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Investigator Site File and Essential Documents

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1.0 Introduction / Background

International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines defines the essential documents that are required to be filed as 'those documents which individually and collectively permit evaluation of the conduct of the trial and the quality of the data produced'. ICH GCP 4.9.4 state that "The Investigator/Institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial"

An Investigator Site File (ISF) is required for every clinical trial to store essential documents. Documentation for each clinical study should be kept in a study specific Investigator Site File with responsibility for maintaining and updating the file clearly delegated on the delegation of duties log.

The essential documents serve to demonstrate the compliance of the Institution and Investigator with all applicable Sponsor and regulatory requirements of the standards of ICH GCP.

2.0 Objective

To describe the requirements for the establishment of an ISF, maintenance and archiving of essential documents for clinical trials in accordance with ICH GCP and Regulations.

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

It is the responsibility of the Principal Investigator (PI) or delegate as documented on the Delegation of Responsibilities Log must ensure that the ISF is established, maintained and archived.

5.0 Associated Documents

SOP_CTSU_17 Data Recording - source data, case report forms, record keeping and archiving

SOP_CTSU_02 Investigator Responsibilities

FM_009_Essential Documents for Conduct of Clinical Trials

FM_010_Overall Investigator Site File Management in Clinical Trial

FM_011_Investigator Site File Content Template

FM_012_Essential Document Storage Location

FM_030_Electronic Investigator Site File Content Template

FM_031_Veeva Vault Document Types

6.0 Procedure

The ISF should be prepared once site selection has been confirmed by the Sponsor as a Clinical Trials Site. The Investigator or delegate is responsible for actively maintaining and updating the ISF and regularly adding study related documents (FM_009_Essential Documents for Conduct of Clinical Trials).

All essential documents, including pertinent correspondence should be filed in the clinical trial ISF within 5 business days of receipt or generation. When available, the final study report should be filed in the ISF.

The ISF should be segmented so that individual trial documentation remains separate, to avoid incorrect filing or loss of documents and correspondence. See FM_010_Overall Investigator Site File Management in Clinical Trial.

Should the PI or the department decide not to participate in the study, the protocol and the ISF will be archived (as applicable).

6.1 Essential Documents

As essential documents individually and collectively permit evaluation of the conduct of a clinical trial and the quality of the data produced they are required to be kept in a secure location with access only to those delegated by the PI. It is the responsibility of the PI or delegate to ensure that all essential documents for the conduct of a study have been collated prior to study initiation and that the ISF is maintained throughout the study and archived as per the Clinical Trial Agreement. SWSLHD and the Ingham Institute have customised essential document templates which should be used for all clinical trials.
All essential study documentation is required to be made available for monitoring, Sponsor audit(s), and regulatory inspection(s) by the regulating authorities.

The version of important documents (e.g. protocol, informed consent forms, case record forms, trial-specific guidelines) should be controlled and contain at least a trial reference number, version and/or date.

Essential documents include, but are not limited to the following:

- Protocol

- Participant Information Sheet and Consent Forms
- Investigator Brochure
- Regulatory documents, applications and responses/approvals
- Delegation Logs
- Safety reports
- Correspondence between delegated site staff and Sponsor

Refer to the Investigator Site File Content Template (FM_011_Investigator Site File Content Template).

The ISF will also incorporate a pharmacy folder (if applicable) that is kept within the site Pharmacy and maintained by the delegated pharmacist. The folder will keep a list of recruited participants, investigational product shipping, receipt and accountability documents. The Pharmacy file will also include the current protocol and Investigator Brochure as well as any other required documentation requested by the Sponsor, or as per local policy. The Pharmacy File will be archived as part of the ISF.

Working copies of documents distributed to members of the clinical trial team should be managed to ensure outdated versions are replaced when amended or updated. Outdated copies should be retrieved and destroyed, retaining at least one for archive.

The PI delegates a member of the clinical trial team to verify contents of the ISF before, during and after completion of the clinical trial. All essential documents. The clinical trial should not start until all essential documents required for ICH GCP are available. And prior to archiving the PI must ensure that all essential documents are filed in the ISF.

All essential documents that are kept in the ISF need to be filed and kept in a secure environment such as a locked office or password protected and secure electronic filing system, refer to FM_012_Essential Document Storage Location for more information.

All essential documents must be archived as per the Clinical Trial Agreement with the Sponsor or in accordance to NSW Health record retention policies. Written approval from Sponsors must be obtained before destroying any records.

6.2 Paper ISF

The ISF should be established using the ISF Contents Template (FM_11_ISF Contents Template).

The following information should be displayed on the cover and spine of the ISF folder, even when supplied by the sponsor:

- Human Research Ethics Committee reference number and Local Project Number
- Name of PI
- Study short name

If an essential document is removed from the ISF, a file note is placed in the ISF stating the purpose of removal and its location.

6.3 Electronic ISF (eISF)

SWSLHD and the Ingham Institute have an eISF called Veeva Vault. Access to the eISF will be administered through the Clinical Trial Support Unit (CTSU) and for any new study requests please email swslhd-clinicaltrialssupportunit@health.nsw.gov.au Training will be provided to all clinical trial staff members using the eISF.

Where all or part of the ISF is held electronically, the same controls should be in place for managing a paper-based ISF. Veeva Vault automatically names documents and amendments are tracked electronically for auditing purposes. See FM_030_Electornic Investigator Site File Content Template and FM_031_Veeva Vault Document Types for more details.

Any process used to convert paper documents to electronic versions (e.g. scanning) should also be validated and used with appropriate quality control checks to ensure data and metadata are not lost. See SOP_CTSU_17 Data Recording - source data, case report forms, record keeping and archiving for more information.

7.0 References

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

Records Management policy for SWSLHD follow link:
http://intranet.sswahs.nsw.gov.au/sswpolicies/pdf/swslhd/swslhd_pd2014_014.pdf

8.0 Amendment history

Version	Date	Details of amendment

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