CLINICAL TRIAL SOP 2: Site Staff Qualifications, Training Records and Capability

Purpose

The purpose of this Standard Operating Procedure (SOP) is:

a) to ensure the appropriate documentation of clinical research site staff qualifications and training records are completed and maintained up to date during the course of the study, and

b) to ensure the provision of resources to perform clinical research at all clinical research sites, according to the principles of the ICH GCP (and requirements of the Integrated Addendum to this Guideline published by the TGA), the National Statement (or its successor), and the requirements of the National Clinical Trials Governance Framework.

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. Where appropriate, the Principal Investigator can delegate tasks to appropriately qualified and trained staff.

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

2.1 Site Staff Qualifications

The Principal Investigator must:

- Be qualified by education, training and experience, including in skills, competencies and training requirements articulated in the National Clinical Trials Governance Framework, to assume ultimate responsibility for the proper conduct of the research.
- Submit and maintain a current Curriculum Vitae (CV), and a current GCP certificate to the Cabrini Research Governance Office (CRGO) if not submitted previously and at any time there are changes to the CV or GCP certificate including:
  - current Australian Health Practitioner Regulation Agency (AHPRA) or Exercise and Sports Science Australia (ESSA) registration details.
  - evidence of in date GCP training.
  - current workplace name and address.
  - As of January 2025, Principal Investigators must also supply evidence of training in Research Integrity to the CRGO. The Australian Clinical Trials Education Centre (A-CTEC) offers a free course in Research Integrity and the Code.
- Ensure all investigational site staff, independent third parties, and external service providers have provided appropriate and current evidence that they are qualified by education, training and experience, including in skills, competencies and training requirements articulated in the National Clinical Trials Governance Framework, to assume responsibilities to perform the delegated study-related duties and functions and that they have the legal authority to do so. Delegation should be consistent with the Roles and Responsibilities specified in the National Clinical Trials Governance Framework.
- Ensure all investigational site staff who have been delegated significant responsibilities have a current CV and current GCP certificate lodged with their research department and CRGO for sighting by the Sponsor and/or regulatory authority.
- Implement procedures to ensure the delegated study-related duties and functions are carried out safely.
- Implement procedures to ensure integrity of all data generated.
- Ensure all investigational staff are aware of and understand SOPs related to delivery of clinical trials.

2.2 Site Staff Training Records

The Principal Investigator must:

- Ensure all required staff, including new staff involved during the course of a study, who assist with the clinical trial are informed about and trained on the Protocol, any Investigational Product, and their research-related duties and functions. This can be in the form of an Initiation meeting held by any communication means e.g. via face-to-face, skype, videoconference, telehealth etc, as well as self-directed reading of relevant documents
- Ensure that for all study specific training provided, there is a training record or log of documents and tools used, including details of who provided the training and when it was provided, by trial specific staff.
- Ensure all required training is completed and the training record is kept up to date. A copy must be kept and be made available for review on request throughout the entire duration of the clinical research trial. The process for maintaining the training record may involve the use of wet ink, scanned copies and/or e-signatures, or electronic documentation in the Site Docs platform.
- Ensure all required staff, including new staff involved during the course of a study, who assist with the clinical trial are trained on SOPs relevant to their role.

2.3 Capability

The Principal Investigator must:

- Undertake the roles and functions of the Site Principal Investigator specified in the National Clinical Trials Governance Framework.
- Demonstrate the potential for recruiting the required number of suitable participants, within the specified recruitment period. This may be in the form of a documented discussion or written evidence.
- Have sufficient time to properly conduct and complete the research within the specified period.
- Have an adequate number of qualified staff and adequate facilities for the foreseen duration of the research.
- Maintain a record identifying appropriately qualified persons to whom they have delegated significant research-related duties (on a 'per person' basis) such as a Delegation Log.
    - The process for maintaining the Delegation Log may involve the use of wet signatures, scanned copies and/or e-signatures, or electronic documentation in the Site Docs platform.
    - Staff who as part of routine practice provide ancillary or intermittent care by completing a procedure on a trial patient/participant (i.e. vital signs, electrocardiography (ECG), venepuncture or imaging) do not need to sign a Delegation Log (or be listed on a 1572 Form for trials conducted under an Investigational Drug Investigation).
    - Where service departments (e.g. pharmacy, laboratories, radiology) are involved in trial-specific activities which are outside of their routine scope (e.g. dispensing Investigational Medicinal Products), the PI may delegate the role of supervising and training departmental staff to a Named Person (e.g. a clinical trial pharmacist). This person would train all staff on any aspects of GCP/the Protocol relevant to their role.

- Provide oversight to any third party to whom any study-related duty or function is outsourced and take responsibility for any study-related duty or function performed and any data generated by the third party.

2.4 GCP Training

In accordance with the National Clinical Trials Governance Framework, it is essential that clinical trial Investigators and clinical trial staff with significant delegated trial related responsibilities have access to and undertake TransCelerate accredited training in the principles of GCP as a minimum requirement.

- Current certificates of GCP training must be supplied to the CRGO for all team members listed on a project.
- Core trial staff should receive TransCelerate accredited GCP training. Refresher GCP training should also be available to trial staff, at appropriate intervals to ensure that staff maintain awareness of current clinical trial standards and legislation.
- Ancillary staff involved in trials with novel/non-routine interventions are not required to receive TransCelerate accredited GCP training, but may partake in an abbreviated format; for example, taking the form of a short departmental trial awareness session covering relevant requirements such as:
  - recording adverse events
  - documenting activities in source notes
  - notifying Protocol deviations and adverse events to the core trial team
  - escalating any other issues identified to the core trial team
- Staff provided abbreviated GCP training may include:
  - pharmacy staff involved in general dispensing, under the oversight of a trial pharmacist who may perform training on relevant trial/GCP requirements.
  - laboratory/diagnostic staff undertaking routine tests used in a trial, under the oversight of a lead contact who may perform training on relevant trial/GCP requirements.
  - chemotherapy nurses with only the role of administering Investigational Products under the oversight of a manager who has undertaken relevant GCP training.
  - ward or other staff performing routine activities within their scope of practice.

2.5 Research Integrity Training

In accordance with the Cabrini Research Governance Office policy and recommended by the National Clinical Trials Governance Framework, it is essential that Principal Investigators at a minimum, have access to and undertake “Research Integrity” training and certification. The Australian Clinical Trials Education Centre (A-CTEC) provides a free course “Research Integrity and the Code”.

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