CLINICAL TRIAL SOP 4: Case Report Forms and Source Documents

Purpose

To describe the procedures related to the completion of electronic and paper based Case Report Forms (CRF), and maintenance of Source Documents.

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.

Definitions

Source Data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.
Collection of accurate Source Data (contained in Source Documents) is essential for compliance with GCP. The format used (whether paper or electronic) should permit the reconstruction of the clinical care given to the participant and describe any significant participant-related events that may occur during the conduct of the trial.
Source data should be attributable, legible, contemporaneous, original and accurate (ALCOA). Changes to source data should be traceable, should not obscure the original entry, and should be explained if necessary. Source data in electronic form should be complete, consistent, enduring and available (ALCOA+).
Where access (e.g. for trial monitors, auditors and inspectors) cannot be limited to trial participants, certified paper copies of trial related information should be printed.

Case Report Form (CRF): The CRF is defined in ICH GCP as - A printed, optical or electronic document designed to record all of the Protocol required information to be reported to the Sponsor on each trial subject. The data collected in the CRF is used as the basis of the trial report and any publications, as well as making up part of the data for regulatory approval for the unapproved therapeutic goods. The PI has ultimate responsibility for the content of the CRF but may delegate the task to suitably qualified individuals. The PI should, however, maintain oversight of the quality of the data provided to the Sponsor.

Procedure

4.1 Completion of Case Report Forms (CRF)

The Principal Investigator must:

- Ensure the accuracy, completeness, legibility, (including any changes or corrections) and timeliness of Source Data and data recording adheres to the Protocol, monitoring plan requirements and also the Supervision Plan.
- Ensure that any party delegated to perform data entry or signing for data completeness is recorded on the Delegation Log and is trained to perform those trial related duties and functions.
- Ensure that changes to the paper Source Document do not obscure the original entry, are traceable (signed and dated) and explained (i.e. an audit trail should be maintained).

4.2 Source Documents

The Principal Investigator must:

- Maintain adequate Source Documents and trial records including all key observations on each of the trial participants.
- Store all trial related documents in their appropriate location, such as participant trial file or Investigator Site File (ISF) as required by the applicable regulatory requirement, Sponsor and Protocol and take measures to prevent accidental or premature destruction of these documents.
- Ensure, for both paper and electronic documents, all changes, corrections and amendments are tracked, and version dates and numbers, are updated to reflect the

changed data and to maintain the integrity of the data. An explanation of the changes is noted in a record of change.

- Ensure all staff are aware that, upon request, direct access to all trial related records is given to the monitor, auditor, HREC, RGO or regulatory authority, to enable Source Data verification, Sponsor audits or regulatory inspection. Direct access is stipulated in the CTRA and outlined to the participant via the PICF.

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Document Approval

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

Document History

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