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Data Recording - Source, Case Report Forms, Record Keeping and Archiving

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1.0 Introduction / Background

The International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines defines source data as "Original documents, data and records (e.g. hospital records, clinical and office charts, laboratory notes pertaining to any, memoranda, subjects diaries or evaluation checklists, pharmacy dispending 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)."

Within SWSLHD source data is documented using electronic medical records (eMR) which includes Cerner PowerChart, Odyssey and Mosaiq or paper and in some cases a combination of all methods. Data may also be directly entered into the Case Report Form (CRF) if a clinical investigation can be obtained at a study visit. This direct entry of data can eliminate errors by not using a paper transcription step before entry into the CRF. For these data elements, the CRF is the source. This should be discussed with the Sponsor at the initiation visit and documented on the Source Data Location Form.

The data collected in the CRFs are used for statistical analysis and clinical trial outcomes. It is for this reason that they are closely monitored by the Sponsor, auditors and Regulatory Authorities.

The overall management of data in clinical trials has rapidly moved towards using only electronic data capture platforms. In response the NSW health cyber security framework have been developed to ensure that measures used to protect systems including how information is processed, stored or communicated. These actions ensure all systems are protected with respect to user access and data protection.

Once a clinical trial is completed and closed, all essential documents must be archived stored for the contracted period with the Sponsor. As per the NSW Health Record retention policy (GDA17 8.1.0) for non-clinical studies, documents are required to be retained for a minimum of 5 years after the date of publication or completion of the study. In accordance with ICH GCP essential documents should be retained until at least 2-years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2-years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained.

Following the archival period, documented written approval from the clinical trial Sponsors must be obtained before destroying any records. If the Sponsor is no longer available the approving HREC should be informed.

The National Clinical Trials Governance Framework released by the Australian Commission on Safety and Quality in Health Care defines the responsibilities of Australian Hospitals in assessing and managing risk of clinical trials in Australian hospitals. The health service organisation must ensure that the clinical trial investigators and the workforce have access to comprehensive, accurate and integrated health care records.

2.0 Objective

To describe the procedure for the overall management of data in clinical trials in accordance with all applicable regulatory requirements including source data completion, signing and correcting CRFs, access to medical records and archiving requirements.

3.0 Scope

This SOP applies to all staff involved in clinical trials at South Western Sydney Local Health District (SWSLHD) and the Ingham Institute.

4.0 Ownership and Responsibility

All staff responsible for caring for a participants on a clinical trial will contribute to clinical trial source data. Authorisation to complete CRFs is a responsibility delegated by the Principal Investigator (PI) and must be recorded in the Delegation of Responsibilities Log prior to the task being undertaken and only after the designee has completed the relevant study related training.

All interactions with clinical trial participants will be documented in the medical records in accordance with PD2012_069 Health Care Records - Documentation and Management including consenting visit, clinical trials visits, telephone calls and clinic visits that have a research component.

5.0 Associate Documents

SOP-_CTSU_04 Clinical trials start up

SOP-CTSU_08 Documentation of training and clinical handover

SOP_CTSU_09 Investigator Site File and Essential Documents SOP_CTSU_13

Participant Recruitment

FM_001_Source Data Location form

FM_002_Contact Report

FM_003_Subject Identification Log

FM_005_Records Management

FormFM_028_Handover Form

FM_038_ Monitoring checklist source

FM_044_ Document Destruction Log

6.0 Procedure

6.1 Source Data

The PI and all delegated clinical trials team members are required to maintain adequate and accurate source documents and clinical trial records that include all pertinent observations on every clinical trial participant.

In Line with ICH GCP Guidelines source data should be documented in accordance with the following guidance:

- **Attributable** – it should be clear who made the entry
- **Legible** – the entry must be readable
- **Contemporaneous** – the entry must indicate both when the event occurred as well as when it was entered.
- **Original** – the entry must be the first place the information was recorded
- **Accurate** – the entry must reflect what occurred
- **Complete** – the entry must be complete, with no missing data

The PI or delegate will clearly establish where all source data pertinent to the clinical trial will be located on the Source Document Location Form (FM_001). The PI will ensure that complete and accurate source documents are maintained for the duration of the clinical trial. The following methods are recommended:

- Verbal communication pertinent to the clinical trial data collection must be documented in the participant's medical records using or on a Contact Report using FM002_Contact Report

- Where protocol-specific worksheets are source data, these must be retained in the participant's medical records.
- Entries using paper source should not be overwritten; corrections should be made as follows:
    - The incorrect entry should be crossed out with a single line so it can be read easily.
    - The original entry must not be obliterated or covered up with correction fluid or any other method.
    - The correct data should be entered and the reason for the error should be added if possible.
    - The person responsible for the correction should initial and date the correction.
- SWSLHD electronic medical records have been assessed by the ICT Department as being 21 CRF part 11 compliant which is the globally recognised standard.
- All clinical trial records must be stored securely at all times in a locked, restricted access area in accordance with the NHMRC National Statement and ICHGCP requirements
- Read Only access to individual participant's eMR will be provided to the Sponsor representatives, Auditors and Regulatory Authorities as per local guidelines and polices for access to electronic systems

6.3 Certifying Documents – Hard Copy

A certified copy is a paper or electronic copy of the original document that has been verified by a dated signature or generated through a validated process to produce an exact copy having all the same information, including data that describe the context, content and structure, as the original. If the original document is retained elsewhere, the copy does not need to be certified (e.g., original lab results are filed in the laboratory). The Sponsor may request to see the original documents or certified copies to verify validity of data for clinical trial related monitoring.

The person certifying the documents will:

- Review the original against the copy to confirm the copy is an exact copy of the original
- Document "I certify that this (insert page numbers) paged document is a true copy of the original document" or similar wording on the first page of the copies. This may be handwritten or stamped.
- Print their name, sign and date the copies

If the copied document/s is multiple pages the person certifying can document in 2 manners:

- Sign or initial and date each copied page.
- Number each page of the copy as 'page 1 of 40', 'page 2 of 40' and so on

Certification for copies received from an outside SWSLHD or the Ingham Institute must contain the information above and indicate it is an unaltered copy as received.

6.4 Certifying Documents – Electronic

The SWSLHD and Ingham Institute utilize Site Veeva Vault as their eRegulatory system. A risk assessment should be made to evaluate concerns about accessibility/longevity of an original paper record and whether the creation of a certified copy may be prudent to safeguard against the impact of a lost original. If the plan is for the copy to genuinely replace the original document, a certified copy which meets the requirements of ICH GCP (to have the same information, including data that describe the context, content, and structure, as the original) should be the default option.

Essential documents which are originated or finalised outside of the eISF system may be certified as an exact copy in the eISF system, thus allowing for the destruction of the paper version. The destruction of the document should be certified using FM_044_Document Destruction Log. This applies to regulatory, essential documents and source documents.

The process for risk-based Quality Control (QC) checks for certified copies before destruction of the originals should ensure that the copy is of sufficient quality for the intended purpose and should include the following attestation by the person certifying the copy:

- congruency of the information contained between original and certified copy
- accuracy of file name; including that it is marked as an updated version of an already existing document
- quality of the image (suitable resolution to allow readability as per the original, legibility and reproduction of color (when applicable) and legibility of wet-ink signatures or annotations and handwriting in general etc. (when applicable)
- audit trail associated with the document (when applicable)

6.5 Redacted Documents

Redacted documents are not considered certified copies per ICH-GCP or FDA definitions and therefore cannot be considered to be source documents.

7.0 Case Report Forms – Hard Copy/Electronic

The Investigator and/or delegate should ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor utilising a CRF. In the majority of cases CRFs are managed electronically using a databases. Such databases must comply with 21CFR Part 11 regulations and are approved for use by the SWSLHD Cyber Security Department. Please contact the Clinical Trial Support Unit for vendors approved by SWSLHD Cyber Security Department.

CRFs should be completed according to the specifications of each study, prospectively and where possible as close to the study visit as possible. In all cases the Clinical Trials Research Agreement should specify the timelines for CRF completion.

All data provided in the CRF by the delegated clinical trial team members are required to meet the following guidelines:

- Data entries must be accurate and legible. All data entries must be verifiable with source data from the participant's medical records).
- If data is unavailable an explanation should be written in the CRF. The terms 'not available', 'not done', or 'unknown' are insufficient and should be avoided, unless otherwise specified in Data Entry Guidelines

Electronic Case report forms have in-built editing systems that will capture all data corrections, date, time and require an electronic signature by the user. In the majority of cases CRF are electronic and are managed securely using an individual username and password provided by the sponsor/CRO. All usernames and password need to be kept by the delegated staff member in a secure location adhering to the Access control component of the NSW Health Electronic Information Security Policy.

Paper CRFs are required to be kept in a secure location.

Incorrect data entries using a paper into the CRF require any corrections to be signed and dated, a line place through the incorrect data point and accurate correction made. The person responsible for and legible. All data entries must be verifiable with source data from the participant's medical records.

The participant's identity should remain confidential. The participant should only be identified on the CRF by means of the allocated study number and/or initials. The Subject Identification Log (FM_003_Subject Identification Log) must be kept securely by the PI or delegate within the ISF/eISF. The Sponsor should not be given a copy of this Log.

In most cases the CRF must be signed by the PI or delegate to assert that he/she believes the record to be accurate and complete.

8.0 Archiving

The Institution/ Investigator must maintain a record of the location(s) of their respective essential documents including source documents for archiving. The storage system used (irrespective of the type of media used) should provide for document identification, version history, search, and retrieval.

Archived materials should include all related paperwork such as:

- Investigator Site Files
- Consent forms
- Patient log and details
- Case report forms

8.1 Management of paper documents for archiving

Maintain the clinical trial documents as specified in the ICH-GCP guidelines with reference to the NHMRC National statement.

All essential documents are stored in a secure location please refer to SOP_CTSU_09 Investigator Site File and Essential Documents and as required by the applicable regulatory requirement(s) and take measures to prevent accidental or premature destruction of these documents.

Archiving of a Research study or clinical trial is required to be managed by a designated staff member and/the responsibility of the PI or delegated in conjunction with the Sponsor.

The archiving boxes are required to be stored securely and protected from damage. It is highly recommended that an external archiving facility is used. Clinical trials paper documents at SWSLHD are to be archived at Government Records Repository (GRR). The PI must retain control of access of all archived documents.

The documents need to be easily accessed by the Sponsor or Ethics Office on request for the purpose of an audit or Inspection.

For each study an Archive Document Log is required to be completed to record all documents that are archived in each box used. Refer to FM_005_Records management Form.

Only essential documents are to be archived. All files, folders and plastic outer protective coverings (where applicable), paperclips, staples and adhesive tape need to be removed before placing in the archive box. Paper coverings to separate documents within the archive box are advisable to ensure integrity of file.

Where required, create a certified copy of data. Photocopy items that are printed on thermal

paper (e.g. ECGs, spirometry) and certify as described in Section 6.3.

Some sections of the ISF hold identifiable information e.g. participant ID logs and consent forms. Do not redact the names. Mark the index to state which sections contain identifiable information so this is clear to any future user.

Each clinical trial should be boxed separately i.e. documents from different clinical trials should not be mixed.

8.2 Transfer of Paper Records into an Electronic Format

Original documents may be transferred from paper into electronic format using the process described in Sections 6.3 and 6.4. The Electronic Medical Records and eISF systems utilised in SWSLHD are validated systems and therefore the transfer of paper records into electronic format meets the global clinical trial requirements.

Paper records must be scanned in a logical order (e.g. retaining the study filing/ indexing system) to ensure that trial reconstruction is possible.

8.3 Management of eISF

The archiving of the eISF will be in compliance with the platform used throughout the clinical trial i.e. HP Content Manager, Veeva Site Vault or the Sponsor specific platform.

A copy of the completed Archive Document versions Log should be sent to the Clinical Trials Support Unit (CTSU) and Research Governance Office as a central repository for all clinical trials conducted in the SWSLHD and the Ingham Institute.

9.0 References

ICH GCP (E6 R2): Good Clinical Practice Guidelines - Annotated by TGA

National Statement on Ethical Conduct in Human Research (2023)

Australian Code for the Responsible Conduct of Research (2018)

General Retention and Disposal Authority (GDA17)

NSW Health Record Management, data collection, registers and reporting

NSW Health cyber security framework

https://sites.veevavault.com/

https://sites.veevavault.help/gr/docs/videos/

PD2012_069 Health Care Record - Documentation and Management

Standard on records management

10.0 Amendment History

Version	Date	Amended by	Details of Amendment
1.0	6 January 2020	M Ford	Amended in relation to change to SOP List and local review of all SOPs
2.0	23 February 2024	Erfan Jaberiyanfar	• Updated list of associated documents. • 8.1 – Updated to indicate GRR. • 8.3 – Updated to include RGO. • Grammatical changes. • Update of reference links.

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