CLINICAL TRIAL SOP 13: Creation, Implementation and Revision of Standard Operating Procedures

Purpose

To document the procedure for the creation and implementation of new Cabrini Research, Cabrini Health Clinical Trial Standard Operating Procedures (SOPs) and review of existing SOPs.

Scope

This SOP applies to any individual delegated the task of writing, reviewing, approving or distributing a clinical trial research SOP on behalf of Cabrini Research, Cabrini Health. This applies in all instances when a need is identified to either create a new SOP or modify an existing one. Authors of SOPs should have experience of the area covered by the SOP and be authorised to create or modify these.

Cabrini Health policies and regulatory requirements

This SOP should be read in conjunction with policies and other documents provided by the Cabrini Research Governance Office (CRGO) relevant to the conduct of clinical research at Cabrini Health including but not limited to:

- Aboriginal and Torres Strait Islander Health – asking for Aboriginal and Torres Strait Islander identity
- Monitoring of Research Policy
- Research Integrity and Misconduct Policy
- Safety Monitoring and Reporting in Research Policy
- Cabrini Research Data Management, Access and Sharing Policy
- Data Classification and Labelling Standard
- Cabrini Authorship and Publications for Research Policy
- Research Participants Complaints and Compliments Procedures Policy
- Cabrini Research Governance Handbook

Researchers at Cabrini must foster quality research and abide by the following directives:

- The National Clinical Trials Governance Framework (NCTGF)
- National Statement on Ethical Conduct in Human Research (2023)
- Catholic Health Australia Code of Ethical Standards
- Act in accordance with Cabrini Research policies in order to protect the rights, safety and welfare of research participants
- Support patient and family carer involvement in their own research participation through abidance with the Australian open disclosure policy, and Charter of healthcare rights.
- Agree to comply with all reasonable directions and policies by Cabrini Research for Cabrini to meet or exceed the requirements of the NCTGF. To the extent that the NCTGF applies to the position, compliance with the specified roles and functions of the workforce, as set out by the NCTGF.

Procedure

Initiating the creation of a new SOP or revision of an existing SOP

All persons engaged in clinical trial research may:

- Identify the need for a new SOP or a deficiency or an improvement in an existing SOP and suggest appropriate modification.
- Notify Cabrini Research and discuss this need with the SOP number and title in the subject header of an email (research@cabrini.com.au).

Cabrini Research will coordinate the following steps in the creation of a new or revision of an existing SOP:

- Actively invite feedback from all users and interested stakeholders, to inform a regular, formal review of the SOP and to enable a continuous improvement approach.
  - This will be undertaken every two years following approval and release of the SOP (including where there may be subsequent revisions to the SOP in future).
  - Assess and verify the need for a new or revised SOP.
- Assign a document ID number and Version date for all new SOPs or to modify an existing SOP.
- Draft the new or modify existing SOP and distribute to relevant stakeholders for review and comment.
- Maintain a record of the review process either on a document tracking review log (including at a minimum the SOP ID, version number, reviewer name, review date, changes and comments noted by reviewer, action by owner, date of action, new version) or electronically by using the tracked changes feature with a file naming paradigm and save files on central drive.
- Incorporate relevant comments and if required redistribute to relevant stakeholders for second review.
- If necessary, repeat the above 2 steps until a final version is ready for approval.
- Update the amendments to previous version history box as necessary, ensuring the 'SOP effective date' and 'SOP review by date' is in alignment with the timeframe identified in this SOP. Ensure the approved SOP footer is updated with the SOP Title, version number, and SOP effective date.

13.1 Approval and Authorisation of the SOP

- Print the final SOP and arrange for approval and final sign off by the Group Director, Cabrini Research. In the amendments to previous version history box, update the input from details.
- Ensure the original signature field and/or amendment history field is completed by the delegated people.
- File the final approved (in writing) new/amended SOP electronically as a pdf document and distribute to all stakeholders, and post on the Cabrini Research Clinical Trials webpage
- Securely store the final, approved, new/amended master SOP.

13.2 Training, Implementation, Distribution of the New or Revised SOP

- All relevant stakeholders must be notified of the new/updated SOP between the authorisation and the effective date.

- Training is to be recorded as per SOP - 02 Site Staff Qualifications, Training Records and Capability.

13.3 Review

- The review date is two years after the effective date. The time between SOP authorisation and the effective date may be reduced in special circumstances (e.g. urgent situations where procedures must be implemented immediately).
- An earlier review date is permitted where necessary (e.g. changes to legislation).

13.4 Superseded SOPs

- Cabrini Research will notify relevant stakeholders of superseded SOPs.
- The superseded SOP will be watermarked with SUPERCEDED and filed.
- The superseded hard copy master SOP will be clearly marked as superseded and be securely stored as a record of previously used SOPs.
- The superseded SOP will be removed or superseded from the website and any electronic platforms.

Current Version

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Document Approval

NAME	POSITION	SIGNATURE	DATE
Professor Gary Richardson	Group Director, Cabrini Research		18 September 2024

Document History

VERSION NUMBER	EFFECTIVE DATE	DETAILS OF AMENDMENTS /EDITIONS