SOP Number: 70
SOP Title: The Study Master File

SOP number:	**070**
Version number:	4.0
Effective date:	April 2019
Review due:	April 2021
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Amendment History

Version	Date	Author/s	Amendment Details
1.0	1 June 2010	Katrina Brosnan	New
2.0	December 2017	Roberta Lusa &Bernadette Morris-Smith,	All sections, incorporating ICH GCP E6 (R2) and teletrials: QH TELETRIAL PILOT VERSION 1.0
3.0	June 2018	Roberta Lusa	All sections, refinement after CRC input: PUBLIC RELEASE VERSION 3.0
4.0	April 2019	Roberta Lusa	Amendments post Round 1 Health Service Directive Consultation

1 Purpose

To describe the procedures related to the maintenance of the Study Master File (SMF) held at all clinical research Sites/units, according to ICH GCP E6 (R2) Section 8 to ensure it is current at all times for the duration of the clinical study.

2 Responsibility / Scope

Applies to all Queensland Health employees (including visiting health professionals, contractors, consultants and volunteers) who propose to undertake, administrate, review and/or govern human research involving Queensland Health patients, facilities and or staff. All study personnel involved in the clinical study must operate within their scope of practice.

3 Glossary

For an explanation of acronyms and the definition of terms used in these SOPs, please refer to Chapter Two Glossary: The Australian ICH GCP (including Teletrials) SOP Compendium

4 Procedure

4.1. The Study Master File

The Principal Investigator must:

- Ensure an SMF is created, if not provided by the Sponsor, prior to study commencement and it must contain at a minimum the Essential Documents listed in Appendix 1. The SMF is stored at the Primary Site.
- Establish the maintenance rules of the SMF and relationship between Primary Site Study Master File (SMF) and Satellite Site Study File (SSSF). For example, the contents of the SSSF, how and which documents generated at the Satellite Site will be sent to the primary Site and filed in the SMF and archiving of satellite Site study file after study close out. When establishing the maintenance rules, it will be important to ensure that key documents from the SSSF are present in the SMF and vice-versa after the close out of the study but prior to archiving, so that a full record of all study activities under the control of the Principal Investigator is contained in the SMF.
- Establish prior to the commencement of the trial and maintain a current record of the location of all Essential Documents including Source Documents and where relevant, study related Essential Documents from Satellite Site. The storage system used during the study and for archiving (irrespective of the type of media used) should provide for

document identification and location, version history, search ability and retrieval for the length of the archiving retention time.

- File Essential Documents in a timely manner.
- Ensure Satellite Sites also maintain SSSF and file study related essential documents in a timely manner, with focus on version control.
- Maintain a current contact list of all Study Personnel including staff at all Satellite Site/s within the Cluster involved in the clinical trial, clearly identifying the Primary Site, the Satellite Site and any External Service Provider.
- Ensure study documentation is kept and archived as specified in The Australian ICH GCP (including Teletrials) SOP Compendium SOP 130 Section 4.2 Archiving.

4.2. The Study Master File (SMF)

- Study related Essential and Source Documents generated for/by the primary Site, as per Appendix 1 at a minimum, will be filed in the SMF.
- Certified copies of study related Essential and Source Documents generated for/by the Satellite Site, the identity of which will be established prior to the commencement of the trial, will be sent to the Primary Site and filed in the SMF, on request by either, the Sponsor, monitor or primary Site staff as per rules established prior to the commencement of the trial and documented in the Supervision Plan
- Where financial documentation, such as the Clinical Trial Agreement and sub-contract, invoicing and remittances etc. may be filed in a separate location to the SMF, the location is to be recorded on the SMF index. A copy may be filed in the SMF if requested by the Sponsor.
- Investigational Product handling documentation e.g. shipping, receipt, IVRS, IWRS, codes, randomisation list and accountability and destruction documents etc. may be kept in a separate file e.g. at the Site pharmacy. In this case the location to be recorded on the SMF index. However, the records must be made available to Sponsors, monitors, auditors and regulatory agencies at any time. The Investigational Product documentation will be archived with the SMF after completion of the study.
- Sample handling procedures are to be clearly documented if performed e.g. in a laboratory manual. Sample management records at both Primary and Satellite Site/s including the storage, processing and transportation of samples between Satellite and Primary Sites are filed in the SMF/SSSF as agreed.
- Other study related materials handling documentation are filed in the SMF/SSSF as agreed.

4.3. The Study Master File (SMF)

The Satellite Site Study File should contain:

- All the relevant site-specific Essential documentation pertinent to the activities that have been and that are to be performed at the satellite Site, similar to Appendix 1.
- All Source Documents generated at the Satellite Site.
- Relevant HREC approval and governance authorisation documentation.
- Sub-contract with the clinical trial agreement in annexure.
- Study specific supervision plan.
- Satellite Site Delegation Log
- Satellite Site Training Records
- Satellite Site, Site Specific Assessment form.
- Investigational product shipping, receipt and accountability documents
- Details of the processing, storage of samples at both Sites and transportation between Satellite and Primary Sites and related documentation (if performed)
- Files notes indicating if the original document is found in another location (eg pharmacy folder with the pharmacy, a document will be found in the SMF)

5 Guidance Documents

1. SOP 80: Case Report Forms and Source Documents
2. SOP 130: Site Close out and Archiving. Section 4.2

6 Appendices

Appendix1 Example Study Master File Index and Contents
Appendix2: Example Study Master File Index