

MELBOURNE HEALTH		OFFICE FOR RESEARCH	
		STANDARD OPERATING PROCEDURE: SOP013	
		Standard Operating Procedure (SOP) Creation, Implementation and Revision	
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1. AIM

To document the procedure for the creation, implementation and review of SOP's.

2. SCOPE

This SOP applies to research 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 Investigator/Sub-investigator.

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 staff may:

- Identify the need for a new SOP or a deficiency in an existing SOP.
- Notify the designated SOP writer, Investigator/Sub-investigator and/or QA officer and discuss the need with them.

The designated SOP writer and Investigator/Sub-investigator QA officer/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 SOP's,

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- 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.

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

The QA officer/document 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/ Responsibilities[revise order for all SOPs 1,2,3,6,4,5,7]
 4. Procedure
 5. Definitions
 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.
- Distribute the draft new or modified SOP to the QA officer or the document reviewer 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 QA officer or the document reviewer.

4.4 Approval and Authorisation of the SOP

- Prior to the release of the SOP it will be reviewed and approved by QA or delegate and finally authorised by the department head or Institutional delegate.

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).

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- All relevant staff shall be trained in the new/updated SOP between the authorisation and the effective date.
- The Institutional delegate or Investigator shall record the 'Effective Date' on (at least) page 1 of the SOP.
- The SOP 'Review Before' date shall be three years from the SOP's assigned "Effective Date".
- The Institutional delegate or Investigator shall record the 'Review Before' date on (at least) page 1 of the SOP.

4.6 Distribution of the new or revised SOP

- At least one controlled copy will be available for use by the study team. Further copies will also be tracked and controlled (see appendix 4).
- Controlled copies shall be clearly identified.
- The master SOP shall be securely stored and used only for making further controlled copies if required.
- Controlled versions of SOPs may be made available in an electronic form, such as a .pdf document.

4.7 Recall of superseded SOPs

- The document controller will communicate when SOPs have been superseded via appropriate means (email/meetings etc.) and instruct confidentially destruction/e-filing 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. DEFINITIONS

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.

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

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reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

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 SOP's by QA or the Institution or Investigator.

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 research projects including clinical trials at a research/trial site and ensures that it complies with GCP guidelines. If a research/trial is conducted by a team of individuals at a research/trial 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.

Quality Assurance Officer (QA)

In general, the person assigned the task of ensuring overall quality of a range of activities to enhance the quality of a given function or system.

Standard Operating Procedure (SOP)

Detailed, written instructions to achieve uniformity of the performance of a specific function.

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
- Appendix 3: Document review form

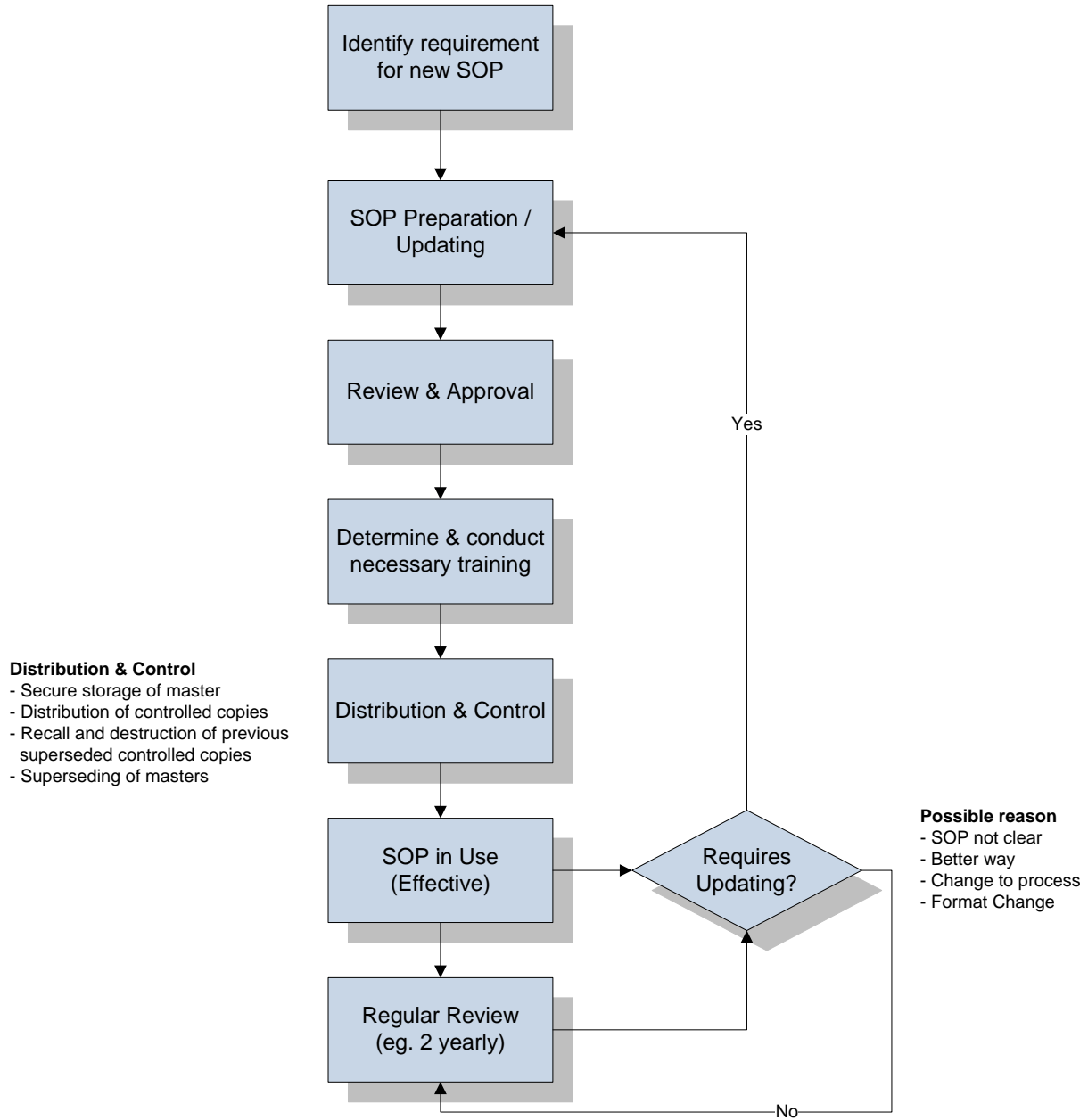
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Appendix 4: Document tracking form
Appendix 5: SOP Change Log

DOCUMENT END

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APPENDIX 1: FLOW CHART



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APPENDIX 2:

REFER TO ATTACHMENT

DOCUMENT END

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APPENDIX X: EXAMPLE OF CHANGE LOG

<i>Version No.</i>	<i>Reason for Issue</i>
1	First issue
2	(List changes from previous version)

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APPENDIX 3: DOCUMENT REVIEW FORM

<i>Document Reviewed (Document ID)</i>	<i>Reviewer comments</i>	<i>QA or Second Reviewer Comments</i>

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APPENDIX 4: DOCUMENT TRACKING FORM

Document ID	Effective date	Date sent	Copy no.	Return (X)	Destroy (X)	Date sent	Copy no.	Return (X)	Destroy (X)	Date sent	Copy no.	Return (X)	Destroy (X)

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APPENDIX 5: SOP CHANGE LOG

<i>Version No.</i>	<i>Reason for Issue</i>
1	First issue
2	18/10/2013 : Review content
3	20/6/2016: Review content
4	1/4/2017: Review content and minor updates to sections 4.5, 4.7
5	31/8/2017: <ul style="list-style-type: none">• Section 3 - add “/Responsibilities” to section title.• Section 5 - Change term Glossary to Definitions.• Replace Appendix 2 with updated format.

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