Guidance

Title: Creation of New Standard Operating Procedures

Document ID: MCTC001

Version: 2

Applicability: Human Participant Research

Author

NAME and TITLE: Stephanie Firth, Project Officer

Iona Walton is signing on behalf of the author to confirm the technical content of this document.

Signature: Signed Electronically by:
Iona Walton - iona.walton@mcri.edu.au
13-Oct-2022 @ 11:35 AM AEDT Reason: Authorship

Institution/Department name: Melbourne Children's Trial Centre

Reviewed and Approval

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.

NAME and TITLE: Kate Scarff, Clinical Research Development Office Lead

Signature: Signed Electronically by:
Kate Scarff - kate.scarff@mcri.edu.au
13-Oct-2022 @ 11:43 AM AEDT Reason: Approval

NAME and TITLE: Carolyn Stewart, MCTC Business and Operations Manager

Signature: Signed Electronically by:
Carolyn Stewart - carolyn.stewart@mcri.edu.au
13-Oct-2022 @ 12:27 PM AEDT Reason: Approval

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

Document History

Revision	Modified by	Date of Release	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.

CONTENTS

1. PURPOSE

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

2. BACKGROUND

An SOP may be put in place to:

- Ensure compliance with regulation or institutional policy
- Standardise practice to ensure data reliability and credibility
- Standardise practice to ensure 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.

3. SCOPE

This Guidance describes the process for creating new SOPs, including 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, please refer to MCTC121 SOP: Document Management and Version Control.

4. RESPONSIBILITY

This Guidance applies to all 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 where existing SOPs 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 and the Melbourne Children's Trials Centre. **The Head of Department or Group Lead** is responsible for ensuring appropriate SOPs are in place which will ensure 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, or a deficiency in an existing document. Deficiencies may include unclear instructions, lack of sufficient detail, or obsolete/inaccurate procedure.

4.4. SOP Author, Reviewer and Approver

The SOPs **author, reviewer, and approver** are responsible for ensuring the content of the SOP:

- Is compliant with relevant state/National/international requirements and professional regulations
- Does not conflict with existing institutional policy or SOPs
- Reflects current 'Best Practice'

5. PROCEDURE

5.1. Identify where an SOP is required

Development of a new procedure may be prompted:

- Internally (eg. 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 should 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 ensure that there is not already an institutional SOP or Guidance in place.

5.2. Is an SOP the best tool?

Ensure an SOP is the most appropriate document and identify what other tools may be valuable.

Policy is typically provided by an Institution and will indicate what they seek to achieve. It reflects the organisation's position on an issue and must be adhered to by all staff within the organisation. Policies must be consistent with internal (corporate and clinical governance) and external (legislation or acts) requirements and organisational objectives.

A **Standard Operating Procedure (SOP)** is a detailed, written instruction to ensure uniformity in the way a specific task or function is performed. These should 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.

A **Work Instruction** describes how to perform a task within a SOP. Only required when specific tasks referenced in an SOP require more detail to clearly and effectively control quality management outcomes. Work instructions may be in the form of flow charts, bullet instructions, text, photos, digitized images, numbered instructions or any combination thereof.

A **Guidance Document** provides recommended practice which provides discretion or leeway in its implementation. It will often provide explanation on background information and the purpose of recommended procedures, such as an interpretation of regulation or organisation policy.

A SOP or Guidance Document will often link to or provide tools in the appendix to assist in standardised implementation of procedure, such as:

- Form
- Checklist
- Timeline
- Flow chart

- Quick reference factsheet / table
- Templates

5.3. Stakeholder Engagement

Before writing an SOP, consider:

- Parties who will be affected by introduction of the SOP
- Parties who may affect changes in the scope of activities covered by the SOP

Tailor the degree of engagement with them 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 SOP
- 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 SOP's key stakeholder(s).

5.4. SOP Version Control

A SOP is a controlled document and must therefore be created and maintained as per the procedure detailed in MCTC121 SOP: Document Management and Version Control. This includes process for:

- Review
- Approval
- Finalisation
- Distribution

- Periodic review
- Superseding previous versions
- Withdrawing obsolete documents

The SOP file should be named as per procedure detailed in MCTC076 Guidance: Electronic File Naming Conventions.

5.5. SOP Drafting

Prepare a draft in accordance with the MCTC111 SOP / Guidance Template. Using the template will facilitate the inclusion of all necessary information is provided and the style and formatting of all SOPs are consistent.

5.6. Numbered Headings

5.6.1. Procedural steps should be listed in order of occurrence

Each new step in the procedure (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. The MCTC111 SOP / Guidance Template is set up to facilitate this format.

5.6.2. Plain Language

A SOP must provide specific, concise instructions which are easy to follow. The following style elements are therefore recommended:

- Short sentences
- Active voice
- Well spaced-out text
- Short paragraphs
- Logical ordering of information
- Bullet points
- Clear headings
- Changes in texture for key information eg. Indented italics, etc.

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

6. GLOSSARY

Clinical Epidemiology and Biostatistics Unit (CEBU)

CEBU specialises in biostatistics, epidemiological methods and data management. The group is jointly supported by MCRI and the University of Melbourne's Department of Paediatrics to provide expertise and support in these areas to all researchers on the Melbourne Children's campus.

Clinical Research Development Office (CRDO)

CRDO provides education and training to facilitate and increase capacity for clinical and public health research across the Melbourne Children's campus. This includes the development and implementation of Standard Operating Procedures and templates to enable researchers to conduct high quality research.

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 participants are protected.

Guidance

A written explanation of recommended practice which provides some discretion or leeway in its interpretation and implementation.

Investigator

A person responsible for the conduct of the clinical trial at a trial site. There are four types of Investigator roles used to describe Investigators with different levels of responsibility for the conduct of clinical trials. These are described below.

Sub/Associate Investigator

Any individual member of the clinical trial team designated and supervised by the Principal investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). May also be referred to as sub-investigator.

Coordinating Principal Investigator (CPI)

If a study is conducted at more than one study site, the Principal Investigator taking the additional responsibility for coordination of the study across all sites in a region is known as the Coordinating Principal Investigator (CPI). This role applies to externally sponsored studies where the Sponsor may be a collaborative research group, commercial Sponsor or

an institution. The Principal Investigator at each site will retain responsibility for the conduct of the study at their site.

Principal Investigator
The PI is the person responsible, individually or as a leader of the clinical trial team at a site, for the conduct of a clinical trial at that site. As such, the PI supports a culture of responsible clinical trial conduct in their health service organisation in their field of practice and, is responsible for adequately supervising his or her clinical trial team.

The PI must conduct the clinical trial in accordance with the approved clinical trial protocol and ensure adequate clinical cover is provided for the trial and ensure compliance with the trial protocol.

Sponsor-Investigator
An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a participant. The term does not include any person other than an individual (eg, it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

Melbourne Children's
The campus encompassing 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 Ethics and Governance Office (REG)
REG supports the HREC and institutional research governance processes at MCRI.

Research Governance Office (RGO)
The Office or coordinated function within Melbourne Children's which is responsible for assessing the site-specific aspects of research applications, make a recommendation to the 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).

Royal Children's Hospital (RCH)

The Royal Children's Hospital is major specialist paediatric hospital in Victoria, the Royal Children's Hospital provides a full range of clinical services, tertiary care, as well as health promotion and prevention programs for children and young people. Its campus partners are the Murdoch Children's Research Institute and The University of Melbourne Department of Paediatrics, which are based on site at the hospital.

Sponsor

An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. For investigator-initiated trials, MCRI or RCH will act as the Sponsor but delegate many sponsor responsibilities to the Coordinating Principal Investigator. In this case the CPI has the role of both Sponsor and Investigator and hence the MCTC has adopted the term **Sponsor-Investigator** to reflect the dual role of the CPI in investigator-initiated trials.

Standard Operating Procedure (SOP)

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

Stakeholder

Any party who has a legitimate expectation in a subject, project or organisation and will either affect or be affected by changes in the subject's activity.

Supporting Department

Any department involved in supporting the conduct of the study. Examples include Clinical Trials Pharmacy, Medical Imaging, Laboratory Services, Cardiology, Audiology, Interpreter and NESB Services.

Template

A Template provides a recommended framework to implement the standardised and recommended procedures detailed in a SOP and/or Guidance.

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)

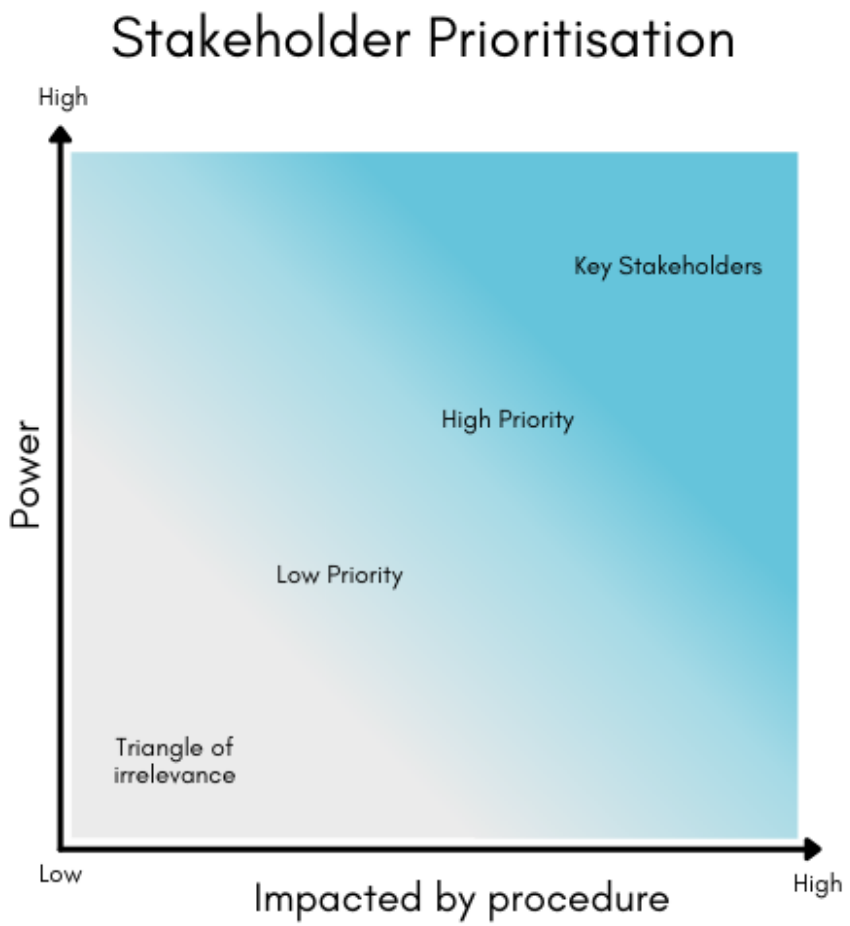
8. COLLABORATORS

This Guidance document was reviewed by the Melbourne Children's Clinical Trial Working Group. Members involved in the review are listed below:

Name/Role	Department/Group	Affiliation
Jenny Munro / Research Governance Manager	Research Ethics & Governance	RCH
Jennifer Luplow / Research Ethics Manager	Research Ethics & Governance	RCH
Kaya Gardiner / Clinical Nurse Consultant Research & Trials	Research Operations	RCH
Supriya Raj / Senior Research Coordinator	Skeletal Therapies	MCRI
Carmel Delzoppo/Data / Quality, Audit & Research Team Leader	Paed Intensive Care/Clinical Sciences	RCH
Karli Williamson / Clinical Trials Manager	Children's Cancer Centre Trial Unit	RCH
Carolyn Stewart / Business & Operations Manager	Melbourne Children's Trials Centre	MCRI
Iona Walton / Administrative Assistant	Melbourne Children's Trials Centre	MCRI
Catherine Wilson / Research Coordinator	Emergency/Clinical Sciences	MCRI

9. APPENDICES

9.1. Appendix 1: Stakeholder Prioritisation



10. RELATED DOCUMENTS

MCTC076 | Guidance: Electronic File Naming Conventions

MCTC111 | Template: Standard Operating Procedure (SOP)/Guidance Document

MCTC121 | SOP: Document Management and Version Control

DOCUMENT END