



SOP 17 Copying and Certifying Essential Documents

1.0 Purpose

To describe the procedures related to the management and control of certified copies of essential documents.

2.0 Scope

Applies to all University of Melbourne Sponsor-Investigators and delegated staff responsible for maintaining essential records in the Trial Master File (TMF), Investigator Site File (ISF), and Site Information Files for multi-centre trials.

3.0 Responsibility

- Sponsor-Investigator: Ensures compliance with this SOP and ICH GCP requirements.
- Delegated Staff: May perform copying and certification if documented on the Delegation Log.

4.0 Definitions

Essential Records: Documents, data, and metadata that permit evaluation of trial conduct and reliability of results (ICH GCP E6(R3)).

Certified Copy: A copy (paper or electronic) verified by dated signature or validated process to contain the same information and metadata as the original, such that it can replace the original (ICH GCP E6(R3)).

5.0 Procedure

Maintain original signed essential records in the TMF/ISF. Originals include signed protocols, agreements, indemnities, delegation logs, and training records.

If originals are removed (e.g., for archiving), create a certified copy before removal and file it in place of the original.

5.1 Creating a certified copy

1. Confirm delegation on the Delegation of Duties Log.
2. Verify the copy includes all content and metadata of the original.
3. Apply certification: stamp or electronic annotation stating “Certified Copy”, include name, signature (electronic or wet ink), and date.
4. Document the certification process in the tracking log.
5. Ensure version control: include version number, date, and pagination on multi-page documents.
6. For electronic copies, use validated systems with audit trails.



5.2 Version Control and Metadata

Certified copies must retain original metadata (e.g., author, date, version). Systems must ensure traceability and auditability.

Final versions must be approved and signed off by the author(s).

6.0 Electronic Systems

Electronic systems used for certified copies must be validated, maintain audit trails, and ensure records remain complete, readable, and accessible for inspection.

Glossary

Certified Copy	A certified copy means a copy of original information that has been verified. As indicated by dated signature, as an exact copy having all of the same attributes and information as the original.
Essential Documents	Documents which individually and collectively permit evaluation of the conduct of a study 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 (GCP) and with all applicable regulatory requirements. Filing essential documents at the Sponsor site and participating trial sites also assists with the successful management of the trial.
Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
Investigator-initiated trials (IITs)	Trials where the investigator initiates and organises a trial with minimal involvement of the institution are referred to as investigator-initiated trials (IITs). In this case, the institution will be usually be responsible for the medico-legal risk and delegate the remaining Sponsor responsibilities to the lead investigator (i.e. Sponsor-Investigator), including the initiation, financing (or arranging the financing) conduct and management (including compliance with GCP and applicable regulatory requirements) of the trial.
Investigator	A person responsible for the conduct of the clinical trial at a trial site. There are four types of Investigator roles used to describe Investigators with different levels of responsibility for the conduct of clinical trials. These are described below. <i>Associate Investigator</i> Any individual member of the clinical trial team designated and supervised by the Principal investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g.,

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	<p>associates, residents, research fellows). May also be referred to as sub-investigator.</p> <p><u><i>Coordinating Principal Investigator (CPI)</i></u> If a study is conducted at more than one study site, the Principal Investigator taking the additional responsibility for coordination of the study across all sites in a region is known as the Coordinating Principal Investigator (CPI). This role applies to externally sponsored studies where the Sponsor may be a collaborative research group, commercial Sponsor or an institution. The Principal Investigator at each site will retain responsibility for the conduct of the study at their site.</p> <p><u><i>Principal Investigator</i></u> The PI is the person responsible, individually or as a leader of the clinical trial team at a site, for the conduct of a clinical trial at that site. As such, the PI supports a culture of responsible clinical trial conduct in their health service organisation in their field of practice and, is responsible for adequately supervising his or her clinical trial team. The PI must conduct the clinical trial in accordance with the approved clinical trial protocol and ensure adequate clinical cover is provided for the trial and ensure compliance with the trial protocol.</p> <p><u><i>Sponsor-Investigator</i></u> An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a participant. The term does not include any person other than an individual (eg, it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.</p>
Sponsor	An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study.
Sponsor-Investigator	<p>The Sponsor-Investigator is a term used for investigator-initiated studies. It is an individual who is responsible for both the initiation and conduct of a study. The term does not include any person other than an individual. This person will be:</p> <ul style="list-style-type: none"> • the Principal Investigator for single-site investigator-initiated studies • the Coordinating Principal Investigator for multi-center investigator-initiated studies
Trial Master File (TMF)	Filing repository controlled by the Sponsor/Sponsor-Investigator. It is the collection of essential documents that allows the Sponsor responsibilities for the conduct of the clinical trial, the integrity of the trial data and the compliance of the trial with Good Clinical Practice (GCP) to be evaluated.

Appendix 1

Essential document tracking log

Essential document tracking log

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PROTOCOL NAME/NUMBER:	Principal Investigator:
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Complete this log for every essential document that is copied and certified, in chronological order.

Essential document name	Document ID Number	Date original removed from Trial Master File	New location of original document	Copied and certified copy replaced original? #^	Person responsible for scanning and certifying*	Comment
<i>Example: site delegation log</i>	1	<i>1 Jan 20XX</i>	<i>TMF</i>	<i>Yes</i>	<i>John Doe</i>	<i>N/A</i>
	2					
	3					
	4					
	5					
	6					
	7					
	8					
	9					
	10					

* The person responsible for copying and certifying copies must be on the study delegation log

A certified copy MUST replace any original essential document removed from the TMF; ^ If being replaced by a pdf version, include file name and storage location in the comments column

Appendix 2

Fields included on ‘certified copy stamp’

This is a certified copy of the original:

Protocol number	
HREC number	
Document ID Number	
Number of pages	
Date of copy	
Name of person taking copy	
Signature	

○ Revision Chronology

Document History			
Version	Effective Date	Summary of Changes	Author
1.0	<i>25/11/2025</i>	Initial Version	Katie Ozdowska