**SOURCE DOCUMENT PLAN: GUIDANCE AND TEMPLATE**

It is important to make clear to all study team members, study monitors (where applicable) and potential auditors which document is the source document. That is, the **original recording** for each item of data you collect for a study.

The source data and their capture methods should be clearly defined prior to participant recruitment (i.e. in the protocol or in a study-specific source data plan).This list should be prepared by the site and signed and dated by the principal investigator. The list should be filed in the investigator’s site file (study binder).

**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 or clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.” [*Section 1.51, Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA Comments*].

Examples of electronic or hardcopy documents that contain source data can include:

* medical records [now Electronic Medical Record (EMR)];
* participant diaries;
* researcher diaries;
* memos;
* recorded data from automated instruments (e.g. blood pressure measurement);
* participant - or researcher-completed questionnaires or rating scales;
* videos;
* photographs;
* pharmacy dispensing and other records;
* laboratory results;
* ECGs and reports;
* imaging scans and reports

When data is entered directly into your electronic Case Report Forms (data collection forms) or database, the Case Report Form/database becomes your source document for that information. For source data being captured directly into an *instrument* (the CRF, a diary or other site-designed worksheet), whether it be paper or electronic, the following factors should be considered when designing the instrument:

* the data collected should match the data that the protocol specifies will be collected;
* the investigator or participant response should not biased by pre-set values present within the instrument. An optional comment field may be appropriate to record additional information, in an event where the pre-set values available do not match the type of data collected.

 **Why are source documents important?**

Source documents are used to:

1. Confirm the study participant exists.
2. Confirm the reported study data is accurate (data integrity).
3. Confirm the study is conducted according to the protocol.
4. Confirm compliance with Principles outlined in the following:
* National Statement on Ethical Conduct in Human Research
* Australian Code for the Responsible Conduct of Research
* Notes for Guidance on Good Clinical Practice (with TGA comments)
* RCH Research Ethics and Governance procedure ‘Investigators’ Responsibilities in Research’

Researchers are required to comply with this to provide/consider participant safety & rights, data validity and mitigate against institutional risk.

**Preparing a source document plan**

1. Review your protocol for your key data points and work out where you will first record / obtain this data. Examples of source data and their corresponding source documents are included in the following table:

|  |  |
| --- | --- |
| **Source data**  | **Source documents – types**  |
| Blood pressure measurement | Medical record or participant study file or Direct onto case report formor Automated monitor printout  |
| ‘Quality of Life’ questionnaire responses | Participant diary (paper/electronic)or Direct onto case report form |
| Survey question response | Survey form completed by participant or interviewer  |
| Record of study drug (tablet) taken at/between study visits by participant | Participant diary (hardcopy or electronic device), pharmacy dispensing log |
| Dose of study drug – calculation | Drug calculation worksheet (ideally) |

1. There should only be one source defined at any time for any data item.
2. With regards to electronic source data, the earliest record that it is practical to retain should be considered as the location of the source data and therefore the source document.
3. With regards to using an electronic medical record (EMR) for source data, it is preferable to list the actual location within the EMR for each parameter. This will increase efficiency of Monitors by reducing monitoring time and decreasing data queries.
4. Turn the page for a sample source document plan – customise this template to your study.

**SOURCE DOCUMENT PLAN**

|  |
| --- |
| **Protocol Number** |
| **Protocol Title** |
| **Principal Investigator** | **Site Name** |

|  |  |
| --- | --- |
| ***Parameter***  | ***Source Document*** |
| Participant information and consent form | *e.g. aEMR (original uploaded), bREDCap (i-pad consent) or paper*  |
| Documentation of consenting procedure | *e.g. EMR, REDCap or paper cCRF* |
| Inclusion & exclusion criteria | *e.g. EMR* |
| Randomisation Number |  |
| Demographics | *e.g. EMR* |
| Medical History | *e.g. EMR, correspondence (GP, family)* |
| Physical examination |  *e.g. EMR, REDCap or paper CRF* |
| Prescribing of study drug, including correct dosage | *e.g. Pharmacy dispensing records and EMR* |
| Study visits dates  |  |
| Study procedures  |  |
| Physical examination | *e.g. Direct entry to REDCap or EMR – or paper record*  |
| Vital signs | *e.g. Direct entry to REDCap or EMR – or paper CRF*  |
| Height & Weight | *e.g. Direct entry to REDCap or EMR – or paper CRF* |
| Questionnaire completion (participant/parent)  | *e.g. Direct entry by participant to REDCap or onto paper questionnaire – or paper questionnaire*  |
| <insert other study specific procedures> |  |
| <insert other study specific procedures |  |
| <insert other study specific procedures> |  |
| Pathology results | *e.g. Direct entry to EMR (if RCH lab)* |
| ECG |  |
| Concomitant medication checks  | *e.g. Direct entry to REDCap or EMR* |
| Adverse Events | *e.g. Diary, Direct entry to REDCap or EMR – or paper record, laboratory reports**Important Notes:** Some information on the SAE CRF could be used as source documentation (e.g. Assessment of relationship to drug, severity of the event) IF that is where it is initially recorded.
* The data that is source documentation must be signed/initialled and dated like other documentation (when entering directly to an electronic system requiring a unique username and password these will act as the signature).

Specify the source document for each data element captured on the SAE CRF |
| Serious Adverse Events | *e.g. EMR (if RCH event) or alternative record such as other hospital discharge summary, laboratory reports**Important Notes:** Some information on the SAE CRF could be used as source documentation (e.g. Assessment of relationship to drug, severity of the event) IF that is where it is initially recorded.
* The data that is source documentation must be signed/initialled and dated like other documentation (when entering directly to an electronic system requiring a unique username and password these will act as the signature)
* Specify the source document for each data element captured on the SAE CRF
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*aEMR – Electronic Medical Record*

*bREDCap - secure, web-based application designed to support data capture for research studies*

*cCRF – Case Report Form (data collection form)*

**Comments:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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I acknowledge that the source documentation for this study is as listed in this Source Document Plan.

**Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** (*signature*)

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**