Standard Operating Procedure

SOURCE DATA DOCUMENTATION

SETTING Trustwide

AUDIENCE All research staff involved in collecting and recording source data, and managing source documentation for studies hosted by UHBW

ISSUE To define source documentation and describe how it should be created and managed to ensure data quality, data integrity, and compliance with GCP and all relevant legislation.

QUERIES Research & Development (R&D) department 0117 34 20233 or research@uhbw.nhs.uk

Document History

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Review date	Version number	Version date	Effective date	Author/ Reviewer	Authorised by
N/A - original	1.0	10/JAN/2022	02/MAR/2022	Sarah Bishop	Diana Benton on behalf of TRG
FEB/2023	V1.1	22/FEB/2023	01/APR/2023	Lucy Riddolls	Margie Pavey
MAY/2024	V1.2	03/MAY/2024	08/MAY/2024	Jess Bisset	Margie Pavey

Version Number	Reason for change
Original V1.0	N/A Original
V1.1	Departmental name change from Research & Innovation to Research & Development. Updated throughout SOP as a minor amendment.
V1.2	Minor updates as part of biennial review

1. Introduction

Data generated from research plays a fundamental role in determining the study outcome and subsequently the direction of future research/treatments.

Appropriate documentation is therefore an essential part of any clinical trial as it supports the work undertaken, enables the clinical management of subjects and permits the accurate reconstruction of the trial.

As a result, clinical information should be recorded, handled and stored in a way that enables accurate reporting, interpretation and verification, whilst the confidentiality of the trial subject's records remains protected (Part 2(9) to Schedule 1 of SI 2004/1031).

Depending on the complexity of the trial design and the number of data points required, the source data requirements are likely to vary.

Additionally, clinical trial data can originate from various sources, for example: medical records, electronic laboratory records subject diaries (paper and/or electronic) pharmacy dispensing records, radiological images etc.

Because of this variability, it is not always possible to have a standardised method of recording clinical source data. However, irrespective of the type of source data utilised, the principles of GCP and all relevant legislation should still be applied throughout. Similarly, practices to ensure good source documentation and data integrity should be implemented.

2. Purpose

The purpose of this SOP is to describe how source data should be recorded and source documentation managed to ensure data quality, data integrity, and compliance with GCP and all relevant legislation.

3. Scope

In Scope: Research sponsored by other organisations and hosted by UHBW.

Out of scope: Research sponsored by UHBW (see SOP 012 Study Data).

4. Responsibilities

The R&D department has a responsibility to ensure that staff delivering research at UHBW are fully aware of the source data capture and management standards which must be complied with.

All research staff undertaking research at UHBW who collect, and record source data are responsible for ensuring the applicable source data documentation standards are met as described in this SOP, the applicable regulations and with GCP.

5. Abbreviations and Definitions

Abbreviations	
CRF	Case Record/report form
eCRF	Electronic Case record/report form
GCP	Good Clinical Practice
SDS	Source Data Sheet
SDV	Source Data Verification
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust

Definitions	
CRF	Document used to record the required data as defined by the protocol for each participant throughout their participation in the study
eCRF	An auditable electronic record of information that is reported to the Sponsor on each trial subject, as per the study protocol.
Source Data	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. Source data are contained in source documents (original records or certified copies) and can be in paper format, electronic format, or a combination of the two.
Source Documents	Original documents, data, and records. Examples include: hospital records; clinical/office charts; laboratory notes; memoranda; subject diaries or evaluation checklists; pharmacy dispensing records; recorded data from automated instruments; copies or transcriptions certified after verification as being accurate and complete; microfiches; photographic negatives; microfilm or magnetic media; x-rays; subject files and records kept at pharmacy, laboratories and/or medicotechnical departments involved in the trial.

6. Procedure

6.1 Source Data

ICH GCP defines source data as:

'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.'

In essence it is the where the data is first captured (either written or electronically).

Source data collection and management practices should be discussed by the research team with the sponsor during the set up stages of the study in line with the protocol requirements.

The location of source documents and the associated source data should be clearly identified at all points within the data capture process. In order to conduct SDV the sponsor must be aware of what constitutes source data. It is therefore recommended that prior to the start of study recruitment there is an agreement with the sponsor covering how, when, where and what source data are recorded. This may be in the form of a 'Source Data Log', a note to file, a list specifying what comprises source data or a study-specific source data agreement. Alternatively data capture methods may clearly be defined in the protocol.

This agreement (or source data log/note to file/protocol) should include details of the data to be transferred (e.g. to CRFs), the origin and destination of data, parties with access to source data and transferred data, and timing of data transfers. The source data agreement (or alternative) should be stored within the Investigator Site File (ISF).

Where data will be entered directly into the CRF i.e. the CRF is the source data, these data should be clearly identified and detailed in the protocol as the source.

6.2 Source Data Sheets

If the sponsor deems that routine collection from data in the medical notes will not be sufficient for trial purposes they may provide the site with study-specific Source Data Sheets (SDS) to facilitate the recording of study specific information in the subject's notes. In this instance it is expected that the UHBW site delivery team will review the SDS during study set up and raise any issues/concerns back to the Sponsor prior to the study commencing at UHBW.

Where the Sponsor has not provided any SDS, and it is agreed locally that routine data capture will not be sufficient to capture all trial requirements, a site specific SDS will be developed. The SDS will be designed by an appropriate member of the delivery team responsible for the study based upon the requirements of the trial protocol and CRF/eCRF. The SDS must then be reviewed and authorised by a senior member of the delivery team and the sponsor prior to the opening of the study at UHBW. The review process and any subsequent amendments should be documented and available for review on request.

SDS must be version and date controlled. The footer of the SDS must contain the short title, protocol version number, SDS type (e.g. screening sheet), and version of SDS, initials of author / amenders and date and include page numbers.

SDS will be reviewed and revised accordingly by the study delivery team and sponsor after the initial participants are recruited to a study to ensure all relevant data is being captured in accordance with the study protocol and CRF/e-CRF.

SDS will be reviewed and authorised by the study delivery team and sponsor upon notification of an amendment and revised as applicable in line with any protocol changes and any changes appropriately documented. Any previous SDS will be superseded by the new version.

SDS must be retained and should be held in the subject's medical record.

For healthy volunteer studies, it is recommended that volunteer records/notes are created to capture source data. This documentation should be maintained and archived separately to trial documentation and be readily available for monitoring and inspection.

6.3 Good Documentation of Source Data

The Principal investigator and research teams should maintain adequate and accurate source documents and trial records that include all pertinent observations on the site's trial participants.

Key decisions and discussions relating to the clinical care of subjects as well as management of the trial must be adequately documented throughout the course of the trial, and retained. Ideally, the documentation will include the rationale behind any decisions and allow reconstruction of decision-making processes.

All forms of source data (whether paper or electronic) should be:

- Attributable. Signed and dated by the person making the entry. (Electronic entries should have clear audit trails). Entries should also include details of staff involved in the consultation and should be countersigned where decisions have been made by staff other than the person making the entry.
- Legible: All data must be readable and permanent. This also applies to metadata that may be recorded to support an electronic record.
- Contemporaneous: Results, measurements or data should be recorded in "real time" as the data was collected. If retrospective entries or annotations are made then this should be obvious, and they should be signed and dated with the date the entries were added.
- Original: Refers to the medium in which the data is recorded for the first time. In instances where a copy is required to replace an original document, the copy must be certified i.e. verified, as indicated by a dated signature, as an exact copy, having all the same attributes and information as the original.
- Accurate: A faithful, complete and reflective representation of the observation or event.

6.4 Modifications to Source Data

An audit trail should be maintained as part of the source documents for the original creation and subsequent modification/transformation of all source data (Requirement 3, ICH GCP 4.9.3 and 5.5.4). This is to ensure that any changes to source data are traceable.

For paper based records, any changes to source data should be signed and dated with the date the entries were added. Any errors should be corrected by drawing a single line through the error, initialling and dating the change, and adding a reason for the error if necessary. Incorrect entries which have had a line marked through them must always be legible and never obliterated. Furthermore, all entries should include details of staff involved in the consultation and should be countersigned where decisions have been made by staff other than the person making the entry.

For electronic based records e.g. laboratory test results in Electronic Health Records (EHRs), secure, computer generated, time stamped audit trails (or alternative methods that fulfil audit trail requirements) should be used to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Such audit trail documentation should be retained as long as the subject's EHRs. Audit trails need to be readable and changes to audit trail data should be prevented by the system. The relevant investigators, sponsors and inspectors should be able to review the audit trail

7. Dissemination and training in the SOP

This SOP will be disseminated to applicable research staff (including R&D) and will be available on the R&D website.

Plan Elements	Plan Details
The Dissemination Lead is:	Research Operations Manager
Is this document: A – replacing the same titled, expired SOP, B – replacing an alternative SOP, C – a new SOP:	A-replacing the same titled, expired SOP
If answer above is B: Alternative documentation this SOP will replace (if applicable):	
This document is to be disseminated to:	All applicable research staff (including R&D)
Method of dissemination:	For major updates to the SOP dissemination will be: 1. To Chief Investigators of UHBW Sponsored CTIMPs 2. Research Unit leads across UHBW 3. Head of Research Governance at UoB (where SOP is applicable) All updates (major and minor to the SOP) will be: 1. Updated on the trust Document Management System 2. Updated on the R&D website 3. Cascaded in the R&D e-bulletin
Is Training required:	All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual (and the Investigator Site File/Trial Master File if required) should be completed to document that the content of this SOP has been read and understood as described in *SOP_007 Research Training UHBW*

8. Related documents

RELATED DOCUMENTS AND PAGES	Medicines for Human Use (Clinical Trials) Regulations (SI/2004/1031) and any amendments Medicines and Healthcare products Regulatory Authority (MHRA), 2014. Good Clinical Practice Guide. Medicines and Healthcare products Regulatory Authority (MHRA) 2012. 4th impression 2015. TSO (The Stationery Office). General Data Protection Regulations Data Protection Act 2018 HRA: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-detailed-guidance/transparency/ SOP_007 Research Training UHBW
AUTHORISING BODY	Trust Research Group
SAFETY	N/A
QUERIES AND CONTACT	Research & Development department on 0117 34 20233 or email research@uhbw.nhs.uk
AUDIT REQUIRMENTS	R&D departmental Quality Management System audits are undertaken annually.