SOP Number: 10
SOP Title: Standard Operating Procedure(SOP) creation, Implementation and Revision

SOP number:	**010**
Version number:	4.0
Effective date:	April 2019
Review due:	April 2021
Author:	Roberta Lusa
Approved by:	A/Director, Health Innovation, Investment and Research Office of the Director- General

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Amendment History

Version	Date	Author/s	Amendment Details
1.0	1 June 2010	Katrina Brosnan	New
2.0	December 2017	Roberta Lusa &Bernadette Morris-Smith,	All sections, incorporating ICH GCP E6 (R2) and teletrials: QH TELETRIAL PILOT VERSION 1.0
3.0	June 2018	Roberta Lusa	All sections, refinement after CRC input: PUBLIC RELEASE VERSION 3.0
4.0	April 2019	Roberta Lusa	Amendments post Round 1 Health Service Directive Consultation. PUBLIC RELEASE VERSION 4.0

1 Purpose

To document the procedure for the creation and implementation of new Standard Operating Procedures (SOPs) and review of existing SOPs according to the principles of ICH GCP E6 (R2) and the NHMRC National Statement on Ethical Conduct in Human Research (2007) - Updated 2018.

2 Responsibility / Scope

This standard applies to all Queensland Health employees (including visiting health professionals, contractors, consultants and volunteers) who propose to undertake, administrate, review and/or govern human research involving Queensland Health patients, facilities and or staff. All study personnel involved in the clinical study must operate within their scope of practice.

This applies to all SOPs when a need is identified to either create a new SOP or modify an existing one.

3 Glossary

For an explanation of acronyms and the definition of terms used in these SOPs, please refer to Chapter Two: Glossary, located at the front of the Australian ICH GCP Standard Operating Procedures (SOP) Compendium.

4 Procedure

Review date is two years after the effective date. The time between SOP authorisation and the effective date may be reduced in special circumstances (e.g. urgent situations where procedures must be implemented immediately).

An earlier review date is permitted where necessary (e.g. changes to legislation, changes to Queensland Health policy and procedures).

4.1 Flow chart

See Appendix 1.

4.2 Initiating the creation of a new SOP or revision of an existing SOP.

All researchers may:

- Identify the need for a new SOP or a deficiency or an improvement in an existing SOP and suggest appropriate modification.
- Notify the Health Innovation, Investment and Research Office (HIIRO) Queensland Health and discuss this need at hiiro@health.qld.gov.au with the SOP number and title in the subject header.

The QH HIIRO Team will:

- Assess and verify the identified need.
- Use the provided SOP template in Appendix 2 and assign a Document ID number and Version 1.0 for all new SOPs or assign a sequential version number to modify an existing SOP.
- Draft the new or modify existing SOP and distribute the draft to relevant stakeholders for review and comment.
- Maintain a record of the review process either on a document tracking review log (including at a minimum the SOP ID, version number, reviewer name, and review
- Date, changes and comments noted by reviewer, action by owner, date of action, new version) or electronically by using the tracked changes feature with a file naming paradigm and save files on central drive.
- Incorporate relevant comments and if required redistribute to relevant stakeholder for second review.
- If necessary repeat above 2 steps until a final version is ready for approval.
- Update the front-page identifier box and / or amendment history box as necessary, ensuring the “SOP effective date” and “SOP review by date” is in alignment with the timeframe identified in this SOP.
- Arrange for final review by QH HIIRO manager if required and incorporate any relevant comments.

4.3 Approval and Authorisation of the SOP

The QH HIIRO Team will:

- Print the final SOP and arrange for approval and authorisation and final sign off by the QH HIIRO Manager.
- Ensure the original signature field and / or amendment history field is completed by QH HIIRO Manager.
- File the final approved (in writing) new/amended SOP electronically as a pdf file on the QH HIIRO drive and QHEPS website.
- Securely store the final, approved, new/amended master SOP (in the QH SOP Compendium hard copy folder which will be used only for making further controlled copies if required.
- Once the authorised QH Australian ICH GCP (including Teletrials) SOP has been approved any changes can only be made by following the steps outlined in this SOP.

4.4 Training, Implementation, Distribution of the new or revised SOP

- All relevant staff shall be trained in or notified of the new/updated SOP between the authorisation and the effective date including support staff and Queensland Hospital and Health Services Human Research Ethics Committees (HRECs) and Research Governance Officers (RGOs).
- Training to be recorded.
- All SOPs will be published.

4.5 Specific Hospital and Health Service (HHS) requirements

- If a HHS or institution or research unit within an institution wishes to deviate (ie requires a specific clause or procedure extra to or in place of a clause or procedure) from the current AUSTRALIAN ICH GCP (including Teletrials) SOPs, they may do so by recording the deviation in a file note which will be appended to the specific SOP.
- If the change is considered significant to QH Teletrials model, refer to point 4.2 above to have these changes considered in the next review of SOP.

4.6 Superseded SOPs

- QH HIIRO will notify relevant stakeholders including all support staff and Queensland HHS HRECs and RGOs of superseded SOPs.
- The superseded SOP will be watermarked with SUPERCEDED and filed in the QH SOP compendium chapter 5 on the QH HIIRO drive.
- The superseded hard copy master SOP shall be clearly marked as superseded and be securely stored as a record of previously used SOPs in the QH SOP Compendium hard copy folder.
- The superseded SOP shall be removed from the relevant website.

5 Guidance Documents

Nil in addition to the Key Guidance Documents

6 Appendices

Appendix 1: Flow Chart
Appendix 2: Standard Operating Procedure Template