



Standard Operating Procedures

6.10 Version Tracking ©2007

| History | | | |
|---------|-------------------------------|----------------------|----------------------------------|
| Version | Date | Author | Reason |
| 1.1 | 10 th Jan 2006 | Contributing authors | New procedure |
| 1.2 | 25 th Feb 2007 | S Whicker | Administrative update |
| 1.3 | 18 th July 2007 | B Fazekas | Update prior to MAB review |
| 1.4 | 16 th October 2007 | B Fazekas | Update after David Currow review |

| Approval | | | | |
|----------|-----------|-------------------|---------------|---------------------|
| Version | Author | Signature | Approval Name | Approval Signature |
| 1.4 | B Fazekas | <i>B. Fazekas</i> | D Currow (CI) | <i>David Currow</i> |
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Scheduled review

Date August 2009

Responsible person PaCCSC Project Officer

6.10 Version Tracking

Purpose

This SOP describes the procedure for keeping track of multiple document versions, how the version is decided, reasons for the updating of documents, and the control mechanisms for distribution of document versions.

Maintaining a historical record of changes to documents over the course of a trial ensures that the ICH GCP guidelines are complied with. In addition, such a system also ensures that same version of a trial document is used across all sites.

Other related SOPs

Protocol Development
Essential Documents
Electronic Data Handling

Attachments

Version tracking.xls

References

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 250207)

<http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf>

NHMRC National Statement on Ethical Conduct in Research Involving Humans 1999 (accessed 250207) <http://www.nhmrc.gov.au/publications/files/e35.pdf>

Guideline for Good Clinical Practice ICH Harmonised Tripartite 1996 (accessed 250207) <http://www.ich.org/LOB/media/MEDIA482.pdf>

Joint NHMRC/AVCC Statement and Guidelines on research practice 1997 (accessed 250207) <http://www.nhmrc.gov.au/funding/policy/researchprac.htm>

Liu MB, Davis K. Lessons from a horse named Jim. Duke Clinical Research Institute. 2001.

Definitions

Minor Modifications

Where the document has been updated for typing, formatting, or noting of changes in non essential site information, and do not impact on the conduct of the study, ethics approval is not required.

Significant Modifications

Where the document has been updated to clarify specific sections, or where the changes are defined as significant modifications (for example, protocol amendments).

Major Modifications

Where the document has been updated and the changes have an impact on the content.

Amendment

An amendment results in a new version. Where there are changes to the approved protocol and must be approved by the ethics committee before the changes can be implemented, such as:

- changes to the intervention or intervention period
- significant changes to study design (eg. introduction of a further intervention arm)
- changes to inclusion or exclusion criteria
- addition of tests or procedure

Version

The tracking system whereby different versions of the same document can be used and identified.

PaCCSC will use a specific and standardised version control.

Procedure Responsibility

Coordinating investigator to:

- determine if a modification is major, minor or an amendment
- approve all changes to essential documents
- ensure that the most recent version is in use
- ensure that ethics approval has been sought if applicable

Project Officer to:

- ensure all protocols comply with the SOP
- distribute new versions to appropriate study staff and committee members
- maintain a record of the documents distributed (essential documents) using a version tracking spreadsheet (version tracking.xls)

Site study coordinator to:

- maintain a file of old and new versions according to Trial Master File Index
- ensure that the most recent version of any document is in use

Recording

All documents to have the version number printed on the document as part of a footnote. All electronic documents have the version number as part of the document file name.

Versions will be referred to with Vx.x.x with these being defined as;

Vx.x.x – a major modification or amendment. V3.2.1 will become V4.1.1 if a major amendment is made.

Vx.x.x – a significant modification or amendment. ie. V3.2.1 will become V3.3.1 if a significant amendment is made.

Vx.x.x – a minor modification or amendment. ie. V3.2.1 will become V3.2.2 if a minor amendment is made.

A tracking document is maintained at the coordinating site. The latest version is the working document. All previous versions of study documents are kept on file for possible reference and to provide historical information regarding the extent of changes. All correspondence to and from IEC/HRECs clearly state the version number currently under review and approved

Reporting

All changes to versions at individual sites are to be reported to all other sites through the National Manager.

Study Protocol Name/number

Document Listing

Document

- Protocol
- Information sheet
- Consent form
- Daily Diary
- Diary instructions
- Form A
- Form B
- Form C
- Form D
- Form E
- Adverse Events

Sample Only

| Trial study | | | | |
|--|---|------------|------------------------|---------------------------------|
| Document Distribution Tracking | | | | |
| Document | File location | Date Sent | Method of Distribution | Sent to: |
| Protocol v9 | C:trial study/protocol | 6/22/2004 | Paper | Local ethics committee |
| Protocol v11.1 - no appendices | C:trial study/protocol | 8/16/2004 | Paper | Local ethics committee |
| Forms A-E v11-1, Consent form v11-1, Daily diary v11-1, diary instructions v11-1, information sheet v11-1, adverse events form v2. | C:Trial study/protocol/study documents. | 10/12/2004 | email | All study investigators (names) |

Version tracking.xls

Version tracking.

Trial study

Protocol Version Tracking

| Document name | File location | Version | Date Created | Superseded by | Reason for change |
|----------------|-------------------------|---------|--------------|---------------|----------------------|
| protocol v11.1 | C:Trial Study/protocols | 11.1 | 8/17/2004 | | consolidate versions |

Sample Only