Standard Operating Procedure

5.1.1 Standard Operating Procedure Development

Version	V2.5
Author/s	G Prael
Approved	M Agar
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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

Standard Operating Procedures (SOPs) are a mechanism by which important trial activities can be standardised and measured against in order to assess the conduct of the study and compliance with the International Conference on Harmonisation of Good Clinical Practice (ICH GCP) guidelines and other applicable regulations.

Objective

This SOP describes the process of SOP development, approval, and maintenance of written procedures to ensure compliance with regulations, guidelines, and policies at study sites. This SOP also describes the procedures for training and updating study staff in existing and new SOPs.

Scope

This SOP applies to all members of the IMPACCT Trials Coordination Centre (ITCC) clinical research team and all staff involved in clinical studies conducted by ITCC, including the 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 PaCCSC/CST National Manager or ITCC National Project Officer

- To develop all new SOPs or revise existing SOPs
- To maintain a table of contents by number and title of SOP
- To maintain a historical record of all previous versions of SOPs
- To ensure appropriate copyright is maintained for all SOPs
- To monitor site compliance with SOPs

Responsibilities of the relevant Scientific Advisory Committee

- To review all new and revised SOPs
- To approve all new and revised SOPs

Responsibilities of the Lead Investigator

- To sign and date SOPs on behalf of the approving committee
- To assume accountability for compliance with SOPs

Responsibilities of all members of the clinical research team involved in supervising, managing, or conducting ITCC study-related activities

- To familiarise themselves with and comply with the ITCC SOPs

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

- To assume accountability for compliance with the ITCC SOPs

Procedure

1. Preparing new SOPs or revising previous SOPs

PaCCSC/CST National Manager or ITCC National Project Officer:

- Develop a new SOP or revise an existing SOP following any of these circumstances:
    - Requests from the relevant Scientific Advisory Committee
    - Changes in practice, policy or regulations
    - Periodic review of SOP
    - Expiry of existing SOP
- Include in each SOP the following template information (see Template 30):
    - SOP title
    - SOP number (generally related to the appropriate section of ICH GCP E6)
    - SOP version
    - Date of current version
    - SOP history
    - SOP approval
    - Number of pages
- Develop the SOP content with:
    - Introduction / Background
    - Objective
    - Scope
    - Ownership and Responsibility
    - Procedure
    - Other related SOPs
    - Other related documents
    - References
    - Acknowledgments
- Maintain a table of contents by number and title of SOP
- Maintain a historical record of all previous versions of SOPs
- Maintain copyright by inserting the copyright symbol in the page header of each SOP

2. Reviewing SOPs

ITCC National Project Officer:

- SOPs are periodically reviewed every two years (or more often if required). The review includes accuracy, currency and compliance with regulations and guidelines using the procedure above.
- When no changes are required to the content of the SOP, a new version number and review date are generated.

3. Approval of SOPs

- New and revised SOPs are distributed to the relevant Scientific Advisory Committee for discussion and approval.
- SOPs are signed and dated by the Lead Investigator of ITCC on behalf of the approving committee.
- The relevant Scientific Advisory Committee is responsible for approval of new and/or revised SOPs.
- ITCC SOPs are covered by the University of Technology Sydney (UTS) Intellectual Property Policy and as such are subject to copyright.

PaCCSC/CST National Manager:

- Following sign-off, the finalised SOP is converted to PDF format
- An electronic copy is saved on the ITCC shared network drive
- New and revised SOPs are disseminated to all team members and study sites via:
    - The provision of paper copy
    - Email distribution notice to all study sites and team members
    - Direct teleconference
    - Upload onto www.uts.edu.au/itcc after email notification

4. Training on new or revised SOPs

The ITCC is responsible for disseminating information about and training on all SOPs within one month of approval of the SOP. Training is via one or more of the following:

- Site coordinators teleconferences
- Individual telephone calls to sites
- Workshops and training sessions

Following receipt and training of new SOP, it is the responsibility of all study sites to:

- Insert the updated table of contents into the site SOP folder
- Insert the new/revised SOP into the site SOP folder
- Train and instruct the relevant site staff including study nurses and administrative assistants. This must be recorded in the Staff Training Log (refer SOP 4.2.4 Delegation of Duties)

Related SOPs

4.2.4 Delegation of Duties

6.10 Version Tracking

Related documents

Template 30: SOP Development Template

SOP Contents Page

SOP Glossary

References

COSA Standard Operating Procedures for Investigational Sites. March 2006. A publication of the Centre for Clinical Research Practice, Inc.

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 06/02/2020)

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

University of Technology Sydney Intellectual Property Policy (accessed 06/02/2020)
http://www.gsu.uts.edu.au/policies/intellectual-property-policy.html

History			
Version	Date	Author	Reason
1.1	16/04/2010	B Fazekas T Shelby-James	New procedure
2.0	1/02/2010	B Fazekas	Ratified by MAB
2.1	18/05/2015	C Hope	Periodic review
2.2	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
2.3	06/12/2018	L Brown	Update to include CST and ©
2.4	06/02/2020	J Lourdesamy	Periodic review
2.5	12/01/2022	G Prael	Periodic review

Approval		
Version	Approval Name	Approval Signature
2.5	Meera Agar