| Study R&I Number: |  |
| Protocol Number: |  |
| Protocol title: |  |
| Principal Investigator: |  |
| Site Number: |  |
| Site name and address: |  |
| Applicable from Date: |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **(Customise as appropriate)** |  | |  | |
| **Source Data Type** | **Nature of Source Document** | **Source Document Location** | | **Comments** | |
| Example: Inclusion Crit. #3 | □ Paper  □ Electronic |  | |  | |
| Example: Exclusion Crit. # 4, 5 and 7 | □ Paper  □ Electronic |  | |  | |
| Example: EDSS | □ Paper  □ Electronic |  | |  | |
| Example: Injection administration | □ Paper  □ Electronic |  | |  | |
| Subject Identification | □ Paper  □ Electronic |  | |  | |
| Informed Consent | □ Paper  □ Electronic |  | |  | |
| Study discussion of Informed Consent | □ Paper  □ Electronic |  | |  | |
| Medical History | □ Paper  □ Electronic |  | |  | |
| Demographics | □ Paper  □ Electronic |  | |  | |
| Inclusion / exclusion criteria | □ Paper  □ Electronic |  | |  | |
| Documentation of eligibility | □ Paper  □ Electronic |  | |  | |
| Study visit documentation | □ Paper  □ Electronic |  | |  | |
| Vital signs | □ Paper  □ Electronic |  | |  | |
| AEs / SAEs | □ Paper  □ Electronic |  | |  | |
| ‘QoL’ questionnaire | □ Paper  □ Electronic |  | |  | |
| Record of study drug (tablet) taken at/between study visits | □ Paper  □ Electronic |  | |  | |
| Other (list below): |  |  | |  | |
|  |  |  | |  | |

**IMAGING (delete if not applicable)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Source Data Type** | **Nature of Source Document** | **Source Document Location** | **Comments** |
| **Source Images** |  |  |  |
| **Reports** |  |  |  |

**At times the monitor may wish to conduct a visit remotely, can Source Data at your site be accessed by the monitor remotely? For example, over Microsoft Teams by screen sharing**

YES NO

**Please confirm local process for alerting that a participant is a clinical trial / records flagged with a date of retention (as per protocol)**

|  |  |  |
| --- | --- | --- |
| **Electronic case report flag** |  |  |
| **Label added to paper notes** |  |  |
| **Other, please give details:** |  |  |

**SIGNATURES**

**PI Section**: By Signing this form the PI is confirming agreement that the information on the Source Data Plan is an accurate assessment of where the data will be recorded and maintained during the course of the study. Upon any changes to source data a REVISED Source Data Index form will be completed and forwarded to the Trial monitor (Insert email here).

|  |  |  |
| --- | --- | --- |
| PI Name: | PI signature: | Date (dd/mm/yyyy) |
|  |  |  |

**\*\*\*The original of this form should be maintained at the site as part of the Investigator Site File and a copy forwarded to the Project Manager.** (Insert PM details here). **\*\*\***

|  |  |  |
| --- | --- | --- |
| PM Name: | PM signature: | Date (dd/mm/yyyy) |
|  |  |  |

**\*\*\*Please retain copy in PM of TMF and forward copy to Sponsor Trial Monitor.\*\*\***

**Sponsor Monitor department**

|  |  |  |
| --- | --- | --- |
| Trial Monitor Name: | Monitor Signature: | Date (dd/mm/yyyy) |
|  |  |  |