Standard Operating Procedures

5.1.1 Standard Operating Procedure Development

Version	V2.2
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Approved	D Currow
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Review date	31/12/2019

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Introduction / Background

Standard Operating Procedures 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 ICH GCP 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 PaCCSC clinical research team and all staff involved in clinical studies conducted by PaCCSC irrespective of individual organisational employment, role or position.

Ownership and Responsibility

Responsibilities of the PaCCSC National Project Officer / National Manager

- 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 PaCCSC Scientific 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 PaCCSC study-related activities

- To familiarise themselves with and comply with the PaCCSC 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 PaCCSC SOPs

Procedure

1. Preparing new SOPs or revising previous SOPs

PaCCSC National Project Officer / National Manager:

- Develop a new SOP or revise as existing SOP following any of these circumstances:
  - Requests from the PaCCSC Trials Management Committee (TMC), the PaCCSC Management Advisory Board (MAB), PaCCSC Scientific Committee (SC), or PaCCSC Data Safety Monitoring Committee (DSMC)
  - 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

PaCCSC Scientific Committee:

- Review the draft SOP to ensure accuracy and completeness
- Submit to other committees as appropriate (TMC, MAB, DSMC)
- Approve the SOP following finalisation

2. Reviewing SOPs

PaCCSC 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 committee for discussion and approval.
- SOPs are signed and dated by the Lead Investigator of PaCCSC on behalf of the approving committee.
- The PaCCSC Scientific Committee is responsible for approval of new and/or revised SOPs.
- PaCCSC SOPs are covered by the UTS Intellectual Property Policy and as such are subject to copyright.

PaCCSC National Manager:

- Following sign-off, the finalised SOP is converted to PDF format
- An electronic copy is saved on the PaCCSC Coordinating Centre 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/paccsc after email notification

4. Training on new or revised SOPs

The PaCCSC Coordinating Centre 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)

Other related SOPs

4.2.4 Delegation of Duties

Other 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 17/10/2017)
https://www.tga.gov.au/sites/default/files/ich13595an.pdf

University of Technology Sydney Intellectual Property Policy (accessed 21/12/2017) 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)

Approval		
Version	Approval Name	Approval Signature
2.2	David Currow	