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Title	**Sponsor Source Data Requirements and Guidance**		

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SOP category	NHS GG&C Sponsor Governance
Staff category	

Staff Category	**R**	**A**	**C**	**I**
R&I Lead Clinical Trial Monitor		X		
R&I Clinical Trial Monitor (CTM)	X			
Project Managers	X			
Chief Investigator				X
Principal Investigator				X
All R&I Staff				X

1. Scope

This standard operating procedure applies to all NHS Greater Glasgow and Clyde Research and Innovation staff and Glasgow Clinical Trials Unit (CTU) staff.

2. Purpose

The purpose of this SOP is to describe the procedures and guidance from the Sponsor regarding source data in clinical trials sponsored by NHS Greater Glasgow and Clyde (NHSGGC) or co-sponsored by NHS Greater Glasgow and Clyde (NHSGGC) and the University of Glasgow (GU). The SOP will provide a definition of source data, describe the types of source used in clinical research and describe the documentation procedure. This SOP can also be followed when undertaking research activity on behalf of another Sponsor i.e. monitoring a trial of behalf of a non-NHSGGC Sponsor.

3. Procedures

3.1. Definition of Source Data/Source Documents

In order to effectively work with Source Data, an appreciation of its definition and potential forms in which it may be encountered is required. A useful definition of Source data in ICH GCP (1.51) is:

Source Data

"***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. Source data are contained in source documents (original records or certified copies"***

Source Documents

"Original documents, data, and records (e.g., 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)"

Source data should be accurate, legible, contemporaneous, original, attributable, complete and consistent (ALCOA).

3.1.1. ALCOA

The acronym **ALCOA** stands for **Attributable, Legible, Contemporaneous, Original and Accurate**. This provides details of the considerations which must be given when dealing with data, by following these rules a high level of data quality will be achieved.

Attributable - Data must be traceable to a person, date, and subject visit. The identity of the person completing a record must be unambiguous. When documenting data on paper, every written element needs to be traced back to the authorised individual who is responsible for recording it. This requires a signature or initials, the date, and an identifier to a subject visit. If corrections/amends are needed on the record, it needs to be initialled, dated, and must explain the reason for the change.

When documenting electronically, the data must be entered by a delegated person using their own unique log-in and audit trails, including changes, must be maintained.

Legible – Data must be easily read. When recording data on paper, the individual must ensure they use a permanent medium (not pencil) and their handwriting must be easily read. To reduce the likelihood of transcription errors, handwriting must be clear.

Contemporaneous - Data must be recorded, signed, and dated at the time of the trial activity, and must not use individual's memory recall. Data needs to be documented in real-time and dated with the current date on paper (no predating or postdating).

Electronic systems must document automatic date and time stamps every time clinical data is entered, edited, or modified with appropriate controls in place.

Original - The source is the earliest record – the first place that data is documented. If corrections or revisions need to be made, changes must not obscure prior entries. Paper source documents must be maintained and kept in their original format and for electronic, an audit trail must track any and all subsequent queries and changes.

Accurate – Source must reflect the trial observations and it is critical that the source is an honest and accurate reflection of the visit. If data requires to be changed then transparency is a must to provide a clear representation of the trial conduct. Changes must be GCP-compliant for both paper and electronic data (Edit checks).

By following the principles of ALCOA the likelihood of transcription errors will be reduced and data integrity will be improved which would allow a trial to be accurately recreated, if required.

3.1.2. Types of Source Data

Source data is documented in source documents which may be in electronic format, paper format or both. The following non-exhaustive list gives some examples of source documents where source data may be located:

- Medical records/electronic health records
- Laboratory reports
- Subject diaries
- Nurses' notes
- Dispensing logs
- Electrocardiogram (ECG) print-outs
- Case report forms (CRF, if identified in the protocol)
- Blood results (signed off electronically or paper copies with investigator sign off)
- X-ray images
- Radiological reports
- Workbooks/Worksheets, etc.

3.2. Identifying Source Data

Data can be recorded in multiple locations at a site and verification of source data is a considerable part of the work of monitors, auditors and inspectors. Therefore, it is essential to identify the location of where this source data is documented, to ensure a trial can be reconstructed. An investigator site taking part in clinical trials sponsored by NHSGGC or co-sponsored by NHSGGC and GU must fully complete, as part of study site set up process, Form 56.002M Source Data Plan and identify all types of source data, location and format. The Source Data plan is a useful tool for NHSGGC monitors, auditors and inspectors to aid their work in verifying that the trial has been performed as per GCP guidelines, current legislation and the trial protocol.

As the location of source data may vary from one investigator site to another, all sites must complete Form 56.002M to ensure the list is site specific. This form is filed in the investigator site file and reviewed by the Clinical Trial Monitor assigned to the trial.

It is viewed as good practice that the identification of any data to be recorded directly on the CRFs (i.e. no prior written or electronic record of data), and to be considered to be source data must be documented in the protocol, ideally at the start of any study.

3.3. Source Data Worksheets/Workbooks

As described in section 3.1, Source is defined as the first place an assessment or observation is recorded. Where data is initially recorded within a worksheet then this will constitute the Source for the patient. This must be a consideration during the design and implementation of a worksheet.

The use of a worksheet for source documentation must accomplish two key items: 1) it satisfies the protocol requirements and 2) demonstrates the patient received the routine standard care in addition to the research assessment (unless standard care has already been documented in the patient's medical notes).

In accordance with Principle 18 of the UK Policy Framework for Health and Social Care (Integrity of the Care Record), ***"All information about treatment, care or other services provided as part of the research project and their outcomes is recorded, handled and stored appropriately and in such a way and for such time that it can be understood, where relevant, by others involved in the participant's care and accurately reported, interpreted and verified, while the confidentiality of records of the participants remains protected."***

This requires that 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, through their medical notes and any originals also retained. Therefore, the site must ensure the relevant data is recorded within the patient's records, or a worksheet (e.g. scan and upload) or a combination of both to ensure patient observations are documented and complete with the aim to avoid duplication.

Worksheets must follow the principles of ALCOA, as described in section 3.1.1, and ensure it is clear who is completing the document, with a signature & date section, patient identifiers clear and data accurate. In addition, in order to ensure worksheets are part of the patient's current medical notes it is easier to produce worksheets which can be uploaded separately rather than a large workbook.

The worksheet is subject to the same retention requirements as source data. If a protocol amendment impacts on the worksheet then management of these updates must be version controlled and a process in place to document these changes.

The generation of worksheets is a Trial and Site specific activity and does not come under the remit of the Sponsor. It is good practice to ensure the worksheets/books are agreed and signed off by the Chief Investigator and ensure their contents are fit for the intended purpose. Input and guidance may be requested from the Sponsor Governance Team, a specific review of developed worksheets by the Sponsor Governance team may be costed during trial set up.

3.4. Sponsor Expectations

The sponsor requires investigators to be aware and maintain control of the location of the source data and be consistent in recording them and provide access, when needed. Data fraud will be dealt with as per SOP 53.002.

Any source data recorded for trial purposes that impacts on the care of a participant must be available in medical notes to other health professionals involved in the continued care of the trial participants.

If using source data worksheets they must be designed accurately to align with the protocol and CRF to avoid an impact to quality. They must be version controlled and a local change

management process must be in place for updating. Site staff must continue to maintain routine documentation as per clinical practice and trial worksheets, however this must not be a duplication of work. The worksheets must either contain all the patient visit documentation or a supplement to the standard of care for the study i.e. trial specific tests.

If a workbook is requested for use across all sites by the trial management team the Sponsor requires source data workbooks/worksheets to be developed following guidelines outlined in this SOP and ensure all aspects of the trial data and ALCOA requirements in compliance, in addition to ensuring the quality of uploading to the patient records.

If source is held electronically the Sponsor expects the same principles of control and availability to healthcare professionals and training to navigate the system in addition to limited user access i.e. a user name and password provided for the monitoring visit duration and access to only requested patients.

4. Referenced documents

- Form 56.002M Source Data Plan
- SOP 53.002 The Handling of Poor Quality and Fraud in Clinical Research

5. Related documents

- SOP 56.002 Project Management Trial Set-up

6. Document history

Version	Date	Description
1.0	15/12/2021	First Release
2.0	08/01/2025	Periodic review, move to new template.