

Standard Operating Procedure:

Essential Documentation Management with Teletrials

**SOP Number: TT-SOP-11**

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| Approved by: | VCCC Teletrials Steering Committee |

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**Amendment History**

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| Version | Date | Amended By | Amendment Details |
| 1.0 | 03 October 2018 | Hannah Cross | New |
| 2.0 | 13 September 2019 | Alana Donaldson | Additional information regarding Site Docs Portal electronic ISF process. |

Developed by the Victorian Comprehensive Cancer Centre (VCCC) in conjunction with the Parkville Cancer Clinical Trials Unit (PCCTU), based on the Clinical Oncology Society of Australia (COSA) Australasian Tele-trials Model.

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1. Introduction and Background

International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines defines essential documents as “documents which individually and collectively permit evaluation of the conduct of the trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements.” (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996, sec. 8.1)

Collection and maintenance of essential documents demonstrates principal investigator and site ICH GCP and local regulatory compliance. Filing essential documents in an orderly and timely manner is important in the coordination and management of clinical trials. Essential documents are kept in a study specific Investigator Site File (ISF) with responsibility for maintaining and updating the file clearly delegated on the delegation of duties log. Specific sections of the ISF can be maintained electronically, with appropriate password protection

1. Objective

To describe the procedures relevant for the collection and maintenance of essential documents for clinical trials coordinated by (SITE) and, where appropriate, satellite sites (SS) involved in Teletrials.

1. Scope

This SOP applies to all clinical trials coordinated by (SITE) and where (SITE) is participating in a Teletrial.

1. Ownership and Responsibility

The principal investigator and (SITE) study team will be responsible for the collection and maintenance of all essential documents throughout the duration of the clinical trial.

1. Glossary of Terms

Please refer to (SITE) TT-SOP-Glossary-of-Terms (see Related Documents) for full supporting glossary of terms.

1. Procedure
   1. Collection of Essential Documents

It is the responsibility of the principal investigator/delegate to ensure all essential documents are collected prior to clinical trial initiation and maintained throughout the study. All essential documents will be filed in study specific ISF and participant folder in a timely manner.

SiteDocs Portal is a collaborative online portal used by sites to store essential documents electronically. Electronic documents are accessed centrally by secure login and managed in collaboration with study team, Cancer Trials Australia, and applicable sponsor/contract research organisation (CRO).

All essential documents may be subject to inspection or audit (as outlined in (SITE)-SOP-08: Hosting a Regulatory Inspection, Sponsor or HREC Initiated Audit (see Related Documents).

For Teletrials, site staff at the satellite site (SS) are responsible for the collection and maintenance of the specific SS documents as defined in the appendix 1 in their own Satellite Site Site file (SSSF) and for the provision of copies of these documents as required to the PS.

1. Investigator Site File

Essential documents are filed in the electronic/paper ISF will be created using the (SITE) Investigator Site File Table of Contents (see Related Documents) to maintain consistency. The electronic ISF folder should display local reference number, protocol short name and principal investigator name. The following information should be displayed prominently on the cover and spine of the ISF:

* Human Research Ethics Committee (HREC) reference number.
* Protocol name and number.
* Protocol short name.
* Site number.
* Name of principal investigator.
* Specific folder number and total number folders.
* Protocol short name.
* For Teletrials: the same identifiers will be used and labelled Satellite Site SF. Where a local RGO number has been allocated to the Teletrial this will also be included in the cover and spine labels.
* Electronic files will be identified by the same identifiers.

Essential documents are filed according to the (SITE) Investigator Site File Table of Contents (see Related Documents). Electronic documents are uploaded and managed within clinical trial electronic ISF without duplication in the paper ISF. Scanned wet ink documents are electronically certified in SiteDocs Portal as an accurate and complete representation of the hard copy. If any documents are filed separately from the ISF (i.e. source documents etc.), a file note should be created and placed in the appropriate section detailing where the documents are stored. An ISF may consist of more than one folder and therefore should be labelled with the specific folder number and the total number of folders i.e. folder 1 out of 2.

All documents contained in the ISF should be retained in a secure area accessible only to the principal investigator and (SITE) study team. All electronically stored sections will have password access with user specific ring-fencing.

The electronic ISF is accessible remotely to clinical research associates to download and upload essential documents where appropriate. Clinical research associates are not required to upload ethical and governance submission and approval documents, patient informed consent forms (PICFs) and protocols on behalf of Cancer Trials Australia.

Provision of essential documents electronically post a monitoring visit will not occur if the documents were made available at the time of monitoring visit however if the documents were not provided at the visit the (SITE) study team will make them available.

1. Curriculum Vitae (CV )

All study team members are required to provide an abbreviated CV, using the (SITE) Clinical Trial Site Specific Curriculum Vitae template or TransCelerate Abbreviated Curriculum Vitae Template (see Related Documents). SS study staff are recommended to use a Transcelerate approved abbreviated CV template. The CV should detail clinical experience and relevant training.

CVs will be updated every two years unless a change in information has occurred. (SITE) will maintain a hard copy central file containing the wet ink signed original CVs. Certified copies of CVs will be filed into clinical trial specific electronic or hard copy ISF, accessible by the clinical research associate.

For Teletrials, the SS staff will retain the wet ink original CVs and will provide the PS with a copy.

1. ICH GCP Certification

All study team members are required to complete a TransCelerate approved ICH GCP training, with refresher training as required within three years. If study team members hold a TransCelerate approved ICH GCP certificate they will not be required to complete any further GCP training requested by individual sponsors. Copies of the certificates will be filed into the relevant clinical trial electronic or hard copy ISF for viewing and collection by the clinical research associate.

1. Medical Licences

Each investigator will list on their completed CV their professional registration number. Up to date and current information about their registration status is available to sponsors via the APRHA website and will not be collected or maintained in the ISF by the study team.

1. Statement of Investigator (1572 Form)

If required, the principal investigator is responsible to sign off the 1572 form. The sponsor is required to provide the principal investigator with a complete and accurate 1572 form to sign. Any external laboratories utilised by clinical trial participants for routine blood draws will not be considered as part of the services engaged for the clinical trial. This is not required as outlined in Frequently Asked Questions – Statement of Investigator (Form FDA 1572) (U.S. Department of Health and Human Services et al, 2010, sec. 29). The original wet ink 1572 will be available for collection by the clinical research associate at their monitoring visit.

For Teletrials, the SS and any local external service providers, will be listed on the 1572. Only the PS is required to hold the 1572 in the ISF.

1. Financial Disclosure Form (FDF)

FDF’s will be collected per requirement from clinical trial sponsor.

The original wet ink FDF will be available for collection by the clinical research associate at their monitoring visit.

For Teletrials, the SS will hold the wet ink originals and will provide copies to the PS.

1. Delegation Log

As outlined in (SITE) TT-SOP-04: Delegation of Duties with Teletrials (see Related Documents).

For Teletrials, a list of delegated duties will be detailed in the Teletrials Site Agreement. The SS will maintain a separate delegation log in the SSSF. The SS signs a hard and retains the delegation log. A copy is emailed to the PS where the PI will approve the delegation of duties in person or electronically using an approved electronic signature. The SS will retain the original but a copy of the log will be provided to the PS with each change of staff.

1. Training records

As outlined in (SITE) TT-SOP-03: Clinical Trial Training with Teletrials (see Related Documents).

For Teletrials, the SS will maintain an electronic record of training as per (SITE) TT-SOP-03. The SS retains the signed original and a copy is emailed to the PS where the PI will approve in person or electronically using an approved electronic signature.

1. Patient Logs

A pre-screening/screening log will be used for clinical trials utilising a pre-screening patient informed consent form (PICF). For all clinical trials, the following two logs will be maintained;

* Participant identification log: a confidential list of names of all clinical trial participants and their allocated clinical trial identification numbers.
* Enrolment Log: chronological enrolment list of clinical trial participants by clinical trial identification number.

To ensure confidentially participant logs will not be provided to the sponsor but may be viewed at monitoring visits.

For Teletrials, the SS will maintain the 2 logs specified above and provide the PS with updated copies of the each log each time a patient is enrolled.

1. Source Documents

Please refer to (SITE) Guidance on eMR FDA 21 CFR 11 Compliance (see Related Documents).

Where the clinical trial protocol requires data to be generated based on calculations (i.e. creatinine clearance, RR intervals or QTcF etc.) the source data used in these calculations will be made available; however there is no requirement to include evidence of the calculation itself.

1. Clinical Trial Correspondence

All electronic correspondence will be maintained in an electronic filing system that will be archived with the clinical trial upon completion, dividing the correspondence into the sections specified in the (SITE) Investigator Site file Table of Content.

1. Archiving of ISF

The ISF will be archived at the conclusion of the trial, as per SITE TT-SOP-011.

For Teletrials, the SSSF (both paper and electronic) will be archived with the PS ISF folders. The archiving details will be retained by both sites for future reference.

1. Dissemination and Implementation

Approved SOPs will be disseminated electronically by (ITE). SOPs will be made available in hard copy format or electronically upon request. Any updates to the existing approved SOPs will be disseminated internally, and will be effective immediately.

1. Monitoring Compliance and Effectiveness

Compliance with this SOP will be monitored as part of the (SITE) monitoring and audit process. Any queries concerning the effectiveness of this SOP identified during the (SITE) monitoring process or through use will be addressed and may result in the requirement to update the SOP.

1. Review and Updating

This SOP will be reviewed every three years, or when changes to legislation or working practices that impact upon the content of this document. This SOP may be merged with another SOP if appropriate or removed entirely if it becomes redundant.

1. Reference(s)

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. (1996). Guideline for Good Clinical Practice

U.S. Department of Health and Human Services, Food and Drug Administration et al. (2010). Frequently Asked Questions – Statement of Investigator

1. Related Document(s)

(SITE) TT-SOP-Glossary-of-Terms

(SITE) TT-SOP-08: Hosting a Regulatory Inspection, Sponsor or HREC Initiated Audit

(SITE) TT-SOP-11 Essential Document Management

(SITE) TT-SOP-04: Delegation of Duties

(SITE) TT-SOP-03: Clinical Trial Training

SITE Investigator Site File Table of Contents

Teletrials appendix 1: Satellite Site SF Table of Contents (*see below*)

eMR FDA 21 CFR 11 Compliance

(SITE) Clinical Trial Site Specific Curriculum Vitae template

Integrated addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)

**Teletrials Appendix 1: Satellite Site Site File Table of Contents:**

* A signed copy of the Teletrials Site Agreement and Supervision plan. (section 7)
* The sub contract with the Sponsor, where appropriate (section 7)
* Files notes to indicate the location of SSSF required documents which may be stored outside the main SSSF.
* All relevant documents generated at the Satellite site including
  + A copy of the HREC trial approval
  + The SS RGO approval, including approvals for any amendments
  + The SS delegation log
  + The SS training Log
  + The SS site assessment form
* All documents relating to the management of trial related samples including:
  + Details of processing, storage and shipment
  + Relevant freezer logs
  + Relevant equipment service records
* Financial invoices and statements documenting the financial reconciliation between the PS and SS, and, where appropriate between the SS and the Sponsor. These may be stored in a separate file where this is the operating model used by the PS and/ or the SS, as detailed in the Teletrials site agreement.
* Records relating to the Investigational product, including
  + records of the investigational product shipping, receipt, allocation and destruction
  + records of transport of IP between the PS and SS
  + relevant temperature logs for storage facilities and equipment service records