

Standard Operating Procedure:

Document Version Control with Teletrials

**SOP Number: TT-SOP-10**

|  |  |
| --- | --- |
| SOP Number: | TT-SOP-10 |
| Version Number: | 1.0 |
| Effective date: | 03 October 2018 |
| Review date: | 03 October 2021 |
| Author(s): | Hannah Cross  VCCC Program Manager |
| Approved by: | VCCC Teletrials Steering Committee |

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

**Amendment History**

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Date | Amended By | Amendment Details |
|  |  |  |  |

Developed by the Victorian Comprehensive Cancer Centre (VCCC) in conjunction with the Parkville Cancer Clinical Trials Unit (PCCTU), based on the Clinical Oncology Society of Australia (COSA) Australasian Tele-trials Model.

**A picture containing screenshot

Description generated with very high confidenceviccompcancerctr.org**

1. Introduction and Background

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

1. Objective

To describe the procedure for version control and tracking of amendments to documents used by (SITE).

1. Scope

This SOP applies to all documents used in the administration of (SITE) clinical trials, including but not limited to SOPs, work practice guidelines, fast facts, templates and training presentations.

1. Ownership and Responsibility

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

1. Glossary of Terms

Please refer to (SITE) TT-SOP-Glossary-of-Terms (see Related Documents) for full supporting glossary of terms.

1. Procedure
2. 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.

1. 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.

1. 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.

1. 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.

1. Dissemination and Implementation

Approved SOPs will be disseminated electronically by (SITE). SOPs will be made available in hard copy format or electronically upon request. Any updates to the existing approved SOPs will be disseminated internally, and will be effective immediately.

1. Monitoring Compliance and Effectiveness

Compliance with this SOP will be monitored as part of the (SITE) monitoring and audit process. Any queries concerning the effectiveness of this SOP identified during the (SITE) monitoring process or through use will be addressed and may result in the requirement to update the SOP.

1. Review and Updating

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

1. Reference(s)

N/A

1. Related Document(s)

(SITE) TT-SOP-Glossary-of-Terms