CLINICAL TRIAL SOP 1: Investigator Responsibilities

Purpose

To define the Investigator responsibilities associated with undertaking a clinical trial in accordance with ICH GCP responsibilities for Investigators in clinical trials and teletrials.

Scope

This SOP applies to all Investigators (Principal and Sub-Investigators), Study Coordinators, visiting medical officers (VMO), and other research staff and volunteers who propose to undertake, administrate, review and/or govern human research involving patients/participants and staff. All study personnel involved in the clinical study must operate within their scope of practice.

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

1.1 Investigator Responsibilities (Principal Investigators/Associate Investigators)

1.1.1 Before the Research Project Commences

The Principal Investigator must:

- At all times, fulfil Roles and Functions as defined in the National Clinical Trials Governance Framework.
- Declare in writing any conflicts of interest, or payments they will receive from other parties with any relationship to the study and notify the Sponsor and the reviewing HREC (via the HREA).
- Ensure any payment provided to the participant for undertaking the trial is noted in the Participant Information Sheet and Consent form.
- Consider at feasibility assessment that adequate participant recruitment is possible.
- Demonstrate adequate staffing levels to ensure success of the study at the site.
- Be thoroughly familiar with the appropriate use of the Investigational Product as described in the Protocol, in the current Investigational Brochure (IB) for medicines or Product Information for devices and in other information sources provided by the Sponsor.
- Be provided with evidence of HREC approval, Cabrini Research Governance Office (CRGO) authorisation, and the registration number of the trial once it is registered on a publicly accessible World Health Organization compliant clinical trials registry before the first participant is recruited to the study.

1.1.2 During the Course and at the Completion of the Research Project

The Principal Investigator must:

- At all times, fulfil Roles and Functions as defined in the Clinical Trials Governance Framework.
- Ensure all staff are trained on and adhere to relevant SOPs.
- Ensure study staff are trained in the Protocol, IB, study procedures, Adverse Event (AE)/Serious Adverse Event (SAE) reporting, and that a system for safety reporting duties is in place for all study staff, including events considered as clinical incidents being reported into Riskman.
- Promulgate all Protocol variations and ensure adequate training of all trial personnel in the reason for and implications of the new Protocol. Ensure all personnel are suitably trained to undertake the trial and deliver the trial intervention.
- Ensure that study related documentation files and procedures are established and maintained throughout the study in accordance with SOP 03 The Study Master File, including procedures for managing the security of information and trial data and a process for managing data security or privacy breaches.
- Ensure study staff have a clear understanding of the process for securely and suitably storing and ensuring accountability for the Investigational Medicinal Product (IMP).
- Sign all trial related documentation during the course of the research project in a timely manner.
- Ensure audit/inspection readiness throughout the study, have oversight of any audit or inspection of their trial, and ensure any deficiencies identified through audit or inspection are actively managed to ensure continuous improvement:

- The PI should follow Sponsor and CRGO requirements to ensure that appropriate Corrective and Preventative Actions (CAPA) have been implemented and findings reported to the CRGO (and where applicable, approving HREC).

- Inform relevant staff when recruitment has been completed and mark the Investigator Site File as closed to recruitment.
- Sign all trial related documentation at the end of the research project such as documents requiring an end date, indicating the research project is completed including but not limited to: Delegation Log, Training Log, Supervision Plan, agreements, progress reports, eCRF/CRF, SAE reports, etc.
- Ensure all trial related staff and third-party providers have been informed of the research project closure, results and publication plan as required and appropriate. Site closure at Cabrini is defined in Monitoring of Research Policy.
- Ensure appropriate ongoing care of participants throughout the trial, if a participant withdraws during the trial and/or if a trial is prematurely terminated.
- Facilitate the participant providing feedback and ensure they know where to provide a complaint or compliment.
- Ensure a lay summary of the trial results (usually provided by the Sponsor) is disseminated to participants in accordance with the HREC/CRGO application/trial Protocol, and be prepared to respond to queries from participants in relation to the trial results.
- Document any deviation from the Protocol as per the Sponsor's guide. Document any serious breaches as per HREC and CRGO requirements.
- Notify the Sponsor, HREC and CRGO if they leave the Institution, in writing with either their new place of employment and contact details or who their proposed replacement is with contact details for recording on all archiving related documentation.
- Ensure study related documents are archived according to SOP 09 - Site Close Out and Archiving.

Current Version

DOCUMENT ID:	Clinical Trial SOP 1: Investigator Responsibilities
VERSION:	1.0
EFFECTIVE DATE:	01 October 2024
REVIEW DATE:	01 October 2026

Document Approval

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

Document History

VERSION NUMBER	EFFECTIVE DATE	DETAILS OF AMENDMENTS /EDITIONS