UTS IMPACCT Trials Coordination Centre

Standard Operating Procedure

8.0 Essential Documents

Version	V2.4
Author/s	B Fazekas
Approved	M Agar
Effective date	01/04/2022
Review date	01/04/2024

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION AS AVAILABLE FROM www.uts.edu.au/itcc

Introduction / Background

All clinical studies need to demonstrate that documentation meets the International Conference on Harmonisation of Good Clinical Practice (ICH GCP) guidelines, and that documentation shows that the study is conducted in an ethical and appropriate manner and all legal and auditing requirements are met.

The correct establishment, maintenance and storage of files enable assessment that the study was conducted in accordance with ICH GCP guidelines. A standardised filing system also enables all the site team, and any external parties, such as monitors and auditors, to locate and review the files.

Objective

This SOP describes the process of establishing and maintaining trial-related files to ensure all required files are kept and can be maintained and located.

Scope

This SOP applies to all sites involved in clinical studies conducted by the IMPACCT Trials Coordination Centre (ITCC), including Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST). Each study site establishes and maintains a filing system that ensures appropriate filing of study documents as specified in ICH GCP.

Ownership and Responsibility

The Coordinating Principal Investigator, ITCC, Principal Investigator and Sponsor. The task may be delegated to another suitably trained individual (e.g. Sub-Investigator, Site Study Coordinator, study nurse etc.) as documented on the Staff Signature and Delegation Log (*refer* SOP 4.2.4 Delegation of Duties) but the responsibility remains with the Principal Investigator.

Responsibilities of the Coordinating Principal Investigator

- To oversee the study
- To ensure the ITCC has developed and maintains the system for the files

Responsibilities of the ITCC

- To develop the Trial Master File (TMF) Index (consistent with the requirements of ICH GCP 8.0 Essential Documents)
- To develop and distribute standardised essential document templates to all sites
- To provide guidance to sites regarding filing, storage and maintenance of study documents
- To ensure all study sites are provided with a full set of essential documents within the Investigator Site File (ISF) required to conduct the study

Responsibilities of the Principal Investigator and/or other designee(s)

- To ensure that all essential documents for that site are produced, stored and filed appropriately using a standard ISF

- To provide file notes where files cannot be located
- To retain original and revised documents to enable a document history to be reviewed
- To ensure that participant files are kept confidential and are stored securely
- To ensure that participant files are complete in preparation for monitoring and audit, and to follow-up on the documentation issues that arise from these visits

Responsibilities of the Sponsor

- To provide necessary information and documents when requested

Procedure

1. Establish a Trial Master File

The Trial Master File Index (Template 20) is created by the ITCC at the initiation of study design and protocol development. The files are subsequently maintained and expanded as required. The Trial Master File (TMF) enables all study related documents at the ITCC to be appropriately filed and stored. The Investigator Site File (ISF) contains the storage and filing requirements for essential documents at the site level as derived from the TMF.

The TMF is maintained electronically and stored on a local University of Technology Sydney (UTS) network drive categorised within study specific folders. Access to the network drive is only granted to internal IMPACCT staff and must be approved by the PaCCSC/CST National Manager or ITCC National Project Officer.

2. Establish and Maintain an Investigator Site File

All files related to each study are stored according to the ISF at all sites. The contents page of the ISF (Template 39) provides the structure for the filing of all essential documents for the conduct of the study at the site.

The ITCC creates the ISF at the time of study initiation at the sites. The files are subsequently maintained by the Principal Investigator (or delegate) and expanded as required. In order to ensure that all sites have access to the same documents as approved by the approving HREC at all times, the ITCC will develop and maintain a REDCap project. This project is specific to each study and is named; Study 'Forms and Documents' (refer to Template 47). Each site is expected to refer to this repository to access the approved forms and documents for each study and to update the local ISF.

The ISF may be maintained in electronic, paper or hybrid format. For PaCCSC/CST/ITCC studies starting from 2019 onwards, sites will be provided with an electronic ISF folder structure that mirrors the ISF index (Template 39) such that most essential documents at the site will be kept in a predominantly electronic format. However, there remain certain essential documents that necessitate the collection of contemporaneous and wet-ink signatures, including but not limited to the Staff Signatures and Delegation Log, pharmacy accountability logs, staff training logs, monitoring visit log etc., which will be maintained in paper format. The storage system used during the trial should be secure and provide for document identification, version history, search, and retrieval. All ISFs that are maintained electronically should meet the following requirements:

- Stored on a secure network where user access is restricted and password protected
- Regularly backed-up
- Standard file naming convention must be used (e.g. Protocol Number/Name_Document type/name_Date)
- All versions of documents must be on file including superseded versions
- Ensure that the document is a high-quality scan/copy, is complete, and is legible.

If these requirements cannot be met, a paper ISF must be maintained by the site.

Depending on the activities being carried out, individual trials may require additional documents not specifically mentioned in the TMF Index/ISF. The Sponsor and/or Principal Investigator should amend the TMF Index/ISF to include these.

The Principal Investigator ensures that all documents are filed in the appropriate section of the ISF, that the file is available, and in good order throughout the study.

If any documents are filed separately from the ISF (e.g. source documents etc.), then a log should be created and placed in the ISF detailing where the documents are stored (*refer* SOP 4.9.2 Source Data and Documents for further guidance).

As per ICH GCP 8.1, it is a requirement that a record is maintained of the location(s) of all essential documents. The ISF should contain a summary log of all essential documents, including the source documents and exactly where they can be located. The Essential Documents Log (Template 11) provides an example of how such a log may look.

3. Maintain Participant files

Participant data is held within one section of the ISF and contains the data collected from participants during recruitment. Each participant has an individual study file prepared which contains all participant data, including:

- All paper data collection worksheets;
- All quality of life and other participant completed documents, with names removed and ID number inserted;
- All concurrent medication forms;
- Study related correspondence;
- Any other documents that relate to participant data that cannot be filed with the clinical file and have had all identifiable information replaced with the participant ID number.

In addition, identifiable data, such as consent forms, pathology reports, medication records and clinical notes or medical assessments, may also be kept in this file or folder to assist with monitoring where required, but only if the participant study file/folder is kept and stored in a secure area where access to the file/folder is restricted to only study site staff. If continuous secure and restricted access storage cannot be guaranteed, or if it is the site institution's policy, then identifiable data must be kept in a separate file or folder to the de-identified data to protect the confidentiality of the participant.

Storage conditions for the ISF and paper participant files must have appropriate environmental controls and adequate protection from physical damage.

4. Changes to an Investigator Site File

The ITCC regularly reviews the ISF contents to ensure its currency and applicability.

Any changes to the ISF made by the ITCC (as a result of changes to regulations or similar) must be acknowledged and implemented by the Principal Investigator within one week of the changes taking place. The Principal Investigator must also notify the ITCC that this has occurred.

Related SOPs

4.9.2 Source Data and Documentation

5.5.1 Electronic Data Handling

5.18 Monitoring

8.4.1 Archiving of Research/Project Materials

8.4.2 Record Destruction

Related documents

Template 11: Essential Documents Log

Template 20: Trial Master File Index

Template 39: Investigator Site File Index

Template 47: Forms and Documents

References

Australian Code for the Responsible Conduct of Research 2018 (accessed 12/02/2020)

https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018

COSA Standard Operating Procedures for Investigational Sites. March 2006. A publication of the Centre for Clinical Research Practice, Inc.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). November 2016 (accessed 23/10/2017)

https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf

National Statement on Ethical Conduct in Human Research (2007)- Updated 2018- (accessed 07/02/2020)

https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

Praxis Australia

History			
Version	Date	Author	Reason
1.1	10/01/2006	Contributing authors	New procedure
1.2	25/02/2007	S Whicker	Administrative update
1.3	18/07/2007	B Fazekas	Update prior to MAB review
1.4	16/10/2007	B Fazekas	Update after David Currow review
1.5	30/06/2010	B Fazekas	Periodic review
2.0	3/02/2011	B Fazekas	Changes ratified by MAB
2.1	3/06/2015	C Hope	Periodic review
2.2	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
2.3	16/03/2020	C Strauss	Periodic review Publication of Australian Code for the Responsible Conduct of Research (2018) Publication of National Statement on Ethical Conduct in Human Research (2007)-updated 2018
2.4	06/01/2022	B Fazekas C Strauss	Periodic review Implement use of REDCap Forms and Documents project

Approval		
Version	Approval Name	Approval Signature
2.4	Meera Agar