York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
SOP
R&D/S109

Source Data

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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Approved by:	Name/Position:	Mags Szewczyk, Head of Research (Non-clinical)
	Approval Date:	16th January 2024
	Name/Position:	Sarah Sheath, SOP Controller
	Approval Date:	16th January 2024

This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewer	Details of significant changes
1.0	14th February 2024		

Contents

1 Introduction, Background and Purpose

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, source data is where the data is first captured (either electronically or in writing).

Source data is a requirement of all research studies although the location of source data will vary between studies.

Documentation of trial activities and results in participants source notes is essential for the clinical management of the patient and allows for the accurate reconstruction of the trial.

2 Who Should Use This SOP

This SOP should be used by all staff involved in the delivery of research studies sponsored, co-sponsored or hosted by the Trust.

3 When this SOP Should be Used

This SOP should be used in the set up and management of research studies sponsored, co-sponsored or hosted by the Trust.

4 Procedure(s)

4.1 Source documents

Source documents are original documents and records (or certified copies) where study data are first recorded.

ICH GCP defines source documentation as 'Original documents, data, and records (for example, hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches. Photographic negatives, microfilm or magnetic media, X-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).'

In some circumstances the Case Report Form (CRF) may be considered a source document.

4.2 Certified Copies

A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original. When a copy is used to replace an original document (e.g., source documents, CRF), the copy should fulfil the requirements for certified copies.

4.3 Identifying Source Data

To ensure adequate source document management and compliance with the UK Clinical Trial regulations, GCP and the study protocol, a Source Data Location List (R&D/F58) should be completed and discussed as part of the study set up.

4.4 Management of Source Data

Source data are all information in original records and certified copies of original records of clinical findings, observations, or other activities in a study necessary for the reconstruction and evaluation of the research.

Source data should follow ALCOA++ principles:

- Attributable to the person generating the data.
- Legible and permanent
- Contemporaneous
- Original record (or certified true copy)
- Accurate

Data governance measures should also ensure that data is:

- Complete
- Consistent
- Enduring (lasting throughout the data lifecycle)
- Available – readily available for review or inspection purposes

Changes to source data should also be traceable, should not obscure the original entry, and should be explained if necessary (e.g., via an audit trail)

5 Related SOPs and Documents

R&D/F58 Source Data Location List

R&D/S09 Set Up and Management of new Studies by Research Delivery Teams