CLINICAL TRIAL SOP 5: Site Initiation

Purpose

To describe the procedures related to site initiation of a clinical trial.

Scope

This SOP applies to all Investigators (Principal and Sub-Investigator), 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

5.1 Site Initiation

Prior to initiation of the study, the Principal Investigator must:

- Mutually agree with the Sponsor a scheduled date, time and location for the Study Initiation Visit to ensure Cabrini is prepared to commence the study.

- Review all study related documentation and be familiar with the Investigational Product and Protocol.
- Ensure that all relevant staff involved with the study, (Associate Investigator, Pharmacist, Clinical Research Coordinator and others as appropriate), have been advised of any meeting related to the trial and are able to attend either in person or via videoconference, or that they will be provided the necessary recording (if applicable) or documents required for their training.
- Be in possession of all required approvals and authorisations to conduct the research project.
- For teletrials, ensure a Supervision Plan is in place, that documents the manner and frequency of supervision to be undertaken with other trial staff, especially those new to the role.

During the initiation Visit the Investigator must ensure the following are available and/or addressed:

- Investigator Site File (ISF) containing all required Essential Documents and review arrangements for organising and maintaining study files.
- A list of all study personnel attending the initiation meeting on an attendance log/Training Log with full name, signature, date and the method attended i.e. in person or via videoconference.
- Signed and dated copy of the curriculum vitae of all study personnel involved in the study.
- Other documents such as, financial disclosures, Training Logs, medical licenses and other Essential Documents as per Sponsor requirements.
- A contact list with names and contact details of all study personnel, Sponsor and independent third-party service providers is available.
- Timeline for shipment, delivery and receipt of Investigational Product and other study related supplies.
- A laboratory manual, where applicable, clearly defining sample handling instructions and processes, shipping procedures, documentation handling, contact list of all laboratories involved and any other laboratory activity to be undertaken during the course of the trial.
- A pharmacy manual (if relevant to the trial) clearly defining any activity linked to the handling or the Investigational Medicinal Product (IMP)/Investigational Medicinal Device (IMD).
- Any specialised equipment required will be available throughout the period of the trial, e.g. centrifuge, freezer, etc.
- The Case Report Form (CRF), completion guidelines and that they are accessible.
- Training in all aspects required by the Protocol is recorded on the Training Log.
- Archiving of study records at the end of the study.
- Subsequent training for staff not in attendance at the Initiation Visit. Such initiation training can be conducted remotely where feasible. It is critical however, that this training is undertaken and documented before they commence activities in the study.
- Supervision Plan for teletrials.

At the conclusion of the initiation the Investigator must:

- File the Sponsor's initiation visit report/letter in the ISF.

Current Version

DOCUMENT ID:	CLINICAL TRIAL SOP 5: Site Initiation
VERSION:	1.0
EFFECTIVE DATE:	01 October 2024
REVIEW DATE:	01 October 2026

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