

# GUIDANCE

**Title:** Electronic file naming conventions

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

**Signature:** 

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## Review and Approval

These signatures confirm the reviewers agree with the technical content of the document and that this document is approved for implementation at the Melbourne Children's.

### NAME and TITLE:

**Signature:** 

**Date:** 29<sup>th</sup> July 2021

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

## Document History

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## 1. PURPOSE

To provide guidance in the conventions of naming electronic files at Melbourne Children's Trial Centre. The objective of this is to improve efficiency and clarity in filing and to facilitate the search and retrieval of documents.

## 2. RESPONSIBILITY AND SCOPE

This guidance applies to all Melbourne Children's employees (including visiting medical officers, visiting health professionals, contractors, consultants and volunteers of The Royal Children's Hospital, Murdoch Children's Research Institute and Department of Paediatrics University of Melbourne) who propose to undertake, administrate, review and/or govern human research involving Melbourne Children's patients and staff.

The standard may be applied to all clinical research studies, including clinical trials, observational and qualitative research.

Adherence to the naming conventions in this guidance is mandatory/recommended for the following documents:

- Essential trial documents managed in the eBinder platform Florence. This includes:
  - Investigator Site Files - for commercially sponsored clinical trials – mandatory
  - Investigator Site Files – externally sponsored collaborative research group clinical trials - mandatory
  - Trial Master File – MCRI sponsored International investigator-initiated trials (IITs) – mandatory
- Observational study documents managed in the eBinder platform Florence – recommended
- Observational and Qualitative study documents not managed in Florence – recommended
- MCTC\CRDO developed policies, standard operating procedures, guidelines, templates and forms – mandatory
- Other Melbourne Children's departments developing policies, standard operating procedures, guidelines, templates, and forms – optional.

## 3. APPLICABILITY

The designated writer of research guidance documents and all relevant research staff.

## 4. PROCEDURE

All electronic files must be assigned uniform file names that:

- a) Describe function
- b) Indicate currency
- c) Ensure a logical sequence of display



The naming convention below is recommended.

#### 4.1. FILE NAMING

Electronic file names should include the following information separated by an underscore:

<b>Trial / Group</b>	The file name should identify the trial or group generating the document Trials should be identified by the trial acronym, HREC number, or the Protocol number. Groups should be identified by an abbreviated short name eg. MCTC, OoR, Legal.
<b>ID</b>	<b><i>Apply to Controlled documents only</i></b> The ID should consist of consecutive numbering, an abbreviated site identifier (see <a href="#">Appendix A</a> for examples), and abbreviated document type (see <a href="#">appendix B</a> ). This must remain consistent as the document is revised and updated.
<b>Date</b>	The date that the document was distributed / published, formatted as YY.MM.DD to ensure that documents are filed in chronological order. Controlled documents may use ddMMMyyyy (eg. 06FEB21), as this will not affect the order the documents are displayed.
<b>Status</b>	<b><i>Apply if not a current, unaltered document</i></b> E.g. Drafts, completed forms, obsolete, Tracked Changes, etc. as per <a href="#">appendix B</a> . This may be updated in the file name should the status change.
<b>Type</b>	<b><i>Apply to Other Essential documents only</i></b> Indicate the type of document here e.g. Correspondence, minutes, etc. See <a href="#">Appendix B</a> .
<b>Title</b>	Concisely describe the contents and function – Abbreviate common words where possible. In the case of controlled documents, this may be updated as required to best describe the function and content of the document. In other cases, this should be kept consistent where possible.
<b>Version #</b>	Increasing in increments of “1” for major updates, and “.1” for minor alterations. Please refer to ‘MCTC121 Version Control’ for further information.

This information must also be listed in the document’s footer prior to distribution.

The order of this information will dictate the order in which files are displayed. As, they should present as follows:



#### 4.1.1. Controlled Documents:

Trial\_Doc ID\_Status (if applicable)]\_ Title\_VVersion #\_Date

For example, the SOP published on the 19<sup>th</sup> February 2021, would appear as follows:

ABC\_MasSOP14\_ Scanning and verifying completed participant forms\_V2.1\_21.02.19

OR

The completed and redacted feedback form, which has now been scanned and filed on the 30<sup>th</sup> November 2021, would appear as follows:

ABC\_RCHFRM3\_RxFLD\_Pat92RCH Wk 5 Feedback\_V1.0\_21.11.30

#### 4.1.2. Other Essential Documents:

Trial\_Date\_Status (if applicable)]\_Type\_Title\_Vversion #

For example, a meeting which was held on the 6<sup>th</sup> September, and minutes were distributed on the 14<sup>th</sup>, would appear as follows.

EFG\_20.09.14\_Min\_Mx team 06SEP20\_V1.0

Should an error have been found with the minutes, the previously circulated minutes would be renamed:

EFG\_20.09.14\_SS\_Min\_Mx team 06SEP20\_V1.0

The minutes with the amendment would then be saved with a new version no and the circulation date, as follows:

EFG\_20.09.17\_Min\_Mx team 06SEP20\_V2.0

This ensures that the files are listed in the folder in chronological order and the chain of events is clear.

#### 4.2. FOLDER NAMING

All folders should be assigned increasing consecutive numbers to keep files in a logical order based on importance and chronology. Folders numbered 1-9 should precede the number with a "0" to ensure files appear in the correct order.

This should be followed by the folder name which concisely describes the topic the contents relate to.



Subfolders should begin with the same numbering as their parent folder, followed by increasing consecutive numbering starting from 1.

All numbers must be divided by a full stop [.].

As an example, see the below excerpt from [MCTC012 Guidance TMF Filing V1.1](#)  
[21.06.06](#):

- 14.0 Quality Assurance
    - 14.1 CMP
    - 14.2 CMP approval
    - 14.3 Monitoring Log
    - 14.4 Monitoring Visit Reports
    - 14.5 Monitoring Correspondence
    - 14.6 DSMB
      - 14.6.1 DSMB Charter
      - 14.6.2 Charter Approval
      - 14.6.3 Minutes
      - 14.6.4 Correspondence
    - 14.7 TSC
      - 14.7.1 TSC Charter
      - 14.7.2 Charter Approval
      - 14.7.3 Minutes
    - 14.8 Local RGO Documentation
    - 14.9 Regulatory Inspection reports
  - 15.0 Statistics
    - 15.1 SAP
- Etc...*

Please refer to [MCTC011](#), [MCTC012](#), and [MCTC013](#) for further examples.

#### 4.3. ABBREVIATED NAMES

In many platforms, including Windows, Sharepoint, Teams, and Florence eBinders, a character limit applies to the file tree name. Exceeding the character limit may cause errors such as preventing the file from saving or being opened.

Abbreviations are therefore recommended for both folder names and document titles where a long file tree is expected. These abbreviations must be uniform and, where possible, intuitive to aid the team in quickly identify the meaning.

Refer to [Appendix B](#) for recommendations.



## 5. DEFINITIONS

### Controlled Documents

A document that has been created or modified through a controlled documentation process. Such a document cannot be modified without going through a documented process of change control.

### 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.

### Guidance

A written explanation of recommended practice which provides some discretion or leeway in its interpretation and implementation.

### File Tree

The location of a file which lists all parent folders in hierarchical order.

### Template

Provides a framework to implement the standardised and recommended procedures detailed in a SOP and/or Guidance.

### Trial Master File

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.

### Site Information File

Filing repository controlled by the site Principal Investigator. It is held at the trial site and contains all the essential documents necessary for the site trial team to conduct the trial as well as the essential documents that individually and collectively permit evaluation of the conduct of the trial at the site and the quality of the data produced.

### Standard Operating Procedure (SOP)

Detailed, written instructions to achieve uniformity of the performance of a specific function.



## 6. RELATED DOCUMENTS

[MCTC011 Guidance ISF Filing V1.1 21.06.06](#)

[MCTC012 Guidance TMF Filing V1.1 21.06.06](#)

[MCTC013 Guidance SIF Filing V1.1 21.06.06](#)

## 7. APPENDICES

### 7.1.1. APPENDIX A: SITE CODES

Hospital	Code	Hospital	Code
Alice Springs Hospital	ASH	Royal Hobart Hospital	RHH
Centenary Hospital for Women and Children	CWC	Royal Women's Hospital	RWH
John Hunter Children's Hospital, Newcastle	JHC	Sydney Children's Hospital Randwick	SCR
Lady Cilento Children's Hospital Brisbane	LCB	The Children's Hospital at Westmead	CHW
Monash Children's Cancer Centre, Melbourne	MCC	Women's and Children's Hospital, Adelaide	WCA
Princess Margaret Hospital for Children, Perth	MHC		
Royal Children's Hospital	RCH		
Royal Darwin Hospital	RDH	<i>Management team Master copies</i>	<i>Mas</i>





## 7.1.2. APPENDIX B: COMMON ABBREVIATIONS

Document Status	Code
Draft	DRA
Filled form	FLD
Internal only	Int
Redacted	Rx
Superseded	SS
Tracked Changes	TC
Obsolete	X
Document Type	Code
Agenda	Agd
Brochure	Br
Form	Frm
Guideline	GdL
Letter /Email / Other correspondence	Cor
Minutes	Min
Standard Operating Procedure	SOP
Template	Tem
Workflow	WF
Document Description	Code
Clinical	CL
Data	Dx
External	EX
General	G
History	Hx
Management	Mx
Patient / Participant	Pat
Statistics	ST
Safety	SF

