UTS IMPACCT Trials Coordination Centre

Standard Operating Procedure

6.10 Version Tracking

Version	V2.4
Author/s	B Fazekas
Approved	M Agar
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Review date	01/04/2024

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION AS AVAILABLE FROM www.uts.edu.au/itcc

Introduction / Background

Maintaining a historical record of changes to documents over the course of a study ensures compliance with the International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines. Furthermore, such a system also ensures that same version of a study document is used across all research sites.

Objective

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

Scope

This SOP applies to all staff involved in clinical studies conducted by the IMPACCT Trials Coordination Centre (ITCC) including Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST), irrespective of individual organisational employment, role, or position.

Ownership and Responsibility

Responsibilities of the IMPACCT Trials Coordination Centre.

- To determine if an amendment is minor, significant, or major
- To approve all changes to essential documents
- To distribute new versions to appropriate study staff and committee members
- To ensure that the most recent version is in use
- To ensure that ethics approval has been sought if applicable
- To maintain a file of old and new versions according to Trial Master File Index

Responsibilities of the Principal Investigator and/or other designee(s) (such as Study Site Coordinator) as documented in the Staff Signatures and Delegation Log (refer SOP 4.2.4 Delegation of Duties)

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

Procedure

1. Type of amendments

- Minor – changes are of correction or editorial nature, or part of a routine update of ongoing documents.
- Significant – changes have an impact on the implementation of the document, may require submission for HREC approval (protocol, Participant Information and Consent form (PICF) etc.), and may require some training.
    - Examples include changes to some of the data collection or assessments, clarification or changes to pharmacy procedures, changes to the contact details in a site specific PICF.
- Major – changes are significant from the previous version; the changes have an impact in the implementation across much or all the document(s) concerned, and most likely require HREC approval, and may also require updates in other regulatory documents study such as CTN, Trial registry, or as a result of ICH GCP.
    - Examples include changes to the inclusion or exclusion criteria of a protocol, changes to the randomisation or intervention, such as adding or dropping a study arm.

2. Recording

- All documents have the version number printed as part of a footnote.
- All electronic documents have the version number as part of the document file name.
- Both electronic file names and document version number also should contain the date in the following format
    - yyyymmdd
- All documents are commenced with a version number of V1.0.0
- Versions are referred to with Vx.x.x with these being defined as:

    - Vx.x.**x** – a minor modification or amendment

    Example: V3.2.1 becomes V3.2.2 when a minor amendment is made.

    - Vx.**x**.x – a significant modification or amendment

    Example: V3.2.1 becomes V3.3.1 when a significant amendment is made.

    - V**x**.x.x – a major modification or amendment.

    Example: V3.2.1 becomes V4.1.1 when a major amendment is made.

- Therefore, the full version number format for any Essential Document should be:
    - V1.0.0 20211230
- 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.

  - Previous versions should be filed in a ‘Superseded’ folder as a sub-folder to the original document position.

- All correspondence to and from Human Research Ethics Committees (HRECs) clearly state the version number currently under review and approved.

3. Reporting

- All changes to versions at individual sites are reported to all other sites through the ITCC.

Related SOPs

5.5.1 Electronic Data Handling

6.0 Protocol Development

8.0 Essential Documents

Related documents

N/A

References

Australian Code for the Responsible Conduct of Research 2007 (accessed 26/02/2020) https://www.nhmrc.gov.au/guidelines-publications/r39

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). November 2016 (accessed 26/02/2020)

https://database.ich.org/sites/default/files/E6_R2_Addendum.pdfNational Statement on Ethical Conduct in Human Research (2007) - Updated March 2018 - (accessed 26/02/2020) http://www.nhmrc.gov.au/guidelines-publications/e72

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 26/02/2020)

https://www.tga.gov.au/sites/default/files/ich13595an.pdf

Praxis Australia Ltd. SOP-05 Document and version control. V1.0 (Template for general use).

History			
Version	Date	Author	Reason
1.1	10/01/2006	Contributing authors	New procedure
1.2	25/02/2007	S Whicker	Administrative update
1.3	18/07/2007	B Fazekas	Update prior to MAB review
1.4	16/10/2007	B Fazekas	Update after David Currow review
1.5	2/09/2010	B Fazekas, T Shelby-James	Periodic review
2.0	3/02/2011	B Fazekas	Changes ratified by MAB
2.1	3/06/2015	C Hope	Periodic review
2.2	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
2.3	26/02/2020	V Yenson S Kent	Periodic review IMPACCT Trials Coordination Centre
2.4	30/12/2021	B Fazekas	Periodic review

Approval		
Version	Approval Name	Approval Signature
2.4	Meera Agar