Western Health

**STANDARD OPERATING PROCEDURE**

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

## Standard Operating Procedure

## Western Health

| | |
|---|---|
| **SOP reference** | 013 |
| **Version:** | 3.0 dated June 2019 |
| **Effective Date** | June 2019 |
| **Review Date** | June 2021 |
| **Approved by** | Mr Bill Karanatsios, Research Project Director |
| **Signature and date** | |

***Amendment History***

| VERSION | DATE | AMENDMENT DETAILS |
|---|---|---|
| 2.0 | 04 Dec 2015 | |
| 3.0 | June 2019 | Updated to align with MACH SOPs |

# 1. AIM

To document the procedure for the creation and implementation of new Standard Operating Procedures (SOPs) and review of existing SOPs.

# 2. SCOPE

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 Principal Investigator (PI)/ Associate Investigator (AI).

# 4. PROCEDURE

### 4.1. Flow chart

See Flow chart in **Appendix 1**.

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

**All staff may:**

| STEP | ACTION |
|---|---|
| **4.2.1.** | Identify the need for a new SOP or a deficiency in an existing SOP. |
| **4.2.2.** | Notify the SOP author or equivalent responsible person and discuss the need with them. |

**The designated SOP writer, PI/AI or Quality Assurance (QA) officer/document reviewer should:**

| STEP | ACTION |
|---|---|
| **4.2.3.** | 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. |
| **4.2.4.** | Ensure that the provided SOP template in **Appendix 2** is used for all new SOPs. |
| **4.2.5.** | 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 designated SOP writer, PI/AI or QA officer/document reviewer should:**

| STEP | ACTION |
|---|---|
| **4.3.1.** | For a new SOP, prepare a draft in accordance with the standard SOP<br>Template which includes the following sections: |

| | |
|---|---|
| | 1. Aim<br>2. Scope<br>3. Applicability<br>4. Procedure<br>5. Glossary<br>6. References<br>7. Appendices<br>8. Authors/Contributors<br>9. Primary Person/Department Responsible for Document |
| **4.3.2.** | Use sub-section numbering (e.g. 6.1, 6.2, 6.3 etc.) as required to keep the document clear and easy to follow. |
| **4.3.3.** | For a modified SOP, edit the current version of the SOP. |
| **4.3.4.** | Distribute the draft new or modified SOP to the QA officer or the document reviewer for review and comment. |
| **4.3.5.** | 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

**The designated SOP writer, PI/AI or QA officer/document reviewer should:**

| STEP | ACTION |
|---|---|
| **4.4.1** | Prior to the release of the SOP it will be reviewed and approved by the QA officer or delegate and finally authorised by the department head or Institutional delegate. |

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

**The designated SOP writer, PI/AI or QA officer/document reviewer should:**

| STEP | ACTION |
|---|---|
| **4.5.1** | 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 (e.g. urgent situations where procedures must be implemented immediately). |
| **4.5.2** | All relevant staff shall be trained in the new/updated SOP between the authorisation and the effective date. |

| | |
|---|---|
| **4.5.3** | The Institutional delegate or Investigator shall record the 'Effective Date' on page 1 of the SOP. |
| **4.5.4** | The SOP 'Review Before' date shall be two years from the SOP's assigned "Effective Date". |
| **4.5.5** | The Institutional delegate or Investigator shall record the 'Review Before' date on page 1 of the SOP. |

### 4.6. Distribution of the new or revised SOP

**The designated SOP writer, PI/AI or QA officer/document reviewer should:**

| STEP | ACTION |
|---|---|
| **4.6.1** | 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). |
| **4.6.2** | Controlled copies shall be clearly identified. |
| **4.6.3** | The master SOP (i.e. with original signatures) shall be securely stored and used only for making further controlled copies if required. |
| **4.6.4** | Controlled versions of SOPs may be made available in an electronic form, such as a pdf document. |

### 4.7. Recall of superseded SOPs

**The designated SOP writer, PI/AI or QA officer/document reviewer should:**

| STEP | ACTION |
|---|---|
| **4.7.1** | Ensure the superseded copies are returned and confidentially destroyed. |
| **4.7.2** | The superseded master SOP shall be clearly marked as superseded and be securely stored as a record of previously used SOPs. |

## 5. GLOSSARY

**Associate Investigator (AI)**

Any individual member of the clinical trial team designated and supervised by the investigator at a study site to perform critical study-related procedures and/or to make important study-related decisions (e.g., associates, residents, research fellows). Also referred to as "Sub-Investigator".

**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 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.

**Principal Investigator (PI)**

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, 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 (QA) Officer**

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. Based on VMIA GCP SOP No.013 Version1.0 Dated 17 September 2007
2. Based on MACH GCP SOP No.013 Version 1.0
3. 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

Appendix 4: Document tracking form

## 8. AUTHORS/CONTRIBUTORS

Bill Karanatsios, Research Program Director, Western Health

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Kerrie Russell, Ethics Administration Officer, Western Health

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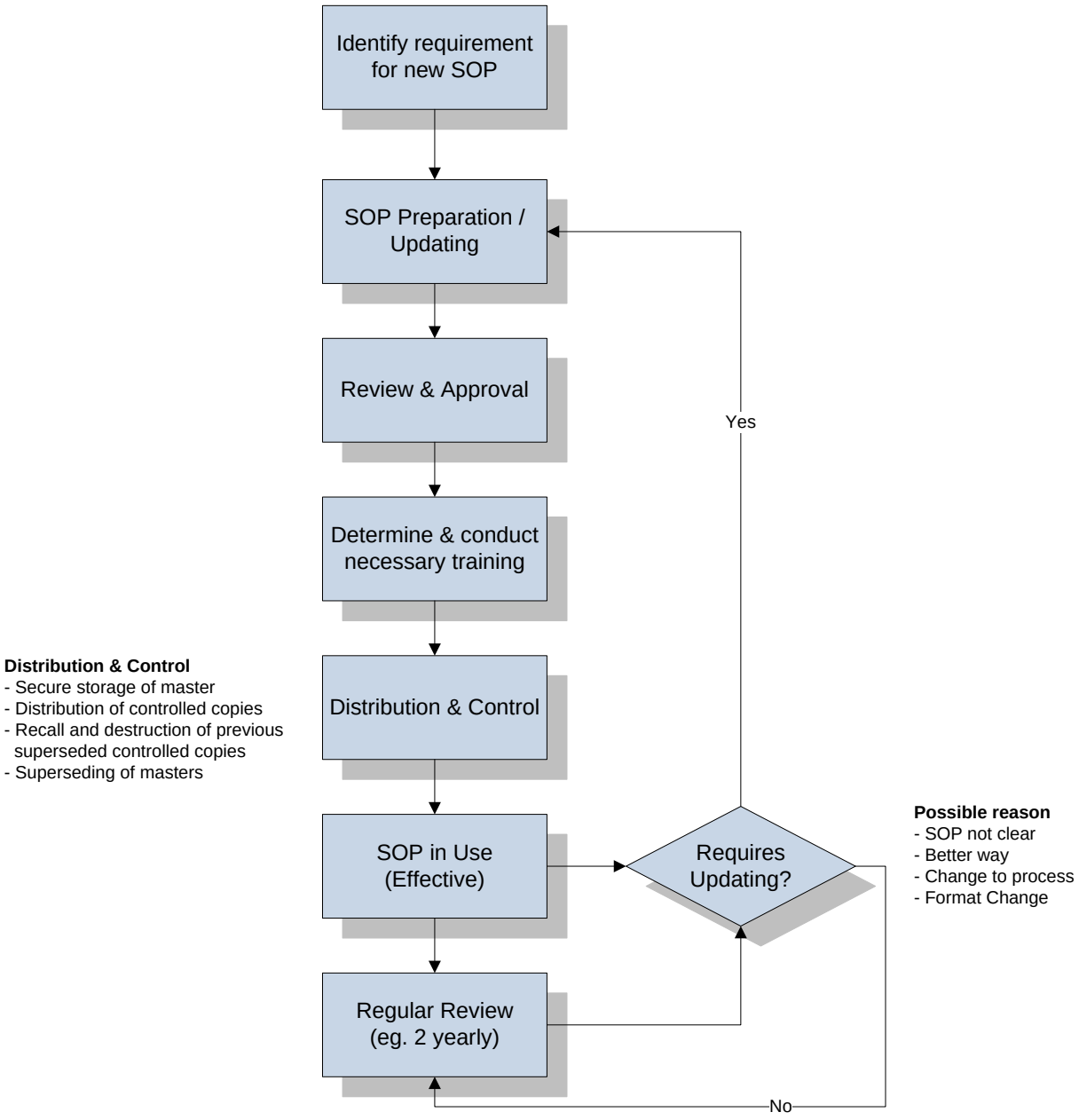
## 9. PRIMARY PERSON/DEPARTMENT RESPONSBLE FOR DOCUMENT

Western Health Office for Research

# APPENDIX 1: FLOW CHART



## APPENDIX 2: STANDARD SOP TEMPLATE

WH GCP SOP013 Appendix 2 version 3 dated May 2019

# SOP TITLE

## Standard Operating Procedures

## Western Health

| | |
|---|---|
| **SOP reference** | **000** |
| **Version:** | |
| **Effective Date** | |
| **Review Date** | |
| **Approved by** | |
| **Signature and date** | |

### *Amendment History*

| VERSION | DATE | AMENDMENT DETAILS |
|---|---|---|
| | | |
| | | |

# 1. AIM

# 2. SCOPE

# 3. APPLICABILITY

# 4. PROCEDURE

### 4.1. Subheading

| STEP | ACTION |
|---|---|
| 4.1.1 | |
| 4.1.2 | |

### 4.2. Subheading

| STEP | ACTION |
|---|---|
| 4.2.1 | |
| 4.2.2 | |

# 5. GLOSSARY

# 6. REFERENCES

# 7. APPENDICES

# 8. AUTHORS/CONTRIBUTORS

# 9. PRIMARY PERSON/DEPARTMENT RESPONSIBLE FOR DOCUMENT

# APPENDIX 3: Document Review Form

WH GCP SOP013 Appendix 3 version 3 dated May 2019

## [HOSPITAL LOGO]

| ***Document Reviewed (Document ID)*** | ***Reviewer comments*** | ***QA or Second Reviewer Comments*** |
|---|---|---|
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# APPENDIX 4: DOCUMENT TRACKING FORM

WH GCP SOP013 Appendix 4 version 3 dated May 2019

## [HOSPITAL LOGO]

| 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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