Standard Operating Procedure	**SOP 17: Source Data and Documentation for Research**
Target Audience	All Research Staff at Buckinghamshire Healthcare NHS Trust
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Prepared by	Research & Innovation Department Governance Team
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Approvals	Head of Research & Innovation - Nicola Bowers

1. Scope

1.1 To outline the requirements for generating, storing and amending source documentation of all clinical research studies conducted by Buckinghamshire Healthcare NHS Trust.

1.2 Source documentation is essential for providing an accurate, reliable and verifiable record of actual events for a clinical research study. The investigator/s responsible for generating and/or amending source documentation, source data and/or source records must only make entries which they know to be accurate and factual.

1.3 All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

1.4 The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

2. Definitions/Glossary

2.1 Acronyms/Abbreviations:

- **GCP** – Good Clinical Practice
- **ISF** – Investigator Site File
- **PI** – Principal Investigator
- **R&I** – Research & Innovation

- **SOP** – Standard Operating Procedure

2.2 Definitions:

- **Audit** – An audit of health or social care involves carrying out a systematic assessment of how well that care is being delivered. Current policy and practice is compared with an agreed standard, so that any problem areas can be identified and improved. Later, the audit can be carried out again to check that the changes made have actually made a difference.
- **Clinical Trial** – An experiment to compare the effects of two or more healthcare interventions. 'Clinical trial' is an umbrella term for a variety of healthcare trial designs.
- **Confidentiality** – During a research project, the researchers must put data protection measures into place, to ensure that all of the information collected about the participants is kept confidential. This means that the researchers must get the participants' written permission to look at their medical or social care records. It also means that any information that might identify the participants cannot be used or passed on to others, without first getting the participants' consent. For example, when researchers publish the results of a project, they are not allowed to include people's names. This confidentiality will only be broken in extreme circumstances: where it is essential for the person's care, treatment or safety, where it is required by a court order, for example in a criminal investigation, or where it is necessary to protect the public.
- **CRA** – Clinical Research Associate: usually a commercially employed person supporting the management of clinical studies, helps with obtaining R&D approval, site initiation, study monitoring and close out.
- **Data** – Data is the information collected through research. It can include written information, numbers, sounds and pictures.
- **Data Protection** – All personal information is protected in the UK by the Data Protection Act 2018. This means that researchers have to put in all the necessary safeguards to protect the confidentiality of the information they collect about research participants. They should explain in the patient information sheet: how the participants' data will be collected, how it will be stored securely, what it will be used for, who will have access to the data that identifies participants, how long it will be kept and how it will be disposed of securely.
- **Delegation Log** – Document detailing who has been delegated each duty by the Principal Investigator.
- **Good Clinical Practice** – Good clinical practice (GCP) is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects.
- **Investigator** – A person who is conducting a (clinical) study. Those researchers leading the team are referred to as chief investigator or principal investigator.
- **Monitor** – The person designated by the sponsor to perform site visits and conduct the monitoring process; e.g. check whether there are any deviations from the protocol and that all source data was transferred into the Case Report Forms correctly.
- **Participant** – An individual who is studied in a trial, often, but not necessarily, a patient.
- **Principal Investigator** – The principal investigator (PI) may be the chief investigator, or where the research is taking place across than one site, the principal investigator is the person at each site who is responsible for the day to day running of the research project.

- **Source Document** – To document the existence of the participant and substantiate integrity of trial data collected. Includes original documents related to the trial, to medical treatment, and history of subject.

3. Responsibilities

3.1 This SOP applies to all clinical trials/research studies within the Trust. It is important to note that for trials/studies that are not sponsored by the Trust, the external sponsor may require use of their own SOPs (including source documentation), and it is the responsibility of the PI to ensure external SOPs can operate without conflict to this SOP and is in accordance with all organizational policies related to research.

3.2 In all cases, investigators and research team members must follow the process within the study protocol for source documentation, as approved by the R&I Department.

3.3 Data protection and privacy regulations must be observed and upheld by the site in the process of forwarding, processing and storing source documentation for participants.

3.4 The trial/study PI is ultimately responsible for the site's collection, management and verification of source documents and source data.

4. Procedure

4.1 Generating Source Documents and Source Data

- Prior to any clinical research study opening to recruitment, it should be agreed with the sponsor what will be considered source documentation. This will depend on the nature of the study, where the participants will be recruited from and where their clinical data would routinely be recorded (e.g. in the electronic patient records, in paper based medical notes, in specific departmental medical notes, etc.).
- Source data and documents must not be deleted, discarded, or destroyed.
- There are two types of source document: Electronic and Paper.
    - For an electronic document to be considered a source document, it must be within a secured computer system (i.e. Evolve, ICE) with an audit trail, must have electronic signatures and must have users and technical support.
    - For a paper document to be considered a source document, it must be an original document linked to the participant (linked via trial ID, Hospital number, NHS number, participant name) with delegated staff wet-signed signatures present within the handwritten notes or printed documents (i.e. pre-printed form).
- Research staff members generating source data and documentation for their respective trials/studies must be on the trial/study delegation log and be authorised by the PI.
    - Colleagues outside of the R&I Department who generate data/results for participants (e.g. operation notes, blood test results, maternity details) are <u>not required</u> to be on the delegation log.
- Participant identifiers (e.g. trial ID number, Hospital number) must be present on source documents to verify the origins of the source data.
- Clinical narratives on source documents must end with the author's printed name, signature and the date/time it was created.
- The investigator generating source documentation is responsible for providing an accurate, reliable, legible and indelible record of actual events. The investigator must

attempt to complete the data required in source documents to their fullest extent (e.g. completing all required fields in forms).

- All source data must be verifiable in the source documents. Verbal clarifications of data ultimately cannot be verified and are therefore inadequate as source data. The consensus in clinical trials is **if it is not documented, it did not happen**.
- Source data must not be recorded on an inadequate document (e.g. a tissue) or without indelible ink (e.g. written in pencil). The investigator responsible for recording the source data must use an acceptable document (e.g. paper), written with indelible ink.

4.2 Storing Source Documents

- Source documents should be kept in a safe space with no public access. Lockable cupboards/offices are most ideal for paper source documents, whereas password protected software/folders/documents are most ideal for electronic source documents.
- A participants' folder should be made for each trial/study to store paper source documents for each participant, filed in an orderly and organised manner within. The folder should be clearly labelled with the trial/study short name (acronym if available) and local RXQ trial identifier.
- Source documents ideally should not be filed in ISFs as there can be multiple folders and may increase the possibility of losing source documents.
- Electronic source documents must only be saved on a secure Trust network drive. Source documents should not be saved on unsecure local devices (e.g. local pc drive, USB stick, SD card) for data protection and confidentiality reasons.
- Electronic source documents ideally should be saved within password protected folders in which only staff members delegated on the trial/study can access.

4.3 Amending Source Documents

- Only staff members delegated on the trial/study can edit or amend the source documents for verification and audit reasons. Ideally, the PI should sign off on all edits/corrections.
- When editing or correcting data in source documents, one clear line through the erroneous data should be used when crossing out (i.e. ~~example~~). The erroneous data should still be legible. Do not scribble out or cover up (e.g. use white-out) the error.
- After crossing out, the editor must state the reason (i.e. Error, Updated, Duplicate), input the correct data if needed and initial, date and sign beside their correction.

4.4 Accidental Destruction/Ruination of Source Documents

- If source documentation is accidentally destroyed or ruined, a Note to File/File Note will have to be made which explains the situation and documents which source data could not be verified. The PI and sponsor Monitor/CRA should also be notified. All Note to Files/File Notes must be signed off by a delegated member of staff on the trial/study. The Note to File/File Note will then be filed in the trial/study ISF.

5. References

- "NIHR Glossary." *National Institute for Health and Care Research*, 2022, www.nihr.ac.uk/glossary/. Accessed 7 Nov. 2022.
- "Introduction to Good Clinical Practice." *National Institute for Health and Care Research*, 2022, https://learn.nihr.ac.uk/. Accessed 25 Nov. 2022.

- “Good Clinical Practice (GCP) Reference Guide.” *National Institute for Health and Care Research,* 2022, https://learn.nihr.ac.uk/mod/resource/view.php?id=4222. Accessed 25 Nov. 2022.
- “8. Essential documents for the conduct of a clinical trial: ICH E6 (R2) Good clinical practice.” *Good Clinical Practice Network*, 2022, https://ichgcp.net/8-essential-documents-for-the-conduct-of-a-clinical-trial. Accessed 25 Nov. 2022.

6. Related Documents

6.1 Related SOPs:

- SOP 05 – Good Practice for Recording Study Data
- SOP 08 – How to Prepare for a Routine Monitoring Visit
- SOP 23 – Research Data Management and Security

6.2 Templates:

- Note to File/File Note - https://learn.nihr.ac.uk/mod/resource/view.php?id=4118
- Delegation of Duties Log (if not provided by sponsor) - https://learn.nihr.ac.uk/mod/resource/view.php?id=4114
- Source Data QC / audit tool - https://learn.nihr.ac.uk/mod/resource/view.php?id=4164

6.3 Useful Links:

- Source Documents in Clinical Trials - https://clinicalresearchinfo.com/source-documents-in-clinical-trials/

7. Summary

7.1 Key Takeaways:

- Source data and documents must not be discarded/destroyed and must be kept in a safe space with no public access.
- Investigators generating source data and documentation must be on the trial/study delegation log and authorised by the PI.
- Source data must be accurate, reliable and verifiable. If it is not documented, it did not happen.
- It must be possible to fully reconstruct a clinical research study from the source documentation alone.
- GCP, data protection and confidentiality practices must be upheld when dealing with all source data and source documentation.