CLINICAL TRIAL SOP 8: Communication with the HREC, RGO, Sponsor and Institution's Insurer

Purpose

To describe the procedures relating to communication with the Human Research Ethics Committees (HREC), Cabrini Research Governance Office (CRGO), Sponsor and Insurer.

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

8.1 Communication with Reviewing HREC

When communication regarding key decision points is verbal, the initiating party should follow up verbal communication with written correspondence/e-mail and send to the call recipient. The title of the letter/e-mail should include the term "FILE NOTE" followed by a text string which should include the decision topic. Such documentation must be filed in the Investigator Site File (ISF).

Prior to study commencement, the Investigator (Principal Investigator/Associate Investigator) and research team or designee, in accordance with their role, must:

- Choose a reviewing HREC who's approval is acceptable to the clinical study being undertaken at Cabrini Health.
- Understand the reviewing HREC requirements, submission processes and be aware of their meeting and submission dates to better liaise with Sponsors.
- Be familiar with the relationships between HREC review and approval, governance authorisation and any other processes/approvals that need to be in place (e.g. does the HREC have sub-committees), before any study start up activities can commence. This process and approval flow will be required by Sponsors, auditors and inspectors.
- Submit an ethics application as per the reviewing HREC submission process.
- Ensure all documentation and correspondence pertaining to the submission and approval processes is filed in the ISF e.g. correspondence to and from the HREC, CRGO or other bodies.

During the study, the Investigator (Principal Investigator/Associate Investigator) and research team or designee, in accordance with their role, must:

- Comply with all conditions and restrictions applied by the CRGO or HREC on the conduct or continuation of the trial.
- Submit all documents/reports/summaries according to the requirements and timelines as stipulated on the respective reviewing HREC approval letter, including but not limited to: Sponsor reports of accumulated safety data outcome analyses; proposed changes to the Protocol; major or Serious Breaches; annual progress reports; and unforeseen events that might affect continued ethical acceptability of the trial.
- Comply with the reporting requirements outlined in SOP 07 Safety Data Monitoring and Reporting Requirements for Clinical Trials, noting that individual reports of Adverse Events, Serious Adverse Events, Suspected Unexpected Serious Adverse Reactions, Unanticipated Serious Adverse Device Events and six-monthly line listings should NOT be submitted to the reviewing HREC unless otherwise advised.
- Although all deviations must to be reported to the trial Sponsor, only the sub-set of deviations that have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the clinical trial must be reported to the HREC. These deviations (also known as 'Serious Breaches') should also be reported by the Principal Investigator to the Cabrini Research Governance Office (CRGO), as they may impact on medico-legal risk, the responsible conduct of research, or adherence to contractual obligations.

- Immediately notify the reviewing HREC of any notification received from a participant in a trial that they intend to initiate a claim for compensation against either the Sponsor and/or the Institution.
- File all documentation in the ISF.

At the end of the study, the Investigator (Principal Investigator/Associate Investigator) and research team or designee, in accordance with their role, must:

- Submit a trial termination/closeout report according to the requirements and timelines as required by the respective reviewing HREC. This may be stipulated in the approval letter and/or on their website.
- File all documentation in the ISF.

8.2 Communication with the Cabrini Research Governance Office (CRGO)

For the purpose of this SOP, the Clinical Trial Research Agreement (CTRA), other site specific trial related documentation and the Cabrini Research Governance Form and costing template constitute a research governance application. This application may be submitted to the CRGO once HREC approval has been granted.

Prior to study commencement, the Investigator (Principal Investigator/Associate Investigator) and research team or designee, in accordance with their role, must:

- Submit the Clinical Trial Research Agreement (CTRA), HREC approval letter, all HREC approved documents, the Cabrini Research Governance Form and costing template, Cabrini specific documents based on HREC approved Master documents, a CV and evidence of relevant GCP training for all investigators, and any other required documentation to the CRGO. Evidence of Research Integrity training by the PI must also be submitted from January 2025. If the PI is not a paid staff member of Cabrini, they must supply a copy of their professional indemnity insurance.
- Ensure all documentation and correspondence pertaining to the submission and approval processes is filed in the ISF.
- Await site specific CRGO authorisation before any study related activity can occur.

During the trial, the Investigator (Principal Investigator/Associate Investigator) and research team or designee, in accordance with their role, must:

- Submit all governance related documents/reports/summaries to the CRGO according to the requirements and timelines as stipulated by the CRGO including but not limited to:
  - changes to the CTRA/Sub-Contract;
  - changes to the budget;
  - any change that might affect continued financial acceptability of the trial;
  - any change that may increase Institutional risk.
- Serious Breaches (those deviations that may have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the clinical trial) should be reported by the PI to the CRGO, as they may impact on medico-legal risk, the responsible conduct of research, or adherence to contractual obligations.
- Immediately notify the CRGO of any notification received from a participant in a trial that they intend to initiate a claim against either the Sponsor and/or Cabrini.
- Ensure all training and accreditation remains current.

At the end of the trial, the Investigator (Principal Investigator/Associate Investigator) and research team or designee, in accordance with their role, must:

- Notify the CRGO the trial has terminated/closed.
- File all documentation in the ISF. Poor compliance with the Protocol or GCP can lead to data being rejected by regulatory authorities, can compromise participant safety and can nullify a trials insurance/indemnity. ICH GCP requires that the PI (or delegate) document and explain any deviation from the Protocol and requires that non-compliance with the Protocol, SOPs, GCP, and/or applicable regulatory requirement(s) lead to prompt action to secure compliance.

8.3 Communication with the Sponsor

The Investigator (Principal Investigator/Associate Investigator) and research team or designee, in accordance with their role, must:

- Comply with the reporting requirements outlined in SOP 7 Safety Data Monitoring and Reporting Requirements for Clinical Trials, and should consult and adhere to existing guidance for safety monitoring and reporting published by NHMRC and the TGA.
- Notify the Sponsor within 24 hours of discovery of any Serious Adverse Events (SAE) involving trial participants under the care of the Investigator and where relevant notify the PI in parallel.
- Notify the Sponsor promptly regarding any changes significantly affecting the conduct of the trial, and/or increasing the risk to participants and where relevant notify the Principal Investigator/Associate Investigator**.** Communication must be followed up with written report/email and filed in the ISF.
- Notify the Sponsor of any Protocol Deviation or Breach (which may include significant deviation from the Protocol) and where relevant notify the Principal Investigator/Associate Investigator**.**
- Be available to meet with the Sponsor to discuss study progress, issues and safety.
- Provide the Sponsor with copies of all correspondence from the reviewing HREC and CRGO.
- Immediately notify the Sponsor of any notification received from a trial participant that they intend to initiate a claim for compensation against either the Sponsor and/or Cabrini Health.

8.4 Communication with the Institute's Insurer

If Cabrini is notified or becomes aware that a trial participant intends to make a claim for compensation against Cabrini or injuries arising as a result of participating in a clinical trial undertaken at Cabrini, Cabrini must promptly notify our insurer in writing that such an action is intended.

Communication with Solicitor, Sponsor and Principal Investigator/Associate Investigator

If the Investigator or trial team are notified or becomes aware that a trial participant intends to make a claim against Cabrini for injuries arising as a result of participating in a clinical trial undertaken at Cabrini, the Investigator or designated trial team member must promptly notify the following in writing that such an action is intended:

- the CRGO
- Cabrini Group Director, Cabrini Research
- the Principal Investigator/Associate Investigator as relevant, and

- the Sponsor.

The Sponsor will generally be responsible for reporting to their respective solicitors.

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