Title: Copying and Certifying Essential Documents

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The author is signing to confirm the technical content of this document

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Reviewed and Approved by:
These signatures confirm the reviewers agree with the technical content of the document and that this document is approved for implementation at the RCH Campus.

Andrew Davidson – Medical Director, Melbourne Children's Trial Centre (MCTC)

Signature:  **Date:** 17th May 2018

This document is effective from the date of the last approval signature and will be reviewed in two years.

Document History

Revision	Modified by	Change No.	Description of Change
1.0	Sarah Bascombe	N/A	New Issue
2.0	Natalie Rose		Update 17/5/2018

Contents

1. PURPOSE

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

2. RESPONSIBILITY AND SCOPE

This SOP applies to Melbourne Children's Campus staff who undertake the following roles associated with investigator-initiated trails, sponsored by MCRI:

- Sponsor-Investigator
- Investigator
- Study Coordinator
- Staff delegated the task of maintaining/archiving essential documents

The SOP applies to the maintenance of essential documents in the Trial Master File, including Site Information Files if the trial is multi-centre, and the Investigator Site File at participating sites.

3. PROCEDURE

3.1. Trial Master File/Study Binder & Essential Documents

As per GCP the original signed documents need to be maintained (i.e. hard copies of originals need to be kept and all updates to these documents which require new signatures should also be kept). These documents may include but are not limited to:

- All original signed Protocol and/or Investigator Brochure Agreement Pages
- All original signed agreements
- All original signed, dated and documented Indemnities, Financial Disclosures and FDA Form 1572 (if applicable)
- Delegation log that contains all original signatures/initials of staff delegated duties for the study

3.2. Essential documents that may be copied

Best practice is for all essential documents to be kept in the Trial Master File/Study Binder and to be originals; however originals of the following documents may be removed from time to time, usually by the sponsor at study close-out.

- Delegation log
- Training log
- Screening log
- Enrolment log
- Financial disclosures
- FDA 1572 (if applicable)

If these (or other) original documents are removed from the Trial Master File, certified copies must be taken and filed in their place within the Trial Master File.

3.3. Certifying copied documents

The PI must delegate the task of copying and certifying essential documents to a study team member. This delegation must be evident on the Delegation of Duties Log. A study team member who is listed on the Delegation of Duties Log is the person who can remove originals from the Trial Master File.

When an original essential document is removed from a study file:

- Complete the tracking log (see appendix 1)
- Make a colour copy of all pages of the document. Verify that the copy contains all of the same attributes and information as the original. This should include the following:
    - Content of each original page appears “in total”
    - Content of photocopied page is legible
    - Content appears on a page with margins and any headers and footers intact
- Stamp the colour copy using the ‘certified copy stamp’ (see appendix 2)
    - Complete each field, date and sign
- File the certified copy in place of the original in the Trial Master File/Study Binder
- Document the conversion process demonstrating a “certified copy” was made of the original document (see appendix 3)

If the document is more than one page long and not paginated, paginate and date using a PDF writer program at time of copy. Only the first page of a multi-page document needs to be certified. To ensure that pages from various versions are not mixed, the print out must:

- Have either the date or version number printed on each page, or
- Be securely bound by a staple, or
- Have the investigator’s or the investigator’s delegate initials and date on each page

3.4. Considerations in the process of copying documents

In addition to the requirements above, the certified copies of essential documents must meet the following requirements:

- Be the same size and dimensions as the original
- Be the same colour as the original

4. 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 the evaluation of the conduct of the study and the quality of the data produced

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
An individual responsible for the conduct of a clinical trial at a trial site and ensures that it complies with GCP guidelines. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the Principal Investigator. In this instance they may delegate tasks to other team members.

Research Coordinators
A research worker works at a clinical research site under the immediate direction of a Principal Investigator, whose research activities are conducted under Good Clinical Practice guidelines. May also be called “Clinical Trial Coordinator” or “Research Coordinator” or “study coordinator”. (ARCP Definition.)

Standard Operating Procedure (SOP)
Detailed, written instructions to achieve uniformity of the performance of a specific function.

Sub / Associate investigator
Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows, clinical research coordinators. The PI will designate who will be nominated as Associate Investigators for that site.

Trial Master File (TMF) / Investigator Site File (ISF) / Study Binder
The Trial Master File (TMF) contains all the essential trial specific documentation prepared/collected before the trial commences, during the conduct of the trial and at trial completion in accordance with Good Clinical Practice. The Sponsor (or Sponsor-Investigator in case of investigator-initiated trials) is responsible for maintaining the TMF.

An Investigator Site File (ISF), sometimes referred to as the “study binder”, contains essential documents on the trial and forms/documents used by the individual site. The Principal Investigator is responsible for maintaining the ISF.

5. REFERENCES

Managing Essential Documents for Clinical Research Procedure (RCH policy RCH0608)

Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, July 2000

6. APPENDICES

Appendix 1: Essential Document tracking log
Appendix 2: Certified copy stamp details

Appendix 1

Essential document tracking log **Page __ of __**

PROTOCOL NAME/NUMBER:	Principal Investigator:

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
Example: site delegation log	**1**	*1 Jan 20XX*	*TMF*	*Yes*	*John Doe*	*N/A*
	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	