Guidance

Title: Creation of New Standard Operating Procedures, Guidance documents, and Work Instructions

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Reviewed and Approval

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19-Sep-2025 @ 04:09 PM AEST
Reason: Approval

This document is effective from the date of the last approval signature and will be reviewed in three years, or earlier if required.

Document History

Revision	Modified by	Effective Date [DD/MM/YYYY]	Description of Change
1.0	CRDO Sarah Bascomb	2014	New Issue
1.1	CRDO Fiona Williams	2017	Periodic review
1.2	CRDO Fiona Williams	July 2017	Minor change: RCH campus amended to Melbourne Children's campus (page 1)

2.0	CRDO Stephanie Firth	26/09/2022	Major change: Separate our document management and control activities into a new SOP. This SOP now has a narrower scope and covers process for identifying and developing a new SOP.
3.0	CRDO Iona Walton	3/10/2025	Major change: inclusion of guidance documents and work instructions.

CONTENTS

1. PURPOSE

To document the procedure for developing new Standard Operating Procedures (SOPs), Guidance documents, and Work Instructions for the purpose of standardising and improving the quality of procedures in human participant research.

2. BACKGROUND

A Standard Operating Procedure (SOP) is a detailed, written instruction to provide staff with instruction about uniformity in the way a specific task or function is performed. These are to be written in a concise, step-by-step, easy-to-read format with the information presented unambiguous and not overly complicated. They must be consistent with internal and external policy and regulation.

An SOP may be put in place to:

- Communicate expectations for compliance with regulation or institutional policy
- Standardise practice to uphold data reliability and credibility
- Standardise practice to uphold patient safety and rights
- Identify and formalise existing standard practices
- To mitigate a specific risk identified in an individual human participant research study
- Improve efficiency
- Assist in training new staff

Research SOPs must comply with the trial protocol and any other applicable state/national/international requirements. For example, GCP in the case of clinical trials.

A Guidance document is a document that one that contains advice on Best Practice, based on institutional policy and procedures and applicable regulations and legislation. They also contain background explanation as to why this practice is recommended. A Guidance document is only developed when needed to support a Standard Operating Procedure (SOP), or suite of SOPs.

Work instructions are the most detailed document, written to support or describe particular processes outlined in Standard Operating Procedures (SOPs) or Guidance documents. Work instructions are often department/group specific. They describe in detail how particular processes must be performed, in alignment with an SOP or Guidance.

3. SCOPE

This Guidance document describes the process for creating new SOPs, Guidance documents, and Work instructions. It includes identifying when one is needed, who to involve in the development, and the drafting process. It does not include version control management or the

document review process. For this information, refer to MCTC121 SOP | Document Management and Version Control.

4. RESPONSIBILITY

This Guidance document applies to all staff employed by the partners of Melbourne Children's who are involved in the planning, conduct, analysis, governance, education / training, or administration of human participant research conducted at the Melbourne Children's.

This includes (but is not limited to):

4.1. Research teams

When conducting research, the MCRI **Sponsor-Investigator** (when MCRI is the Sponsor) or MCRI site **Principal Investigator** (when Melbourne Children's is a participating site in an externally led research study) is responsible for developing SOPs, Guidance documents or Work Instructions where existing documents are not already in place. The Sponsor-Investigator/Principal Investigator may delegate this responsibility to an appropriately qualified member of the study team.

4.2. Supporting departments

Supporting departments vary for each research study and may include RCH Clinical Trial Pharmacy, RCH Medical Imaging, Laboratory Services and the Melbourne Children's Trials Centre. **The Head of Department or Group Lead** is responsible for ensuring appropriate SOPs, Guidance documents or Work Instructions are in place which will support consistency and quality of relevant outputs.

4.3. Melbourne Children's Staff

All Melbourne Children's staff involved in the planning, conduct, analysis, governance, education / training, or administration of human participant research, may identify the need for a new SOP, Guidance document or Work Instruction, or a deficiency in an existing document. Deficiencies may include unclear instructions, lack of sufficient detail, or obsolete/inaccurate procedure.

4.4. Author, Reviewer and Approver

The **author, reviewer, and approver** are responsible for ensuring the content of the new document:

- Is compliant with relevant state/national/international requirements and professional regulations
- Does not conflict with existing institutional policy or other documents

- Reflects current 'Best Practice'

5. PROCEDURE

5.1. Identify where an SOP is required

Development of a new SOP may be prompted:

- Internally (e.g., Quality Assurance activities, risk evaluation, updates to institutional policy, response to feedback, etc.)
- Externally (external audit, legislative requirements, practice guidelines, etc.)

These should be identified prior to commencing a new activity but may be identified at any stage if required. Examples of tasks that require standardisation include:

- Recruitment and randomisation
- Handling of investigational product
- Sample processing
- Processing of service requests
- Processing and storing records
- Monitoring / Quality Assurance
- Handling and/or maintenance of equipment
- Reporting requirements

Prior to developing a new SOP, staff are required to consult with research support departments [e.g., Clinical Epidemiology and Biostatistics Unit (CEBU), Clinical Research Development Office (CRDO), RCH Research Ethics & Governance (REG)] and campus policy libraries etc. to assure that there is not already an institutional SOP in place.

5.2. Is an SOP the best tool?

An SOP may not always be the most appropriate document. Depending on the purpose of the document, a Guidance or Work instruction may be more fit for purpose.

A Guidance document is be created when an SOP, or suite of SOPs, already exists for a particular procedure but additional description or information is required. A Guidance document is created to inform staff on Best Practice based on current policy and procedures, as well as requirements for relevant legislation and regulations. A Guidance document will also provide background and explanation as to why the Guidance recommends this practice, and why the Guidance must be followed.

Work instructions are created to support either SOPs or Guidance document, to provide a detailed instruction on how to complete or follow a practice described in the parent documents. A Work instruction is often made for team-level instruction; to provide an in-

depth description of how whole or parts of SOPs and Guidance documents are eg. step-by-step how to complete a particular activity or operation (e.g., a pathology work instruction detailing exactly how to spin a particular type of sample.

5.3. Stakeholder Engagement

Before writing an SOP, Guidance or Work instruction, consider:

- Stakeholders who will be affected by its introduction
- Stakeholders who may effect changes in the scope of activities covered by the document

Tailor the degree of engagement with stakeholders based on the importance of their impact and the degree to which they are impacted (see Appendix 1: Stakeholder Prioritisation).

Ensure that you:

- Collaborate directly with key stakeholders when creating the document
- Seek review from, or consult, high priority stakeholders
- Consider the opinions of low priority stakeholders

Common examples of key stakeholders include:

- Principal Investigator
- Trial staff
- Supporting departments (if directly affected)

High priority stakeholders may include:

- Government regulatory bodies
- Institutional policy makers
- Department heads
- Relevant supporting departments (if indirectly affected)
- Trial participants (if directly affected)

As the degree of impact will depend on the procedure, it is important to assess every new document with key stakeholder(s).

5.4. Version Control

SOPs, Guidance, and Work Instructions are controlled documents and must therefore be created and maintained as per the procedure in MCTC121 SOP | Document Management and Version Control. This includes a process for:

- Review
- Approval

- Finalisation
- Distribution
- Periodic review
- Superseding previous versions
- Withdrawing obsolete documents

The file is to be named as per procedure in MCTC076 Guidance | Electronic File Naming Conventions.

5.5. Drafting

Prepare a draft in accordance with the appropriate template, depending on what document you are creating.

- SOP: MCTC111 Template | SOP,
- Guidance: MCTC110 Template | Guidance,
- Work Instruction: MCTC219 Template | Work Instruction.

Using the templates will ensure the inclusion of all necessary information, and that the style and formatting of all documents is consistent.

5.6. Numbered Headings

5.6.1. Procedural steps are to be listed in order of occurrence

Each new step in the document (and the subprocesses where applicable) should be assigned a heading which begins with increasing consecutive numbers. Subprocesses must begin with the same numbering as their parent process, followed by increasing consecutive numbers. Numbers must be divided by a full stop (e.g. 1.2.4).

5.6.2. Plain Language

SOPs, Guidance, and Work Instructions are to provide specific, concise instructions which are easy to follow. The following style elements are recommended:

- Short sentences
- Active voice
- Written in third person (e.g. The PI reviews the documentation)
- Well spaced-out text
- Short paragraphs
- Logical ordering of information
- Bullet points
- Clear headings
- Changes in font for key information e.g. Indented italics, etc.

Refer to the RCH Style guide and Plain Language Resources for more detailed guidance.

6. GLOSSARY

Refer to MCTC218 Glossary for an updated list of glossary terms.

7. REFERENCES

Australian Commission on Safety and Quality in Health Care. The National Clinical Trials Governance Framework and user guide for health service organisations conducting clinical trials. Sydney: ACSQHC; 2022 available at https://www.safetyandquality.gov.au/sites/default/files/2022-05/final_design_-_national_clinical_trials_governance_framework_and_user_guide_-_30_may_2022.pdf

Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice ICH E6 (2) 2016 – Annotated with TGA comments available at https://www.tga.gov.au/publication/note-guidance-good-clinical-practice

Policies and Procedures : Policy and Procedure Development and Review guide (rch.org.au)

Policies and Procedures : Policy and Procedure Manual (rch.org.au)

8. COLLABORATORS

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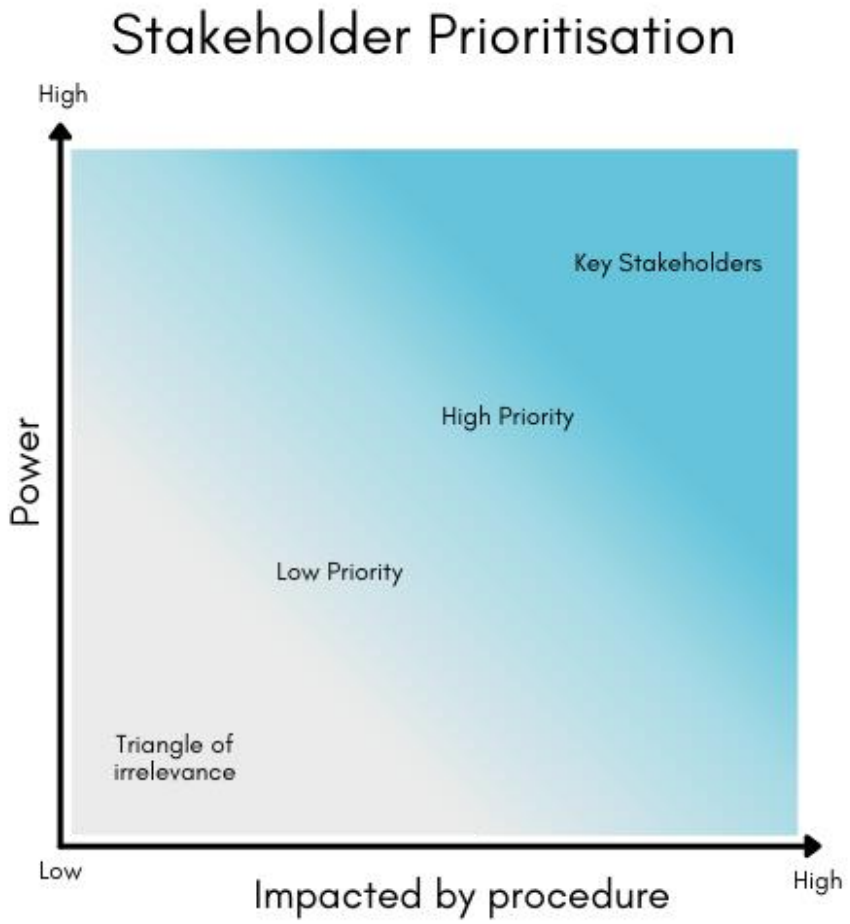
9. APPENDICES

9.1. Appendix 1: Stakeholder Prioritisation



10. RELATED DOCUMENTS

MCTC076 Guidance | Electronic File Naming Conventions

MCTC110 Template | Guidance

MCTC111 Template | Standard Operating Procedure

MCTC121 SOP | Document Management and Version Control

MCTC219 Template | Work Instruction

DOCUMENT END