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SOP 07 The Study Master File

1.1 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.

1.2 Scope

This Standard Operating Procedure (SOP) applies to all relevant employees, including but not limited to, visiting health professionals, contractors, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving patients/participants, facilities and or staff. All study personnel involved in the clinical study must operate within their scope of practice.

ICH GCP defines Essential Documents as, 'documents which individually and collectively permit evaluation of the conduct of the trial and the quality of the data produced'.

A Study Master File (SMF) (otherwise referred to as the **Investigator Site File (ISF)** in some jurisdictions) should be established at the beginning of the trial so that Essential Documents can be filed in an organised way that will facilitate the conduct of the trial, audit, and inspection. Contents should enable the adequate reconstruction of trial conduct at the site along with any key trial decisions.

The SMF/ISF contains identifiable data and proprietary information and should be stored securely with restricted access to authorised staff. It should be actively maintained as the trial progresses. All documentation filed should be complete, accurate and legible. If Essential Documents are stored separately from the SMF/ISF, (e.g. staff training records, maintenance/calibration records for key equipment used in the trial) a file note in the SMF/ISF should indicate their location. Superseded documents should be retained but scored through to indicate that the document is no longer in use. Direct access to all trial related records stored in the SMF/ISF should be provided when requested by monitors, auditors, ethics committees or regulatory authorities. Essentials Documents stored in the SMF/ISF should be originals or certified copies of original documents. Essential Documents include the correspondence generated during a trial. These documents (e.g. emails, telephone call reports, meeting minutes) are an important component in reconstructing the trial as they contain key decisions and discussions relating to the care of participants and the management of the trial.



For Satellite Sites, key trial documents (for example study Protocol/IB), as well as clear evidence of the manner and frequency of supervision of the Satellite Site by the Primary Site (e.g. minutes of calls with Satellite Site staff to review patients/participants and study progress) should be maintained in both the SMF/ISF and the Satellite Site Study File (SSSF).

1.3 Procedure

7.1 The Study Master File – Principal Investigator Responsibilities

The Principal Investigator must:

- Ensure an SMF is created, if not provided by the Sponsor, prior to study commencement and ensure that it contains at a minimum the Essential Documents listed in Appendix 8 Study Master File Index Example. The SMF is stored at the Primary Site (Satellite Site Study File in the case of the PI initiating a Satellite Site).
- Where the Teletrial Model is implemented, have control of all Essential Documents and records generated by the Investigator/Institution/Satellite Site before, during, and after the trial.
- Establish the maintenance rules of the SMF and relationship between the 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 (PI) is contained in the SMF. As the SMF contains identifiable data and proprietary information, it should also be stored securely with restricted access to authorised staff.
- 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 the 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 [SOP 13 Site Close-Out and Archiving](#).



7.2 The Study Master File

- Study related Essential and Source Documents generated for/by the Primary Site, as per Appendix 8 at a minimum, will be filed in the SMF.
- The Study Master File (SMF) should be prefaced with an index of contents as well as indicate the location(s) of all Essential/Source Documents.
- 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. See [Appendix 8 for example of Study Master File Index](#). A copy may be filed in the SMF if requested by the Sponsor.
- Investigational Product handling documentation e.g. shipping, receipt, Interactive Voice Response System (IVRS), Interactive Web Response System (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 is 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.

7.3 The Study Master File – Contents

The content of the Satellite Site Study File (SSSF) can be decided with the study team and the Sponsor. The SSSF may be a sub-set of the Study Master File (SMF) and should be prefaced with an index of contents as well as indicate the location(s) of all Essential/Source Documents.

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 8.
- All Source Documents generated at the Satellite Site (or indicate the location of all Source Documents for example the EMR 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.

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- 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 e.g. pharmacy folder with the pharmacy, a document will be found in the SMF.



Appendix 8

Study Master File Index with document location Example

Example 1

FILE SECTION	DOCUMENTATION	LOCATION	RESPONSIBLE	
			Primary	Satellite
CONTACT LIST	Contact list for all study related personnel at both Primary and Satellite Sites.		Holds for all Satellite Sites	Satellite Site only. Copy to Primary Site as indicated on Supervision Plan Request full list if needed
CORRESPONDENCE (NOT HREC OR GOVERNANCE)	General correspondence with Sponsor, teleconference and meeting notes		All Satellite Sites	Copy from Primary
AGREEMENTS	Clinical Trial Agreement location, site indemnities, confidentiality agreement(s) location, letters of intent, Health Service Directive for clinical trial regulatory process for Satellite Sites		Held at Primary Site	Sub-Contract which includes master CTRA from Primary
FINANCE	Financial disclosure Forms as appropriate		Held at Primary Site	Copy from Primary
ETHICS COMMITTEE APPROVALS ACKNOWLEDGEMENTS COMPOSITION	All ethics correspondence and documentation including all versions of the informed Consent Form, ethics committee composition,		Held at Primary Site	Copy from Primary

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FILE SECTION	DOCUMENTATION	LOCATION	RESPONSIBLE	
			Primary	Satellite
CORRESPONDENCE	statement of committee compliance to the National Statement, approval letters, reports to ethics committee, correspondence as applicable to commercial sponsorship, submission package(s), sample informed Consent Form, approved advertising materials/wording, other information provided to study participants and approved by ethics, tracked changes to Protocol and summary tables, insurance certificate			
INVESTIGATIONAL BROCHURE AND SAFETY UPDATES	All versions as provided to ethics, safety updates from Sponsor		Held at Primary Site	Copy from Primary
PROTOCOL	All versions as provided to and as approved by ethics, signed Protocol signatory page should also be in this		Signed by Primary Site	Copy from Primary
REGULATORY DOCUMENTS	Australian CTA or CTN Form (fully executed), other regulatory agency Forms, all correspondence to the regulatory agencies		Held at Primary Site	Copy from Primary
SAMPLE CRF	Approved version of sample CRF (a blank set that can be duplicated)		Held at Primary Site	Copy from Primary
CRF COMPLETION GUIDELINES	Any correspondence, presentations and/or CRF completion guidelines provided by the Sponsor		Sent to Primary Site	Copy to Secondary
SERIOUS ADVERSE EVENTS	Documentation tracking the incidence and reporting of SAEs, reports to ethics, reports		Site specific Primary notified of	Site specific Primary notified of

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FILE SECTION	DOCUMENTATION	LOCATION	RESPONSIBLE	
			Primary	Satellite
	to the applicable agency (interim and final)		any SAEs at the same time as Sponsor	any SAEs at same time as Sponsor
MONITORING	All general monitoring correspondence unless specifically belonging in another file section, pre-trial monitoring report, feasibility assessments, monitoring visit reports and follow-up letters, monitor-site correspondence, close-out visit reports		Sponsor visit face-to-face or via digital platform	Via telehealth or face-to-face
AUDIT	Auditor correspondence, audit reports (if available) and auditor follow-up letters		Held at Primary Site	Only if requested
LABORATORY	Clinical laboratory certification (NATA, CLIA), laboratory normal values for medical/laboratory/technical procedures and/or tests included in the Protocol, all provided		From Primary Site	Only if used
CURRICULUM VITAE	Signed and dated copies of CVs for all medical staff, (Principal Investigator, Associate Investigators) and other staff delegated significant duties as listed on the Delegation Log for the duration of the research project		All Investigators and staff with significant duties from all sites	Site specific staff and key Primary
SIGNATURE LOG	Site personnel signature sheet with a list of signatures and initials of all persons authorised to make entries and/or corrections on the CRFs and e-CRFs and certain delegated tasks		All staff from all sites	Site only

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FILE SECTION	DOCUMENTATION	LOCATION	RESPONSIBLE	
			Primary	Satellite
SHIPPING RECORDS FOR IMP AND OTHER STUDY RELATED MATERIALS	Shipment records, date of shipment, batch numbers, method, shipment receipt records, certificate of analysis for Investigational Product, storage conditions		Site specific and on ward to Satellite. Stored in Pharmacy	Site specific receipt, use and return
ACCOUNTABILITY AND DESTRUCTION RECORDS	Investigational Product accountability and destruction correspondence and records		Site specific and on ward to Satellite Stored in Pharmacy	Site specific receipt, use and return
DECODING AND UNBLINDING	Any correspondence relating to decoding and unbinding. Documents how identity of blinded Investigational Product can be revealed in case of emergency.		Site specific and Satellite information stored	Site specific
PARTICIPANT SCREENING LOGS	Screening logs including participant identification logs (site only for identification in case of emergency), participant registration/screening logs containing a chronological listing of screening/enrolment of participants.		Site specific (Primary has copy of Satellite Site for emergency)	Site specific
PARTICIPANT IDENTIFICATION CODE LIST	A confidential list of names of all participants allocated to trial numbers upon enrolment in the trial. Allows Investigator/Institution to reveal participant identity in the case of emergency or for reasons of safety		Primary has all details	Site specific only
PARTICIPANT ENROLMENT LOGS	Chronological enrolment of participants by participant number		Site specific only	Site specific only

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FILE SECTION	DOCUMENTATION	LOCATION	RESPONSIBLE	
			Primary	Satellite
VISIT LOG	Records for all site visits, monitoring visits, Sponsor visits, auditor visits, agency audits		Sponsor visit	Only if Sponsor visits
DATA QUERY TRACKING	Data query tracking, monitors site queries and correspondence		Sponsor visit	Remotely accessed
CLINICAL STUDY REPORT	Final clinical study report (signed copy) if provided		Sent to Primary	Copy from Primary
SIGNED INFORMED CONSENT FORMS	Informed Consent Forms should be fully signed with all signatories dating their own signature. In addition, time of consent should be recorded in order to establish that consent was obtained prior to any trial procedures. Where informed consent is placed in the health and medical record, a file note stating this must be added to this section of the file		All sites	Held at site, witnessed and processed by telehealth if required
OTHER-STUDY SPECIFIC	Other documents not included in the previous sections		All	Copy from Primary where relevant
SUPERVISION PLAN	A plan recording the oversight for the project and staff involved in the study and the role of the Primary Site overseeing the Satellite Sites and reporting structure for the study.		Held at site	Explained to all site staff
MONITORING PLAN			At Primary Site	Copy from Primary

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FILE SECTION	DOCUMENTATION	LOCATION	RESPONSIBLE	
			Primary	Satellite
SAFETY MONITORING PLAN			At Primary Site	Copy from Primary
OTHER (SPECIFY)				

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Example 2:

1. Contact List
2. Project Documents incl. IP and safety
 - 2.1 Investigational Brochure
 - 2.2 Safety Updates (reports, expedited safety letters/notifications, etc.)
 - 2.3 Protocol
 - 2.4 CRF (blank)
 - 2.5 CRF Completion Guidelines
 - 2.6 IP Shipping Records (refer to Pharmacy Folder/Records)
 - 2.7 Accountability Records (refer to Pharmacy Folder/Records)
3. Contracts
 - 3.1 Site Agreements (CTRA, Indemnities, Confidentiality Agreements, staff personal information consent, etc.)
4. Regulatory Authority Documents
 - 4.1 Regulatory Agreements
 - 4.2 Financial Disclosure Forms (FDFs)
 - 4.3 Other Regulatory Documents (CTA, CTN, etc.)
5. Human Research Ethics Committee (HREC)
 - 5.1 Initial Submissions/Approval
 - 5.2 Other Submissions/Approval
 - 5.3 Clinical Study Report
 - 5.4 HREC Correspondence
6. Site Staff Qualification
 - 6.1 Curriculum Vitae and Medical Licences
 - 6.2 Training (GCP, study specific, vendor specific)
 - 6.3 Delegation of Authority Log
7. Supervision Plan
8. Subject / Participant related Documents
 - 8.1 Blank Informed Consent Forms (signed Forms in participant files)
 - 8.2 Screening Log
 - 8.3 Enrolment Log

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- 8.4 Subject Identification Log
- 8.5 Other (blank subject diaries, emergency card, recruitment material, etc.)
- 9. Safety Related Documents
 - 9.1 Safety Monitoring Plan
 - 9.2 Risk Management Plan
 - 9.3 Serious Adverse Events Log
 - 9.4 Serious Adverse Events Form(s) - blank
 - 9.5 SUSARs
 - 9.6 Other Safety Reports eg Breaches, Annual Safety Reports
- 10. Laboratory
 - 10.1 Central and Local Lab Accreditation/Certification (NATA, CLIA) (print or website reference)
 - 10.2 Central and Local Lab Normal Ranges
 - 10.3 Central Lab Manual/Instructions
 - 10.4 Biospecimen Shipment Logs Records
 - 10.5 Other (equipment calibration certificate, temperature logs,
- 11. Monitoring Reports
 - 11.1 Site Visits (incl. initial)/Monitoring Visits/Sponsor Visits
 - 11.2 Protocol Deviation Log
 - 11.3 Audit (correspondence, reports, follow up letters, etc.)
 - 11.4 Monitoring Plan
- 12. Correspondence
 - 12.1 General with Sponsor, Teleconference, Meeting Notes
- 13. CRF
 - 13.1 Blank CRF if Paper Available
 - 13.2 CRF Completion Guidelines
- 13.3 Data Query Documentation

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Glossary

TERM	DESCRIPTION
ADE	Adverse Device Effect
ADR	Adverse Drug Reaction
AE	Adverse Event
AHPRA	Australian Health Practitioner Regulation Agency
AI	Associate Investigator
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ARPANSA Code of Practice	ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research
CAPA	Corrective and Preventative Actions
CASA	Civil Aviation Safety Authority
CIOMS	Council for International Organizations of Medical Sciences
CPI	Coordinating Principal Investigator
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Approval scheme (previously Clinical Trials Exemption (CTX) scheme)
CTN	Clinical Trial Notification scheme
CTPRG	Clinical Trials Project Reference Group
CTRA	Clinical Trial Research Agreement
CV	Curriculum Vitae
DSMB	Data and Safety Monitoring Board
EMR	Electronic Medical Record
GCP	Good Clinical Practice
HHS	Hospital and Health Service
HREC	Human Research Ethics Committee
IATA	International Air Transport Association

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ICH	International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
IP	Investigational Product
IMD	Investigational Medicinal Device
IMP	Investigational Medicinal Product
IVRS	Interactive Voice Response System
IWRS	Interactive Web Response System
National Statement	National Statement on Ethical Conduct in Human Research (NHMRC)
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance
PI	Principal Investigator
PICF	Participant Information and Consent Form
PMS	Post Registration or Marketing Surveillance Study
RGO	Research Governance Officer
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SMF	Study Master File
SSA Form	Site Specific Assessment Form
SSI	Significant Safety Issue
SSSF	Satellite Site Study File
SUSAR	Suspected Unexpected Serious Adverse Reaction
TGA	Therapeutic Goods Administration
UR	Unit Record
USADE	Unanticipated Serious Adverse Device Event
USM	Urgent Safety Measure

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○ Revision Chronology

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