Guidance

Title: **Electronic file naming conventions**

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Document History

Revision	Modified by	Date of Release	Description of Change
1.0	Stephanie Firth	28/07/2021	New Issue
2.0	Iona Walton	18/01/2024	Addition of internal Melbourne Children's naming conventions for internal uploading. Updates when dates and version number should be included in file names.

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1. PURPOSE

To provide guidance in the conventions of naming electronic files at Melbourne Children's Trial Centre.

1.1 Quality Improvement

Using the electronic file naming conventions provided in this guidance facilitates the search and retrieval of documents, improving the quality of electronic filing systems for clinical research studies and general operations.

2. BACKGROUND

With the introduction of Florence eBinders and increased electronic filing of both trial and general operations documents online, it has become apparent an electronic file naming convention would reduce incorrectly labelled or misplaced documents. Systems such as SharePoint, Florence eBinders, Teams, OneDrive and Shared drive, are pre-set to file documents in alphabetical or numerical order. Hence these file naming conventions have been designed in accordance with these pre-set conditions.

3. SCOPE

This guidance may be applied to all clinical research studies, including clinical trials, observational and qualitative research, as well as general operations.

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

Mandatory	Recommended	Optional
Essential trial documents managed in the Florence eBinders™ platform. Including: • Investigator Site Files – for commercially sponsored clinical trials. • Investigator Site Files – externally sponsored collaborative research group clinical trials. • Trial Master File – MCRI sponsored international investigator-initiated trials (IITs).	Observational study documents managed in the Florence eBinders™ platform.	Other Melbourne Children's departments developing policies, standard operating procedures (SOP), guidelines, templates, and forms.
MCTC/CRDO developed policies, standard operating procedures (SOP), guidelines, templates and forms.	Observational and Qualitative study documents not managed in Florence.	

4. RESPONSIBILITY

This guidance applies to Melbourne children's campus employees who are responsible for authoring SOPs, guidance, templates for clinical research and any staff involved/delegated the responsibility for naming electronic documents for general operations.

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.

5. PROCEDURE

All electronic files must be assigned uniform file names that:

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

5.1. FILE NAMING

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

Trial / Group	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 e.g. MCTC, Office of Research (OoR), MCRI Legal (ML).
ID	***Apply to Controlled documents only*** The ID should consist of consecutive numbering, an abbreviated site identifier (see Appendix A for examples), and abbreviated document type (see appendix B). This must remain consistent as the document is revised and updated.
Date	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. 06FEB2021) in document title, as this will not affect the order the documents are displayed. *Note that there are specific requirements for controlled documents filed in online databases and in this case the publication date and version number is not included in the file name. Refer to section 5.1.3 for further information.*
Status	***Apply if not a current, released document*** E.g. Drafts, completed forms, obsolete, Tracked Changes, etc. as per appendix B. This may be updated in the file name should the status change.
Type	Indicate the type of document here e.g. Correspondence, minutes, etc. See Appendix B.

Title	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.
Version #	Increasing in increments of "1" for major updates, and ".1" for minor alterations. Please refer to 'MCTC121 Version Control' for further information. *Note that there are specific requirements for controlled documents filed in online databases and in this case the publication date and version number is not included in the file name. Refer to section 5.1.3 for further information.*

The electronic file name must also be included in the document's footer prior to distribution.

The order of fields in the file name will dictate the order in which files are displayed in the filing system, i.e. systems such as SharePoint, Florence eBinders, Teams, OneDrive and Shared drive. See sections 5.1.1 to 5.1.4 for guidance on the order of fields in file names for controlled documents, other essential documents, internal databases and superseded/archived documents.

5.1.1. Controlled Documents

Trial _Doc ID_Status (if applicable)]_ Title_Date(once finalised/published)_Version #

Example 1: A drafted SOP on scanning and verifying completed participated forms, would appear as follows:

TrialX_MasSOP14_DRA_Scanning and verifying completed participant forms_V0.1

Note the publication date is not included in the file name because this is a draft document.

Example 2: The first published guidance on how to conduct DSMB meetings and create a charter published October 7th 2022, would appear as follows:

TrialX_MasGuid23_DSMB Conduct and Charter_07OCT2022_V1.0

Note that there are specific requirements for controlled documents filed in online databases. Refer to section 5.1.3 for further information.

5.1.2. Other Essential Documents

Trial_Date_Status (if applicable)]_Type_Title_Version #

Example:

A meeting which was held on the 6th September 2020, and minutes were distributed on the 14th 2020, 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 as follows:

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.

5.1.3. Internal Document Databases

Doc ID _Status (if applicable)]_Type_Title

For internal document databases, including the Melbourne Children's Database, the file name of controlled documents should not use the version number or publication date. The document name must remain the same for each upload to ensure links to documents on websites/databases are not broken with each version update.

For example, a new guidance document on digital signatures that is ready for review, would appear as:

MCTC178_DRA_Guidance_Digital Signatures and eSignatures

And once published the file name would be updated to remove the document status as per below:

MCTC178_Guidance_Digital Signatures and eSignatures

5.1.4. Archived or Superseded Documents

When a document is updated or becomes obsolete, the previous version/obsolete document should be downloaded and filed with an updated file name that includes the publication date and version number of the superseded document, i.e. matching the publication date and version number in the document footer. .

For example, the Guidance document example in 5.1.3 is being superseded and the current version (v1.0, published 02JAN2024) is being downloaded to be kept in a superseded SharePoint folder. This downloaded copy will be named:

MCTC178_Guidance_Digital Signatures and eSignatures_02JAN2024_V1.0

5.2. 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 contents.

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 MCTC069 eTMF Filing Guideline, MCTC070 eSIF Filing Guideline and MCTC071 Investigator Site File Filing Guidance – MCRI Sponsored trials for further examples.

5.3. ABBREVIATED NAMES

In many systems, 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 in search and retrieval activities.

Refer to Appendix B for recommendations.

6. 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.

Investigator Site 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.

7. COLLABORATORS

Name/Role	Department/Group	Affiliation
Iona Walton / Project Officer	Clinical Research Development Office	MCRI
Kate Scarff / CRDO Lead	Clinical Research Development Office	MCRI

8. APPENDICES

8.1.1. 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	*Management team Master copies*	*Mas*

8.1.2. 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
Factsheet	FS
Form	Frm
Guidance	Gdc
Letter /Email / Other correspondence	Cor
Minutes	Min
Standard Operating Procedure	SOP
Template	Tem

Workflow	WF

9. RELATED DOCUMENTS

MCTC069 Guidance | eTMF Filing Guideline

MCTC070 Guidance | eSIF Filing Guidelines

MCTC071 Guidance | eISF for MCRI Sponsored Trials

MCTC121 SOP | Document Management and Version Control