Ingham Institute and SWSLHD Standard Operating Procedures for Clinical Trials

Case Report forms, Source Documents, Record Keeping and Archiving

Version:	2, Dated 5th October 2017
Effective Date:	5th October 2017
Review Before:	October 2019

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION

Updated Version

Updated by: Kelsey Dobell-Brown – Clinical Trials Manager – SWSLHD

Approved by: Prof Meera Agar – Clinical Trials Director - Ingham Institute/SWSLHD

1.0 PURPOSE

To describe the procedures related to the completion of case report forms and electronic case report forms, source documents, record keeping, and archiving.

2.0 SCOPE

This SOP applies to all staff involved in clinical research within SWSLHD including, but not limited to, Investigators, Research Nurses, Study Coordinators and Clinical Trial Assistants.

3.0 APPLICABILITY

All staff responsible for caring for a patient on a clinical trial may 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 Log (SOP 06 Delegation of Duties), prior to the task being undertaken, and only after the designee has completed the relevant study related training.

4.0 PROCEDURE

4.1 Completion of Case Report Forms (CRF) electronic Case Report Forms (eCRF)

The investigator(s) and delegated personnel should:

- Ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRF/eCRF and in all other trial required documentation
- CRFs should be completed according to the specifications of each study, prospectively and where possible as close to the study visit as possible. Data from participants' visits should be entered into the CRF within 5 business days from the visit (or insert org specific details). Further guidance for timeframes of CRF completion must be obtained from the Sponsor and if required, documented in the CTRA.
- Data entries must be accurate and legible. All data entries must be verifiable with source data from the participant's medical records. Any discrepancies with the source data should be documented.
- Entries 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.
- 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 participant Identification Log (a confidential record of participants with their full name and study number) must be kept securely by the Principal Investigator.
- The CRF must be signed by the Principal Investigator or designee to assert that he/she believes the record to be accurate and complete.

Updated Version

- CRFs should be kept in a secure location during the course of the study. On completion of the study CRFs should be archived as per study protocol and local regulatory requirements.

4.2 Source documents, record keeping and archiving

The investigator(s) should:

- maintain adequate and accurate source documents and trial records that include all pertinent observations on each of the site's trial subjects. Source data should be:
- **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
- In addition, any changes to source data must be traceable, should not obscure the original entry and should be explained if necessary
- At SWSLHD, protocol specific templates can be used for all patients who participate in a clinical trial to record specific visits. The template is used for both electronic and paper medical records.
- Maintain the trial documents as specified in **SOP_GCP06_01 Appendix 2 - The Study 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.
- Ensure that upon request of the monitor, auditor, HREC, or Local Research and Ethics Office, make available for direct access all requested trial related records.
- As per GCP, study documentation should be maintained for a minimum of 5 years and up to 15 years if a Serious Adverse Event has been reported for adult studies. Or 25 years for paediatric studies.
- For legal reasons or as per NSW Health policy, sites may consider indefinite archiving periods for medical records. Refer to the link listed below - Reference 6.3 – NSW medical record retention policy.
- The TGA position on document retention states:

  "The TGA requires records to be retained by the sponsor for up to 15 years following the completion of a clinical trial. However, in Australia the overriding consideration for sponsors with respect to record retention is the issue of product liability and the potential need for sponsors of products to produce records at any time during, and possibly beyond, the life of a product in the event of a claim against the sponsor as a result of an adverse outcome associated with the use of the product"

- ICH-GCP requirements for record retention state:

Updated Version

"Ensure that essential documents are retained until at least 5 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 5 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period if required by applicable regulatory requirements or by an agreement with the sponsor".

- Original documents should be retained, however secure electronic filing systems are a widely accepted form of corporate record keeping and retention within SWSLHD using a records management system known as HPRM. See glossary for further information.

5.0 GLOSSARY

Case Report Form (CRF)

A printed, document designed to record all of the protocol required information required to be reported to the sponsor about each study participant.

Electronic Case Report Form (eCRF)

An electronic data base designed to record all of the protocol required information required to be reported to the Sponsor about each study participant

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Human Research Ethics Committee (HREC)

A body which reviews research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines.

The National Statement requires that all research proposals involving human participants be reviewed and approved by an HREC and sets out the requirements for the composition of an HREC.

HPRM

HP Records manager (HPRM) has been implemented across the SWSLHD in order to facilitate compliance with NSW state records legislation and Record management standards. The District are obliged to comply with NSW State Records legislation and standards.

The District policy on Records Management (SWSLHD_PD2014_014) indicates that records should be captured into the LHDs recordkeeping system, the approved system being HP Records Manager.

As stated in the District Guideline on Managing Shared Drives (SWSLHD_GL2014_022), Share drives are not recordkeeping systems and are not fully compliant with the *State Records Act 1998*, so they should not be used to store records unless a facility/ service does not have access to the District's corporate electronic Document Records Management System – HP Records Manager.

Updated Version

International Conference on Harmonisation (ICH)

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use is a joint initiative involving both regulators and research-based industry focusing on the technical requirements for medicinal products containing new drugs.

Principal Investigator

An individual responsible for the conduct of a clinical trial at a trial site and ensures that it complies with GCP guidelines. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the Principal Investigator. In this instance they may delegate tasks to other team member.

Source Documents

Source documents are defined as per ICH GCP 1.52 as "Original documents, data and records (e.g. hospital records, clinical and office charts, laboratory notes, 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)." Any person participating in a clinical trial will generate source data from a number of places as identified above.

Source data is 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 or certified).

Sub Investigator

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).

6.0 REFERENCES

ICH Harmonised Guideline "Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2) dated 11 June 2015

http://www.records.nsw.gov.au/recordkeeping/rules/retention-and-disposal/authorities/general-retention-and-disposal-authorities/files/gda17-public-health-services-patient-client-records/view

7.0 APPENDICES

Appendix 1: SOP Change Log

DOCUMENT END

Updated Version

APPENDIX 1: SOP CHANGE LOG

Version No.	*Reason for Issue*
1	First issue – Approved by the Research and Ethics Steering Committee on the 29th September 2015
2	Reviewed and updated as per ICH-GCP E6 R2 Guidelines

Updated Version