DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION.

Version control will be managed through the Department of Research and Innovation.

The Department of Research and Innovation, in collaboration with the Cancer Centre Clinical Trials Unit, has developed a series of standard operating procedures (SOPs) designed to facilitate good clinical trials practice and compliance with applicable regulatory requirements for clinical trial research at Bendigo Health. These SOPs are based on those developed by the Parkville Cancer Clinical Trials Unit (PCCTU) who have kindly granted permission for adaptation and use at Bendigo Health.

SOP 9: Clinical Trial Research Document Version Control

Version No:	2.0
Effective Date:	20-Dec-2021
Supersedes:	01-Sep-2020
Review Date:	20-Dec-2023

	Final revisions by:	Approved on behalf of the Interdisciplinary Research Steering Committee by Chair:
Name	Dr. Rani Watts	Dr. Angela Crombie
Position Title	Clinical Trials Research Manager	Director of Research and Innovation
Signature		
Date	20-Dec-2021	20-Dec-2021

This is a controlled document. It should not be altered in any way without the expressed permission of the developer and the approver.

1. Introduction and Background

Version control ensures amendments to clinical trial research documents are tracked, verifiable and the correct version is used according to the relevant ethical, regulatory or local approval.

2. Objective

To describe the procedure for version control and tracking of amendments to documents used for clinical trial research at Bendigo Health.

3. Scope

This standard operating procedure (SOP) applies to all documents used in the administration of Bendigo Health clinical trials, including but not limited to SOPs, work practice guidelines (WPGs), fast facts, templates and training documentation.

4. Ownership and Responsibility

This SOP applies to all members of the study team who create, edit, receive and utilise documents.

5. Glossary of Terms

Please refer to Bendigo Health's *Clinical Trial Research Standard Operating Procedures Glossary of Terms* (see Related Documents) for a full supporting glossary.

6. Procedure

6.1 Version Numbers

Sequentially unique numbers are used to distinguish one version from another. This procedure is utilised for all documents where more than one version exists, or is likely to exist in the future.

The following guidelines are observed:

- A sequential numbering system.
- Significant amendments will increase by single increments i.e. version 1.0 to version 2.0.
- Minor amendments will increase by fraction increments i.e. version 1.1 to version 1.2.
- Only approved documents will utilise version number updates.
- All drafts will be labelled with the existing version number, the word "*draft*" and the number of the draft i.e. version 1.0 draft 1.
- The version number is present on the footer of each page.

6.2 Electronic Naming Conventions

- Electronic naming of all documents can utilise underscores, commas or dashes, but avoid full stops.
- If the document is a draft, this is added to the file name to easily identify unapproved documents.

6.3 Content Protection

Documents will be saved in a format that protects the approved content from being edited. For templates where information is added by the user, the template itself should be protected and remain unchanged with the user only having the ability to add information.

This can be achieved through a number of means:

- Portable document format (PDF) is a file format which allows the transfer of documents independent of software or operating system and has the function to lock content and enable editing where desired.
- Microsoft Office programs specifically Word and Excel have the function to restrict editing to certain users or just to the author. This allows users to read documents without making changes to the content.

6.4 Document Tracking

It is a regulatory requirement to show evidence of changes made to amended documents. This can be documented by either capturing the tracked changes or by summary in an amendment history table. Amendment history tables will show evidence of the following:

- History of previous version number and date.
- Author, editor and approver.
- Brief summary of relevant changes.

7. Dissemination and Implementation

The Department of Research and Innovation at Bendigo Health is responsible for the dissemination and implementation of the Bendigo Health SOPs related to clinical research. Any content updates will be tabled at the Clinical Trials Sub-Group and the Interdisciplinary Steering Committee meetings. Content updates will be accompanied by relevant promotions and training.

Approved SOPs will be published on the Bendigo Health intranet and available through the SiteDocs portal. SOPs will be made available in hard copy format upon request to: clinicaltriasresearchsupport@bendigohealth.org.au.

Any updates to the existing approved SOPs will be disseminated internally, and will be effective immediately.

8. Monitoring Compliance and Effectiveness

SOP compliance will be monitored as part of the Bendigo Health SOP monitoring and audit process, initiated by the Clinical Trials Sub-group.

Any queries concerning the effectiveness of the SOP identified during the Bendigo Health monitoring and audit process or through use will be escalated to the Interdisciplinary Research Steering Committee to advise.

9. Review and Updating

This SOP will be reviewed every two years, or when changes to legislation or working practices impact upon the content of this document. This SOP may be merged with another SOP if appropriate or removed entirely if it becomes redundant.

10. Reference(s)

N/A

11. Related Document(s)

SOP Glossary of Terms

12. Amendment History

Version	Date	Amended By	Details of Amendment
2	10-Nov-2021	Jasmine Gillingham Dr. Rani Watts	• Revisions made in line with amendments to those made by the Parkville Precinct Clinical Trial Unit; • Minor administrative amendments