# Standard Operating Procedure (SOP) Creation, Implementation and Revision

## Standard Operating Procedure

Office of Health and Medical Research  
Queensland Health

<table>
<thead>
<tr>
<th>SOP reference:</th>
<th>013</th>
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<tbody>
<tr>
<td>Version number:</td>
<td>1</td>
</tr>
<tr>
<td>Effective date:</td>
<td>01 June 2010</td>
</tr>
<tr>
<td>Review due:</td>
<td>May 2011</td>
</tr>
<tr>
<td>Author:</td>
<td>Katrina Brosnan</td>
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<tr>
<td>Approved by:</td>
<td>Dr Jane Jacobs, Director, Research Ethics and Governance Unit</td>
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### Amendment History

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<th>Version</th>
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<th>Author/s</th>
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1 Purpose

To document the procedure for the creation and implementation of new SOP’s and review of existing SOP’s.

2 Responsibility / Scope

This standard applies to all Queensland Health employees (including visiting medical officers, visiting health professionals, contractors, consultants and volunteers) who propose to undertake, administrate, review and/or govern human research involving Queensland Health patients and staff.

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

3 Applicability

The designated SOP writer and all relevant research staff.

4 Procedure

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 in an existing SOP.

The QH REGU Team will:

- Assess and verify the identified need and if appropriate assign a Document ID number to the new SOP or a new version number to a modified SOP.
- Ensure that the provided SOP template in appendix 2 is used for all new SOP’s,
- Maintain a Document Register of approved SOPs that includes as a minimum the Document ID, version number, approval date, effective date and review before date.
- Maintain a folder containing all approved SOPS, with their original signature blocks completed.

4.3 Preparation of a new SOP or revision of an existing SOP

The REGU Reviewer will:
For a new SOP, prepare a draft in accordance with the standard SOP Template which includes the following sections:

1. Aim
2. Scope
3. Applicability [revise order for all SOPs 1,2,3,6,4,5,7]
4. Procedure
5. Glossary
6. References
7. Appendices

Use sub-section numbering (eg 6.1, 6.2, 6.3 etc) as required to keep the document clear and easy to follow.

For a modified SOP, edit the current version of the SOP – making appropriate alterations to the version number and date in the footer.

Distribute the draft new or modified SOP to the stakeholders networks committees for review and comment.

Incorporate relevant comments and arrange for further review if required.

Print the final SOP and arrange for approval and authorisation by the QH REGU Team.

4.4 Approval and Authorisation of the SOP

Prior to the release of the SOP it will be reviewed and approved by the QH REGU Team and – if not previously submitted for review – to the relevant network committee before implementation.

Signature blocks must be completed on each original SOP.

4.5 Assigning ‘Effective’ and ‘Review Before’ dates to the SOP

The SOP effective date shall usually be one calendar month from the date of authorisation. However, the lapsed time between SOP authorisation and the effective date may be reduced in special circumstances (eg urgent situations where procedures must be implemented immediately).

All relevant staff shall be trained in or notified of the new/updated SOP between the authorisation and the effective date.

The QH REGU reviewer shall record the ‘Effective Date’ on page 1 of the SOP.

The SOP ‘Review Before’ date shall be two years from the SOP’s assigned “Effective Date”. However, earlier review dates may be implemented where necessary (eg changes to legislation).

The QH REGU reviewer shall record the 'Review Before' date on page 1 of the SOP.
4.6 Distribution of the new or revised SOP

- The master SOP (ie. with original signatures) shall be securely stored and used only for making further controlled copies if required.
- All known researchers and support staff and QH regional REGU offices will be notified of this new SOP.
- Sites can add to the content of an approved QH SOP - to localise it to their site - but cannot delete any content of approved SOPS.
- Site specific SOPS can be created out of these but where there is marked digression from the QH SOP, discussion must take place with QH REGU prior to release for implementation.

4.7 Superseded SOPs

- QH REGU will notify all known researchers and support staff and QH regional REGU offices of superseded SOPS.
- The superseded master SOP shall be clearly marked as superseded and be securely stored as a record of previously used SOPS.

5 Glossary

Clinical Research Coordinators
A research worker works at a clinical research site under the immediate direction of a Principal Investigator, whose research activities are conducted under Good Clinical Practice guidelines. May also be called “Clinical Trial Coordinator” or “Research Coordinator”. (ARCP Definition.)

Good Clinical Practice (GCP)
A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Governance Office/r
The Office or coordinated function within a Public Health Organisation which is responsible for assessing the site-specific aspects of research applications, make a recommendation to the District CEO / delegate as to whether a research project should be granted authorisation at that site, and overseeing that authorised research at the site meets appropriate standards (research governance).

Delegate
A person delegated specific but appropriate QA tasks in relation to SOP generation.
REGU reviewer
A person employed by the QH REGU to review SOP’s.

International Conference on Harmonisation (ICH)
International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use is a joint initiative involving both regulators and research-based industry focusing on the technical requirements for medicinal products containing new drugs.

Investigator
An individual responsible for the conduct of a clinical trial at a trial site and ensures that it complies with GCP guidelines. If a trial is conducted by a team of individuals at a trial site, one investigator should be designated as the responsible leader of the team and should be called the site Principal Investigator. In this instance they may delegate tasks to other team members.

Standard Operating Procedure (SOP)
Detailed, written instructions to achieve uniformity of the performance of a specific function.

Sub / Associate investigator
Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows, clinical research coordinators. The P.I. will designate who will be nominated as Associate Investigators for that site.

6 References
1. Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, July 2000, sections 1 and 5

7. Appendices
Appendix 1: Flow chart
Appendix 2: Standard SOP Template (word doc)
Appendix 3: Document review form (word doc)
Appendix 4: Document tracking form (word doc)
Appendix 2

SOP TEMPLATE

1. AIM
2. SCOPE
3. APPLICABILITY
4. PROCEDURE
   4.1 Subheading
   4.2 Subheading
5. GLOSSARY
6. REFERENCES
7. APPENDICES
   Appendix 1: Appendix title
   Appendix (last): SOP Change Log

DOCUMENT END
### APPENDIX 3 : DOCUMENT REVIEW FORM

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## APPENDIX 4: DOCUMENT TRACKING FORM

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