# STANDARD OPERATING PROCEDURE (SOP)

**Title:** **Document Management and Version Control**

**Document ID:** MCTC121

**Version:** 1.0

**Applicability:** Human Participant Research

**Author**

**NAME and TITLE:** Stephanie Firth, Project Officer, Clinical Research Development Office (CRDO)

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

**Signature:** Signed Electronically by:
Stephanie Firth - stephanie.firth@mcri.edu.au
18-Aug-2022 @ 11:14 AM AEST Reason: Authorship

**Department name:** Melbourne Children's Trials Centre,

## Reviewed 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:** Kate Scarff, Clinical Research Development Office (CRDO) Lead

**Signature:** Signed Electronically by:
Kate Scarff - kate.scarff@mcri.edu.au
22-Aug-2022 @ 09:06 AM AEST Reason: Approval

**NAME and TITLE:** Carolyn Stewart, Melbourne Children's Business Operations manager

**Signature:** Signed Electronically by:
Carolyn Stewart - carolyn.stewart@mcri.edu.au
18-Aug-2022 @ 01:01 PM AEST Reason: Approval

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

**Document History**

| Version | Date of Release | Modified by | Description of Change |
|---|---|---|---|
| 1.0 | 17/08/2022 | CRDO – Stephanie Firth | New Issue |

# Contents

## 1.0 PURPOSE

To provide guidance in the procedure for document management and control, including drafting, issue, filing and revision of documents at Melbourne Children's. The objective of this is to ensure all sites and contributors are working on the same document versions, and to improve efficiency in filing and access.

## 2.0 SCOPE

This SOP 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.

This is required for (but not limited to) controlled documents such as:

- Protocol
- Participant/Parent Guardian Information Statement and Consent Forms
- Standard Operating Procedures (SOPs), Work Instructions, Manual of Procedures (MoPs), and associated template forms/logs/checklists
- Guidance Documents
- Data Management Plan, Data Sharing Plan, Clinical Monitoring Plan

This SOP does not differentiate between electronic and paper files, unless otherwise specified.

## 3.0 RESPONSIBILITY

It is the responsibility of the Principal Investigator (PI) to distribute or delegate distribution of the current documentation and information to all relevant staff and/or patients involved in the study, and to recall the issue of any previously provided versions.

It is the responsibility of all Melbourne Children's employees to ensure they have read, understood and adhere to the currently authorised version of documents applicable to their role. All employees should be vigilant for procedures and information which require standardisation and take the initiative to address the need for document revisions and/or a new SOP.

## 4.0 PROCEDURE

### 4.1 Document Registry

A Controlled Document Registry will record:

- Document ID (if required)
- Document title
- Version number
- Approval date
- Effective date
- Review deadline
- Withdrawal date

The Registry may also be used to record other information e.g. author, reviewer(s), authoriser(s), alterations, deviations, etc. Ensure that this registry is kept up-to-date and records all documents that have been published for the study. It is recommended that this registry is kept electronically to ensure the registry's clarity and accessibility.

This **tracker should be viewable for all project staff** and used to ensure that all in-use documents have been reviewed and approved correctly, and the project is conducted in a standardised manner as per the current written procedures. This may be uploaded in a read-only format to a central location such as a shared computer drive, team website, Teams/Sharepoint, or Florence eBinders.

## 4.2 Version Control

### 4.2.1 Version numbering

For major amendments where there is a change in procedure, the primary version number should increase in sequentially: e.g. version 1.0, version 2.0, version 3.0. For minor amendments such as administrative changes, minor errors etc., the version number should increase in sequential increments of 0.1 e.g. version 3.1, 3.2, 3.3, etc.

### 4.2.2 Central document control

When using paper files and/or a Shared Drive such as Teams, SharePoint, etc, one individual should be designated **'document controller'** to ensure document consistency within the project. The 'document controller' should have exclusive access to edit a published document registry, version trackers, and Master copies of all current and superseded documents in the Study Binder.

The 'document controller' must be notified of new issue documents and published document amendments. They are responsible for ensuring that a copy of the currently released document and all superseded versions are filed with an updated version tracker where the version tracker is not an intrinsic part of the document, and for keeping the document registry up-to-date.

Should amendments be required, the document controller will 'release' the document to an individual or team for editing, and 'lock' the document to any other edits while it is released.

Where an eBinder Platform such as Florence or SiteDocs is being used, version tracking and control is maintained by an embedded software audit trail. It is therefore not necessary to keep ocument version trackers in most cases.

Binder software is considered fit for purpose if it can:

- Restrict editing and viewing access to files where required
- Ensure document version control
- All actions can be audit tracked

## 4.3 Development

### 4.3.1 Drafting

All documents in draft form should be clearly marked as such in both the file name and in the document proper.

Ensure drafts are watermarked or otherwise clearly identified as a draft in the document content. Drafts should be created as per standardised templates to ensure clarity and consistency. Before you commence drafting a new document, check with the relevant support group if a template is available. For example, CRDO, CEBU, RCH Research Ethics & Governance Office and LifeCourse.

### 4.3.2 Review

The document should be reviewed by at least one other party with expertise relevant to the document subject matter close to the document's completion. This review will ensure it is grammatically correct, understandable, relevant, accurate, and compliant with the relevant regulations and guidelines.

The author should also consider:

- Who will be impacted by new document and/or process; and
- Who may have an impact on the new document and/or process

and engage these stakeholders for review.

When sending a document out for review, the Document Controller will 'release' the document as detailed in 4.2.1 Central document control to ensure the most current version is being viewed and/or edited at all times.

### 4.3.3 Authorisation

The controlled document must be approved by the lead individual/delegate of:

- The publishing group
- The most affected group(s)

Should the authoriser(s) require changes, the document will return to the author for additional changes. It is recommended that consideration is given to the Authoriser in the development process.

The author, reviewer and authoriser must be different people. Formal review and approval must be documented in the document version tracker.

### 4.3.4 Finalising

When the document is ready to be finalised:

- Remove the 'Draft' watermark
- Update the footer containing the document version number and publication date
- Schedule a date for periodic review (See 4.5 Periodic Review)
- If changes have been tracked or comments made in a word document, save a new version of the document with tracked changes 'approved', tracking turned off, and any comments deleted.
- The final version must be signed off by the author(s) with hard copy or electronic signatures.
- The final version must be reviewed, approved and signed off by the relevant department head(s) or delegate(s) with hard copy or electronic signatures.
- If applicable, signature blocks must be completed with hard copy or electronic signatures in the version tracker.

## 4.4 Document Issue

Following approval, the finalised document must be distributed by all relevant department, employees and/or research participants with:

- A description of document contents and/or changes eg. Summary of Changes, as a part of the document (see MCTCC111 Template: SOP / Guidance Documents), or in the body of distribution correspondence. Eg. email communication about the new document issue.

- The name / ID of any of the document(s) being replaced.
- The date of implementation
- The date of scheduled review (See 4.5 Periodic Review)
- If applicable, an outline of who is affected by the issue/changes to documentation
- If applicable, training guidelines for affected staff

Where the document must not be altered it should be published as a .pdf or other non-writable file format. Should the site/department be permitted to customise the document, it should be published as a .pdf with writable form fields, a .docx, or equivalent writable file format. It must be made clear which sections can be altered and which are essential.

The relevant department and/or employees should confirm receipt of the new documentation and the withdrawal of any superseded or obsolete documents.

**Employees working with or being guided by the document should be trained prior to the effective date, and MUST be trained prior to commencing duties relevant to the document.** Training should be documented in the training logs.

### 4.4.1 Issue via eTMF platforms

Trials using **Florence eBinders** may do this by uploading the new document to Florence and sending an announcement. This will ensure that shortcuts to the superseding document are automatically updated.

Trials using SiteDocs may do this by uploading the new document to SiteDocs and generating a workflow to ensure all relevant users are notified and trained. If a document is superseded, the workflow will now carry over to the new document. A new workflow will have to be generated.

## 4.5 Periodic Review

Documents should be reviewed and updated as required e.g. Responding to changes in regulatory requirements, improving in study processes. Should no update be required, the document must be reviewed **at least** every three years from the effective date. The projected review date must be recorded in the document register.

Three months prior to the review date the author, reviewer or approver of the document should initiate the review, and, if required, begin processes as per 4.6 Superseding Documents or 4.7 Obsolete Documents as applicable. Should no changes be required the document can be reissued with the same version number.

The authoriser must sign and date the version tracker to indicate that the review is complete, and a new review date will be set. The document controller will update the Document Registry and version tracker as required.

### 4.5.1 Approval via eTMF platforms

Within Florence eBinders, the authoriser(s) may sign an addendum page and update the expiry date on the document, to indicate their approval for the documents ongoing use.

Within SiteDocs, if a document is signed and time stamped by the authorising staff member (I.e. Quality Officer, Clinical Trials Manager) via a workflow, it is deemed to be approved for the documents ongoing use.

## 4.6 Superseding Documents

Revisions can be required for a number of reasons, including changes in regulatory requirements, in response to adverse events, to provide additional or clearer information to study participants, or even to reflect a change in

branding. All employees should be vigilant for procedures and information which may require amendment, and communicate the need for document revisions where required. Please refer to CRDO's guide on Corrective and Preventative Action Plans for more guidance.

### 4.6.1 Drafting a Superseding document

While the document is being revised the new version must be clearly labelled as a draft in both the electronic file name and in the document proper to ensure it is clear which document is currently in use. Please refer to 4.3.1 Drafting to review this process.

**PLEASE NOTE:** Minor changes such as small administrative and aesthetic alterations, or rectification of minor document errors, can be reissued without being formally reviewed and approved. In such cases, the author can contact the document controller for document 'release' to make changes, and the updated version should have a version number increased by an increment of 0.1.

### 4.6.2 Issuing updated documents

Issue the superseding document as per the process detailed in 4.4 Document Issue

### 4.6.3 Withdrawing a superseded document

Withdraw the superseded document as per the process detailed in

## 4.7 Document Withdrawal

Where using paper files and/or a shared drive, the 'document controller' must:

- Use a marker to put a diagonal line over all pages of the hard copy in the Trial Binder
- Watermark the electronic file 'Superseded' or 'Obsolete' as applicable
- Update the Electronic file name with the new status
- Update the corresponding document tracker
- Update the document registry

When using an eBinder platform, the withdrawn document will:

- Be filed in the version history superseding document; or
- Be moved to a new folder which can only be accessed by the Binder administrator and/or archivist.

All hard copies outside the Study Binders must be destroyed, and the files removed from active use. All relevant departments/sites must confirm with the document controller that all out-of-use documents have been withdrawn/destroyed.

## 4.8 Obsolete Documents

If a document falls out of use, is replaced by a new document (as opposed to being superseded by an updated version of the same document), or otherwise must be removed from use, a member of the research team should submit a request for discontinuation in writing, which must be approved by the Principal Investigator or their delegate.

On approval, studies using a shared drive and/or paper filing must Withdraw the document, updating its status to 'obsolete', and archive the file.

Where using an eBinder platform such as Florence or SiteDocs, the entire tracked file should be moved to an 'obsolete' folder located in the same place the document was previously filed.

## 5.0 GLOSSARY

### Clinical Epidemiology and Biostatistics Unit (CEBU)

CEBU specialises in biostatistics, epidemiological methods and data management. The group is jointly supported by MCRI and the University of Melbourne's Department of Paediatrics to provide expertise and support in these areas to all researchers on the Melbourne Children's campus.

### Clinical Research Development Office (CRDO)

CRDO provides education and training to facilitate and increase capacity for clinical and public health research across the Melbourne Children's campus. This includes the development and implementation of Standard Operating Procedures and templates to enable researchers to conduct high quality research.

### Clinical Trial

The World Health Organization (WHO) definition for a clinical trial is: 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.

### Corrective and Preventive Action Plan

A Corrective and Preventive Action (CAPA) plan is a quality system plan and incorporates:

1. Identifying the issue, including scope and impact
2. Identifying the root cause of the issue – how/why it occurred
3. Identifying actions to prevent recurrence of the issue (corrective action) or, identify actions to prevent an issue from occurring (preventive action)
4. Documenting that the corrective actions/preventive actions were completed

Documenting that the corrective/preventive action has resolved the problem

### 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.

### 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.

*Associate Investigator*

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., associates, residents, research fellows). May also be referred to as sub-investigator.

*Coordinating Principal Investigator (CPI)*

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.

*Principal Investigator*

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.

*Sponsor-Investigator*

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.

## Melbourne Children's

The campus encompassing all staff from The Royal Children's Hospital, Murdoch Children's Research Institute and Department of Paediatrics University of Melbourne who initiate or carry out research under one or more of these institutional affiliations.

## Melbourne Children's Trials Centre (MCTC)

Melbourne Children's Trials Centre (MCTC) is a collaboration between the Royal Children's Hospital, The Murdoch Children's Research Institute, The Royal Children's Hospital Foundation and The University of Melbourne. This Centre brings together expertise in research, clinical practice, and education and incorporates anyone who initiates or carries out research under one or more of these institutional affiliations.

## Monitor

A person appointed by the Sponsor to undertake the role of monitoring for the trial. Monitors should be appropriately trained and should have the scientific and/or clinical knowledge needed to monitor the trial adequately.

## Participant

A participant is a person that is the subject of the research.

## Protocol

A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial.

## Royal Children's Hospital (RCH)

The Royal Children's Hospital is major specialist paediatric hospital in Victoria, the Royal Children's Hospital provides a full range of clinical services, tertiary care, as well as health promotion and prevention programs for children and

young people. Its campus partners are the Murdoch Children's Research Institute and The University of Melbourne Department of Paediatrics, which are based on site at the hospital.

### Sponsor

An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. For investigator-initiated trials, MCRI or RCH will act as the Sponsor but delegate many sponsor responsibilities to the Coordinating Principal Investigator. In this case the CPI has the role of both Sponsor and Investigator and hence the MCTC has adopted the term **Sponsor-Investigator** to reflect the dual role of the CPI in investigator-initiated trials.

### Standard Operating Procedure (SOP)

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

### 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.

## 6.0 REFERENCES

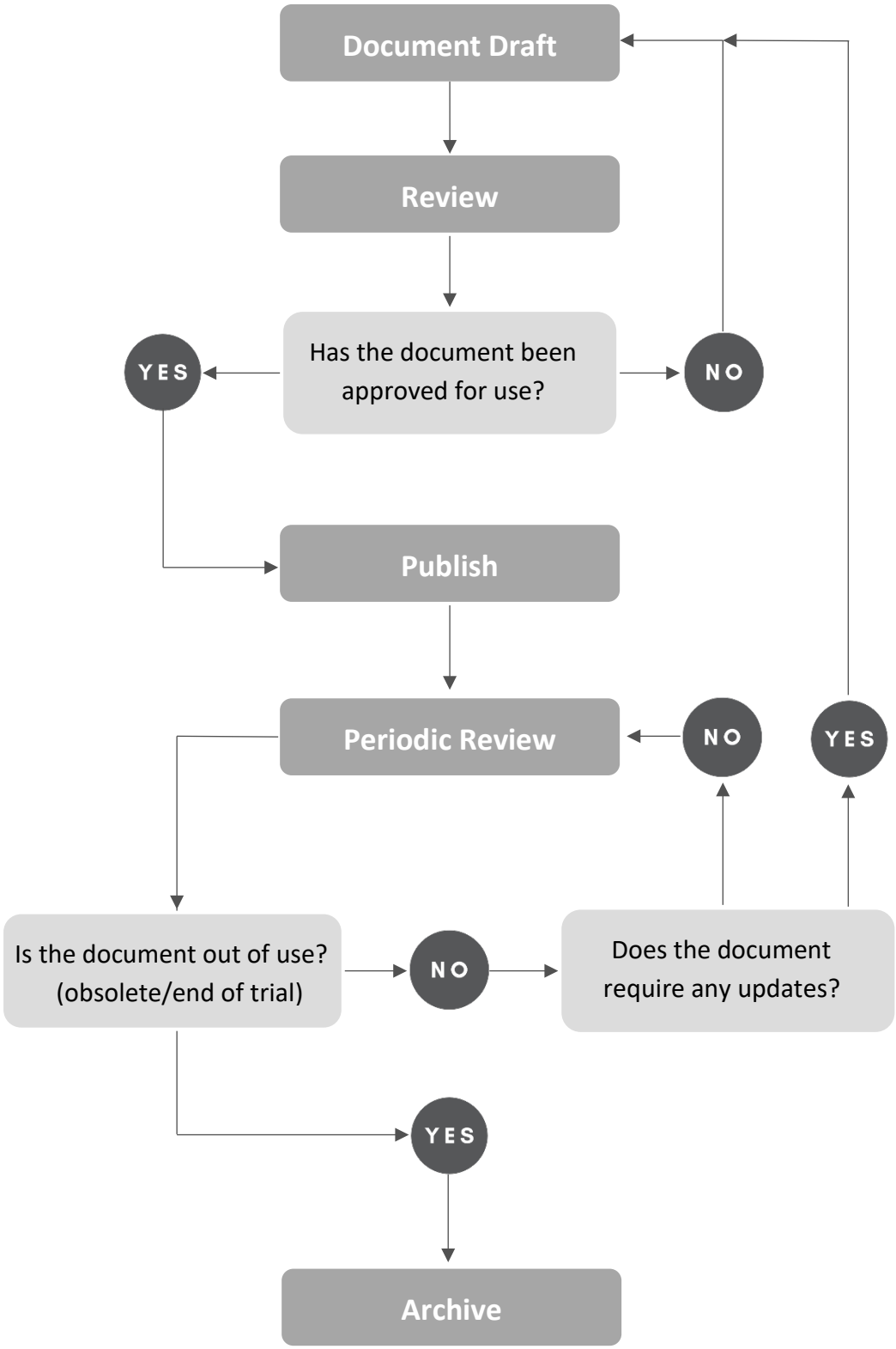
Clinical Trials Project Reference Group: National Standard Operating Procedures for Clinical Trials, including Teletrials in Australia available at https://www.health.gov.au/sites/default/files/documents/2021/02/national-standard-operating-procedures-for-clinical-trials-national-standard-operating-procedures-for-clinical-trials-including-teletrials-in-australia.pdf

## 7.0 COLLABORATORS

Melbourne Children's Clinical Trial SOP Working Group.

## 8.0 APPENDICES

### APPENDIX A: Document Workflow



## 9.0 RELATED DOCUMENTS

MCTC001 | SOP Creation of New Standard Operating Procedures V1.0

MCTC111 | Template SOP

MCTC076 | Guidance Electronic File Naming Conventions V1.0