CLINICAL TRIAL SOP 6: Participant Informed Consent Process and Documentation in Clinical Trials

Purpose

To describe procedures and documentation management relevant to the initial and ongoing informed consent process, including consenting via telehealth. The objective is to seek and retain voluntary, informed consent through ongoing communication and information exchange between a patient/participant and a clinician about the best interests of each participant. The provision of sufficient information to make an informed decision is understood as "informed consent" and this term will be applied in this context in this Standard Operating Procedure (SOP).

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 the informed consent or taking the consent of 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

Informed Consent: A process of information exchange that culminates in a potential trial participant (or their legally acceptable representative) confirming willingness to participate, and to continue to participate, in a study.
For clinical trials, consent is documented using a written, signed and dated Participant Information and Consent Form (PICF).
A person's decision to take part in a trial must be voluntary and based on sufficient information and adequate understanding of both the proposed research and the implications of participation, including the risks and potential benefits of (and alternatives to) taking part.

Consent must be obtained before the first study-specific procedure or intervention is undertaken.

Procedure

6.1 Informed Consent Process

- In obtaining and documenting Informed Consent, all persons involved in the research must comply with the National Statement Chapter 2.2, the National Clinical Trials Governance Framework (including the Roles and Functions of Identified Positions) and applicable regulatory requirements, and adhere to ICH GCP R2 and to the ethical principles that have their origin in the Declaration of Helsinki. All persons involved in research must also comply with specific Cabrini Health policies relating to the conduct of research.

6.2 Establishing the Informed Consent Process

- The Principal Investigator (PI) for any research project retains overall responsibility for ensuring a participant's consent has been obtained in the correct manner prior to the participant's entry into the project. At their discretion, the PI can delegate the duty for obtaining consent to a suitably qualified Associate Investigator as described in SOP 1 Investigator Responsibilities, SOP 2 Site Staff Qualifications, Training Records and Capability, and the National Clinical Trials Governance Framework. Delegation of all activities must be recorded in a Delegation Log or similar. The PI remains responsible for any delegated activity.
- The Investigator must ensure that they have the relevant Cabrini Research Governance Office (CRGO) approval, inclusive of approval by an appropriate HREC, for all written information and any other media used to provide information to potential participants, before these forms, information or other materials may be used to obtain consent from any participant.
- When changes have been made to approved Participant Information resources the Investigator must have the relevant HREC's written approval and written authorisation from the CRGO before these may be used to obtain consent or continued consent from any participant.

6.3 Process for Obtaining Informed Consent

- If a participant expresses interest in participating in a research study, the PI or delegate must ensure that the potential participant has a copy of the current version of the HREC and CRGO approved Participant Information and other approved media. This can be provided in person, by telehealth or by telephone and email or weblink.
- As per the Cabrini Health policy Aboriginal and Torres Strait Islander Health – asking for Aboriginal and Torres Strait Islander Identity, potential participants, or their legally acceptable representative, should be asked if they (the patient) identify as Aboriginal, Torres Strait Islander or both, irrespective of appearance, country of birth or whether the staff member knows the patient or their family background. The question should be asked in full as **"Are you (name of the person) of Aboriginal or Torres Strait Islander origin?"** It can be helpful to introduce the question by saying "the following questions will help us plan for and improve the services we provide." If the person identifying as Aboriginal or Torres Strait Islander indicates they have specific needs related to their care or admission to Cabrini Health, the person receiving the information should document the specific needs and follow the internal escalation process outlined in the policy. The participants response and any specific needs related to their care should be recorded in the participants trial file.
- Potential participants, or their legally acceptable representative, should be given adequate time to read any information or to watch any approved media and to discuss with any family and friends and/or their family doctor, prior to agreeing to participate. The PI or delegate may also offer the potential participant the opportunity to bring a friend or family to any meeting with the PI/delegate.
- Whilst delegates such as Study Coordinators/Nurses or other appropriately qualified person may initiate the process of recruitment, and provide guidance around the written information and media, all medical questions must be answered only by Medical qualified person working within their scope of practice and appropriate to oversee the use of an unregistered medicine.
- The PI or delegate must assess the potential participant's understanding of what they are agreeing to, that they are aware of the purpose of the study, what will be involved and any risks that may exist. The participants must demonstrate that they fully understand the implications of decisions that may be made within the course of the research.
- After all questions are satisfactorily answered, potential participants who wish to participate in the research will provide a record of their agreement either through physically signing a paper copy of the consent form or electronically signing a consent form using an approved format that accurately documents the time, date and authenticity of their signature. The PI/delegate will countersign and date that the consent process has occurred. Ideally this will be done contemporaneously; however, under special circumstances related to the nature of the study the HREC and CRGO may approve this signature to occur at a later time with appropriate documentation.
- Witnesses are not a requirement in Australia unless they are providing a signature on behalf of a person who cannot sign themselves. If a witness is required, the witness should sign and personally date the witness section of the consent forms.
- Once all parties have signed the Informed Consent documentation, the participant will receive a copy of this and all other written information and media provided to the participant that were used as part of the consent process. A copy of the signed consent

documentation must be placed in the participants trial file and the Investigator Site File (ISF).

- If Informed Consent is obtained by telephone, this must be recorded (including the reason for remote consenting) on the Informed Consent form, and in the participants trial file and ISF, stating (as an example): "The protocol was discussed with [participant's name] via telephone on [DD/MMM/YYYY]." Signatures from participant and Investigator may not be on the same form but should be filed together.
- Participants may withdraw their consent at any time without giving a reason.
- For culturally and linguistically diverse (CALD) individuals and are from non-English speaking backgrounds, a NAATI accredited interpreter/translator is to be engaged via a telephone or video conference interpreting service (ONCALL Language Services) for the patient to have a conversation with the PI or delegate. The interpreter/translator would facilitate an oral translation of the Patient Information Sheet and any question and answer correspondence between the patient and the PI or delegate. Participants may give their consent orally in the presence of an impartial witness (i.e. someone not involved in the conduct of the trial). The witness signs and personally dates the consent form to attest that the information in the PICF was read and explained to the participant or legal representative and that consent was freely given.
- Documentation of consent can be done on a pre-printed Consent Statement Declaration (Appendix 1) to facilitate consent documentation. A copy of the Consent Statement Declaration must be placed in an appropriate location and may include the ISF, or participant trial file.

Process for confirming consent where new information arises: Re-consent

- This process applies to the necessity to obtain and document a participant's expressed willingness to remain in a study. This may arise if changes/amendments* are made to the Protocol after the trial has started. The PI or delegate must ensure the HREC and CRGO receive these changes and provide ethical approval for the changes and discuss the need, or immediacy of need, to inform existing participants.

  *Note: Administrative changes alone does not justify generation of a new consent form. This is to avoid causing unnecessary anxiety to study participants and administrative burden to research staff. These administrative changes can be incorporated when there are new significant changes which will impact a study participant's willingness to continue study participation. Examples may include:
  - Changes to footer information
  - Changes to information which does not have ethical or safety bearing
  - Changes to information which does not change the purpose, methods, demands, risk and potential benefit

- The PI will ensure that all currently enrolled participants are re-contacted in a timely* manner with the relevant new information as approved by an HREC and CRGO. Unless there is a significant safety concern HRECs will not usually require that patients/participants be recontacted immediately. There are potential implications for blinding of any studies and care must be taken when developing the process for recontact. If approved by the HREC and CRGO, continued consent may be obtained verbally and recorded in the participant's participants trial file and ISF.

*Note: Timely manner- As a general guidance this would mean by next scheduled visit. If new information is deemed critical in the opinion of the Investigator then an unscheduled visit can be organized after discussion with the study sponsor. A participant's condition and place of residence must be taken into consideration when deciding if an unscheduled clinic visit is appropriate or if information can be relayed via telephone first followed by written consent at the next scheduled visit. Documentation of communication via telephone must be present in the participant's trial file. Any costs related to an unscheduled visits will be borne by the study sponsor.

- Where there is an amendment to the PICF, this should be signed by the participant as confirmation of their willingness to continue in the trial. This must be recorded and kept in the participant's participants trial file and ISF.
- Where the Investigator determines that the new information provided in a revised written consent form (e.g. amended/updated informed consent form provided by a clinical trial sponsor) does not have any relevance to an individual participant, the participant does not need to be informed of the revised consent form. Examples may include
    - When the changes only relate to the active phase of the research/trial and the participant is in long term follow up
    - Where a participant's physical condition has declined and the treating Investigator feels the burden of re-consenting is greater than the expected benefit to the participant or that the new information in the consent form is not relevant to the participant, for example a participant has entered a palliative care facility.
    - Administrative updates e.g. changes in the contact details when patient is on survival follow up and updates are deemed irrelevant

- The Investigator must clearly document the reason that the revised written consent was not relevant to each individual participant in question. Documentation of the decision must be done by the Investigator and not study coordinator and filed in participants' trial file.
- When there is an amendment to Informed Consent, the Investigator has the option to obtain written consent from a study participant on the tracked change copy of the CRGO approved Informed Consent form. The Investigator may also request from the study sponsor a 1 page summary of important changes that has ethical and/or safety information to facilitate the re-consenting discussion with study participants. The 1 page summary must be reviewed and approved by CRGO prior to its use. Re-consent will still be done on the PICF (Tracked or Clean Copy) in hard copy or electronic version.
- The Investigator has the option to use a pre-printed Re-Consent Statement Declaration (Appendix 2) to facilitate re-consent documentation.

6.4 Research Involving Participants who are Unable to Give Consent

- The Investigator must ensure that the National Statement, Chapter 2.2 and ICH GCP E6 (R2) 4.8.15 are complied with, and the following is taken into consideration:
    - The Declaration of Helsinki states that research involving participants who are physically or mentally incapable of giving consent, for example, unconscious patients/participants, may be done only if the physical or mental condition that prevents giving Informed Consent is a necessary characteristic of the research

group. In other words, in these cases, the study must be relevant to the physical or mental condition of the participant that prevents them from being able to consent to participate in the study.

- Where an adult is unable to give consent to participate in a study, once the Investigator has received HREC approval, and if there is an option to do so under the relevant legislation, the Investigator may apply under the relevant jurisdictional Act to obtain consent for the adult to participate in research that involves a 'medical research procedure' or 'experimental health care' – provided the relevant legislated criteria apply.

Telehealth

- E-consent may be the preferable option for certain trials, such as teletrials, as consent signatures can be obtained contemporaneously.
- If Informed Consent is obtained by telehealth consultation, all persons who are not known to each other must produce identification to the other person to ensure verification of each person's identity and to confirm the identity of the participant who is giving valid consent.
- A description of how study procedures, visits, assessments, collection of data and medical consultations will be undertaken e.g. they may be conducted in person or via telehealth or a combination of both, are to be clearly detailed in the HREC application and the PICF and clearly described to the participant during the consent process.
- With telehealth, all measures will be taken to ensure privacy and confidentiality of the participant's identity.
- If Informed Consent is obtained by telephone, this must be recorded on the Informed Consent Form and filed in the participant's trial file and the ISF. The Investigator must then sign the Consent Form on the date they received the Consent Form, NOT the date they obtained consent from the participant.

6.5 Informed Consent Documentation

Ensure the essential elements are present as described in the National Statement, Chapter 2.2 and ICH GCP E6 (R2) Section 4.8.10.

- The Master PICF is supplied by the Sponsor. Any necessary national or local adaptation will be made as required for submission to the reviewing HREC and CRGO.
- Once the PICF is signed and dated by both participant and the Investigator, the original PICF (and/or copy) is kept in the participants trial file and ISF and a copy is given to the participant.

Appendices

Appendix 1: Consent Statement Declaration- Sample ONLY
Appendix 2: Re-Consent Statement Declaration – Sample ONLY

Appendix 1: Consent Statement Declaration (Sample ONLY)

The following participant has agreed to participate in the following clinical trial:

<Insert Protocol Title: >

Participant: _____ consented to take part in the above stated

Study on: _____ (dd/mmm/yyyy)

I confirm that consent was obtained prior to any study procedures being performed.
The participant has received a copy of the current informed consent form.

Signature: _____

Name: _____ Date: _____

Statement of Physician obtaining informed consent:

<Insert Protocol Title: >

I have fully explained this research study to the participant _____.

In my judgement, the participant was provided with sufficient information, including risks and benefits to make an informed decision. I have provided the participant with a copy of the signed and dated Cabrini site specific consent form Version _____ dated _____

Investigator Signature: _____

Name: _____ Date: _____

Appendix 2: Re-consent Statement Declaration (Sample ONLY)

<Insert Protocol Title: >

Participant: _____ re-consented to continue to take part in the above stated study on _____ (dd/mmm/yyyy)

I have fully explained the changes/amendments to this research study.
In my judgement, the participant was provided with sufficient information, including risks and benefits to make an informed decision. I will provide the participant with a copy of the signed and dated Cabrini site specific consent form version _____ date _____

Signature: _____

Date: _____

Name: _____ (please print)

Current Version

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

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