

Title: Standard Operating Procedure (SOP) Creation, Implementation and Revision

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Based on VMIA SOP 013

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Author Signature:  **Date:** 13TH July 2017
The author is signing to confirm the technical content of this document

Institution name: Melbourne Children’s

Reviewed and Approved by:

These signatures confirm the reviewers agree with the technical content of the document and that this document is approved for implementation at the Melbourne Children’s Campus.

Andrew Davidson – Medical Director, Melbourne Children’s Trial Centre (MCTC)

Signature:  **Date:** 13th July 2017

This document is effective from the date of the last approval signature and will be reviewed in two years.

Document History

Revision	Modified by	Change No.	Description of Change
1.0	CRDO Sarah Bascomb	N/A	New Issue (2014)
1.1	CRDO Fiona Williams	1	Periodic review (2017)
1.2	CRDO Fiona Williams	2	Minor change: RCH campus amended to Melbourne Children’s campus (page 1)

Contents

1.	PURPOSE	2
2.	RESPONSIBILITY AND SCOPE	2
3.	APPLICABILITY	2
4.	PROCEDURE.....	2
4.1.	Flow chart.....	2
4.2.	Initiating the creation of a new SOP or revision of an existing SOP.....	2
4.3.	Preparation of a new SOP or revision of an existing SOP	3
4.4.	Approval and Authorisation of the SOP.....	3
4.5.	Assigning 'Effective' and 'Review Before' dates to the SOP.....	3
4.6.	Distribution of the new or revised SOP	3
4.7.	Recall of superseded SOPs	4
5.	GLOSSARY	4
6.	REFERENCES.....	5
7.	APPENDICES.....	5

1. PURPOSE

To document the procedure for the creation and implementation of new SOPs and review of existing SOPs.

As SOP is a detailed, written instruction, the purpose of which is to achieve uniformity in the way a specific task or function is performed. An SOP is a controlled document. It is created through a controlled documentation process, meaning that it cannot be modified without going through a documented process of approval.

2. RESPONSIBILITY AND SCOPE

This standard applies to all employed by the partners of Melbourne Children's (including visiting medical officers, visiting health professionals, contractors, consultants, students and volunteers) who propose to undertake, administrate, review and/or govern human research involving Melbourne Children's patients and staff.

This applies to all SOPs 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 document reviewer 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 SOPs
- 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 hardcopy or electronic folder containing all approved SOPs with signature blocks completed

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

The document author/reviewer will:

- For a new SOP, prepare a draft in accordance with the standard SOP Template which includes the following sections
 1. Purpose
 2. Scope
 3. Applicability
 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
- Distribute the draft new or modified SOP to stakeholders for review and comment
- Incorporate relevant comments and arrange for further review if required
- Arrange for approval and authorisation of the final SOP

4.4. Approval and Authorisation of the SOP

- Prior to the release of the SOP it will be reviewed, approved and authorised by the relevant department head or delegate
- Signature blocks must be completed with signatures (hard copy or electronic) on each SOP

4.5. Assigning 'Effective' and 'Review Before' dates to the SOP

- The SOP can be considered effective once the new/updated SOP has been communicated to relevant staff and the staff have been trained (where applicable) in the new/updated SOP
- The document author shall record the 'Effective Date' on page 1 of the SOP
- The SOP 'Review Before' date shall be two years from the SOPs assigned "Effective Date" but earlier review dates may be implemented where necessary (e.g. changes to legislation)
- The document author shall record the 'Review Before' date on page 1 of the SOP

4.6. Distribution of the new or revised SOP

- The master SOP shall be securely filed and used only for making further controlled copies if required
- Copies of the approved SOP will be placed in an accessible location for relevant staff to access; electronic copies should be provided as locked PDFs.

- All known relevant researchers and research staff will be notified of this new SOP

4.7. Recall of superseded SOPs

- The superseded master SOP shall be filed securely as a record of previously used SOPs
- Other copies of a superseded SOP (electronic or hard copies) shall be deleted or destroyed

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” or “study coordinator”. (ARCP Definition.)

Controlled Document

A document that has been created or modified through a controlled documentation process. Such a document cannot be modified without going through a documented process of change control. A controlled document will have a version number, an approval signature and be dated. In most cases there is a review and authorisation step in addition.

Delegate

A person delegated specific but appropriate QA tasks in relation to SOP generation

Document controller

A person responsible for the distribution and maintenance of SOPs.

Document reviewer

A person delegated the task of reviewing SOPs by QA or the Institution or Investigator.

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.

The organisation conducting the research, following a human research ethics committee (HREC) approval, must authorise research governance/SSA before a research project can commence at that site.

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 study at a study site, ensuring that the study complies with GCP guidelines. If a study is conducted by a team of individuals at a study site, the investigator is the responsible leader of the team and may be called the Principal Investigator. In this instance they may delegate tasks to other team members.

Melbourne Children's

This term is used to encompass all staff from The Royal Children's Hospital, Murdoch Children's Research Institute and Department of Paediatrics University of Melbourne who initiate or carry out research under one or more of these institutional affiliations.

Research

"Includes at least investigation undertaken to gain knowledge and understanding or to train researchers" (National Statement on Ethical Conduct in Human Research 2007 [Updated May 2015]). For the purpose of this guidance, research includes any research that requires submission to and approval from an HREC and/or research governance office. This may include (but is not limited to) observational research, clinical trials, quality assurance projects and laboratory research.

Research Governance Office

Research governance is a framework for institutions to use to ensure research is conducted responsibly and safely and is scientifically and ethically sound. Research governance considers the legal compliance, financial management, accountability and risk management associated with at a participating site.

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 study team designated and supervised by the investigator at a study site to perform study-related procedures and/or to make important study-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

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

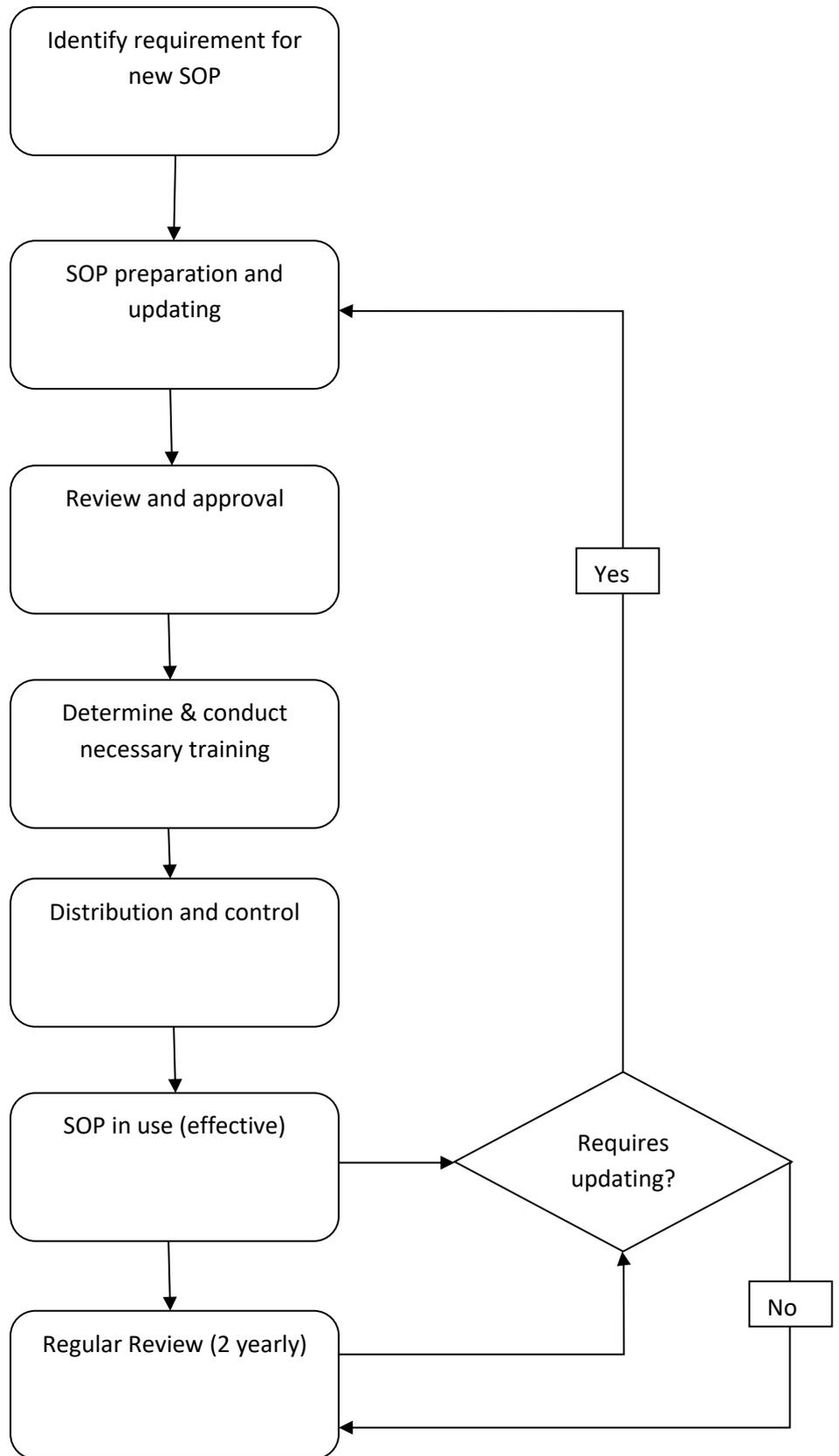
7. APPENDICES

Appendix 1: Flow chart

Appendix 2: Standard SOP Template

DOCUMENT END

APPENDIX 1: FLOW CHART



APPENDIX 2: STANDARD SOP TEMPLATE

Title:

Document ID:

Version:

Author:

Author Signature: _____ **Date:** <insert date>

The author is signing to confirm the technical content of this document

Institution/Department name: <insert institution/department name>

Reviewed and Approved by:

These signatures confirm the reviewers agree with the technical content of the document and that this document is approved for implementation at the <insert department/research group>.

NAME and TITLE:

Signature: _____ **Date:** <insert date>

NAME and TITLE:

Signature: _____ **Date:** <insert date>

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1.0	[Author]	N/A	New Issue

1. PURPOSE
2. SCOPE AND RESPONSIBILITY
3. APPLICABILITY
4. PROCEDURE
 - 4.1 Subheading
 - 4.2 Subheading
5. GLOSSARY
6. REFERENCES
7. APPENDICES
 - 7.1 Appendix 1: Appendix title
 - 7.2 Appendix 2: Appendix title

DOCUMENT END