



SOP 15 Document Management and Version Control

1.0 Purpose

To provide the procedure for document management and control, including drafting, issue, filing and revision of clinical trial documents. This SOP ensures:

- All staff within a clinical trial team and contributors are working on the same document versions during document development/updates.
- All staff are using the most recent approved version of a document.
- Efficiency in filing and access to documents throughout the trial life cycle.

2.0 Scope

This SOP applies to University of Melbourne employees involved in managing controlled documents associated with clinical trials. Staff may adopt this SOP as written or use it as a reference when developing or amending their own procedures for document management and version control.

This includes:

- Staff conducting trials at University of Melbourne at the Sponsor level (Sponsor-Investigators, and members of the central coordinating trial team)
- Staff supporting externally sponsored trials when University of Melbourne is a recruiting site (Site Principal Investigator and their site team).

University of Melbourne-Sponsor-Investigators and University of Melbourne Site PIs are responsible for implementing the procedures set out in this SOP.

Controlled documents include (but are not limited to):

- 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.

This SOP should be used for clinical trials of investigational medicinal products /investigational medical devices to facilitate the management of essential documents in accordance with ICH Good Clinical Practice, E6 (R2 & R3). This SOP may be used by staff conducting other types of clinical research at the discretion of the Sponsor/Investigator/Site Principal Investigator, to support best research practices.



3.0 Responsibility

It is the responsibility of the Sponsor-Investigator/Site Principal Investigator (PI) to manage controlled documents generated for their trials in accordance with this SOP. It is the responsibility of University of Melbourne 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 of 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 Database

The Sponsor-Investigator/Site PI/delegate will set up and maintain a controlled document database (i.e SharePoint, Shared Computer Drive, OneDrive) to record the following for all trial-specific controlled documents:

- Document title
- Document status
- Version number
- Approval date
- Effective date

You might also include:

- Author's name
- Reviewer's name
- Approver's name

The Sponsor-Investigator/Site PI/delegate will ensure the controlled document database is viewable for their respective central coordinating team/site team and for review by internal/external auditors and regulatory inspectors. This may be uploaded in a read-only format to a central location such as a shared computer drive, team website, Teams/SharePoint.

4.2 Document Version Control

4.2.1 Version numbering

For major amendments such as a change in procedure or additional information provided, 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.

4.3 Document 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 properties.

4.3.2 Document review, approval/authorisation

- Submit drafts for review by PI and relevant stakeholders.
- When the document is ready to be finalised, remove 'draft' in version control.
- Update the footer containing the document version number and publication date.
- 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).

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 e.g. Summary of Changes, as a part of the document, or in the body of distribution correspondence. E.g. email communication about the new document issue.
- The name / ID of any of the document(s) being replaced.
- The date of implementation.
- 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 is advisable to include a [Creative Commons License Attribution Noncommercial 4.0 International \(CC BY-NC 4.0\)](#). 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 training logs.

4.5 Document Revisions

Documents should be reviewed and updated as required e.g. responding to changes in regulatory requirements, improvements in study processes.

If changes are required, the author should follow the procedures outlined in *4.3 Document Development*, followed by procedure outlined in *4.6 Document Withdrawal* to retire the

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superseded version. If the author/reviewers identify that the document is no longer required, the publishing group will initiate the procedures outlined in 4.7 Obsolete 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.

4.6 Document Withdrawal

Where using paper files and/or a shared drive, the responsible person must: Use a marker to put a diagonal line over all pages of the hard copy in the Trial Binder or 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

All hard copies outside the TMF/ISF must be destroyed, and the files removed from active use.

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.

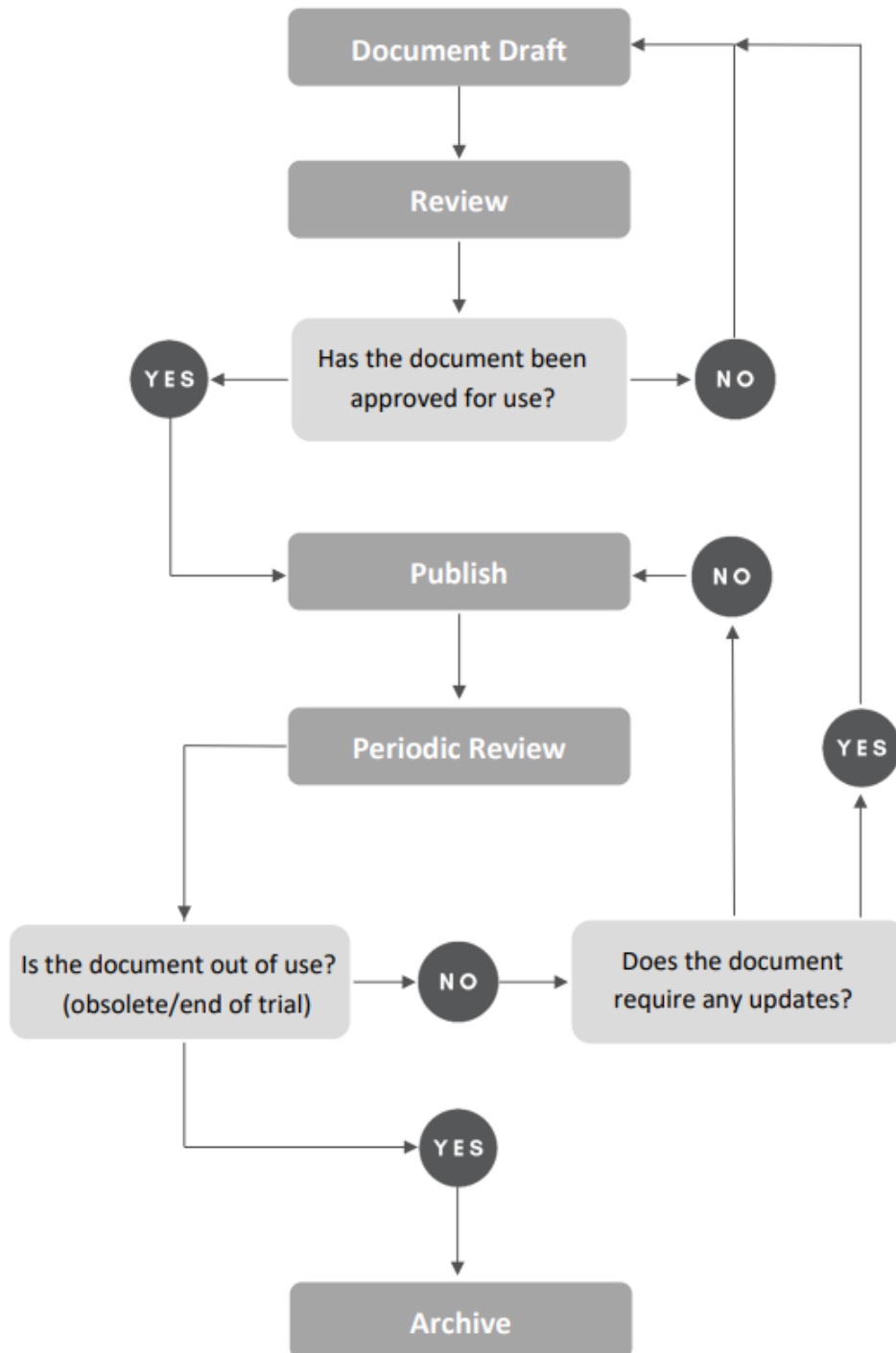
4.7 Obsolete Documents

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, approval from by the Principal Investigator or their delegate should be sort. On approval, studies using a shared drive and/or paper filing must withdraw the document. The person responsible will update the document status to 'obsolete' and archive the file.

Where using an eBinder platform such as SiteDocs, the person responsible should move the obsolete document to a folder titled 'Obsolete documents', created in the same place the document was previously filed.

Appendix 1

Document Creation and Update Workflow



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Glossary

Clinical Trial	A clinical trial as defined by the NHMRC are trials that can involve investigating new or existing medicines, medical devices and other medical or non-medical interventions. For example, a clinical trial could involve new drugs, medical devices, biologicals, vaccines, surgical and other medical treatments and procedures. Psycho-therapeutic and behavioural therapies help service changes, preventative care strategies and educational interventions are also examples of clinical trials. Researchers might also conduct clinical trials to evaluate diagnostic or screening tests and new ways to detect and treat disease.
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.
Human Research Ethics Committee (HREC)	A body which reviews research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines. The National Statement requires that all research proposals involving human participants be reviewed and approved by an HREC and sets out the requirements for the composition of an HREC.
Investigational Medicinal Product (IMP)	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
Investigational Medical Device (IMD)	A device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device.
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.

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<p>Investigator</p>	<p>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.</p> <p><u>Associate Investigator</u> 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.</p> <p><u>Coordinating Principal Investigator (CPI)</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>Principal Investigator</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>Sponsor-Investigator</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>
<p>Participant</p>	<p>A participant is a person that is the subject of the research.</p>
<p>Protocol</p>	<p>A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial.</p>
<p>Participant Information and Consent Form (PICF)</p>	<p>The PICF provides information about research and its requirements so that the prospective participant can decide if they wish to take part in the research. In general, this includes the purpose, methods, demands,</p>

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	risks, and benefits of the research. It must provide information to participants in a concise format that they are likely to understand. It must be participant centered.
Research	For the purpose of this guidance, research includes any research that requires submission to and approval from an HREC and/or research governance office. This may include (but is not limited to) observational research, clinical trials, quality assurance projects and laboratory research.
Standard Operating Procedure (SOP)	Detailed, written instructions to achieve uniformity of the performance of a specific function.
Sponsor	An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study.
Sponsor-Investigator	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: <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.

○ Revision Chronology

Document History			
Version	Effective Date	Summary of Changes	Author
1.0	20/11/2025	Initial Version	Katie Ozdowska