

Standard Operating Procedure:

Informed Consent Process with Teletrials

**SOP Number: TT-SOP-02**

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**Amendment History**

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Developed by the Victorian Comprehensive Cancer Centre (VCCC) in conjunction with the Parkville Cancer Clinical Trials Unit (PCCTU), based on the Clinical Oncology Society of Australia (COSA) Australasian Tele-trials Model.

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Description generated with very high confidenceviccompcancerctr.org**

Introduction and Background

Informed consent in the context of a clinical trial is a process of information exchange, which involves giving written and verbal information, discussion and clarification of this information and obtaining the clinical trial participant’s verbal and written consent. The clinical trial participant or their legally acceptable representative must be informed of all relevant aspects to their decision to participate and give their informed consent voluntarily prior to participating in any clinical trial procedures.

“In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki.” (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996, sec. 4.8.1)

The investigator obtaining consent must be competent to do so; because they:

* Have received specialist training.
* Have been assessed and are aware of the limits of their knowledge.
* Have agreed to take on the responsibility.
* Do not take on responsibilities outside of their level of competence.
* Carry out the procedure.

1. Objective

To describe the procedure for obtaining written informed consent for participation in a clinical trial.

1. Scope

This SOP applies to all clinical trial investigators who obtain informed consent from clinical trial participants or their legal acceptable representative.

This SOP applies to the informed consent process for teletrial participants consented at satellite sites. This SOP also applies to all members of the study team.

It is important that this SOP is read and understood before the informed consent process starts with any potential clinical trial participant and should be referred to if any doubt arises regarding the process of informed consent during the course of the clinical trial.

1. Ownership and Responsibility

The principal investigator retains overall responsibility for ensuring clinical trial participant consent has been obtained in the correct manner prior to enrolment to the clinical trial. This responsibility can be delegated by the principal investigator to a sub-investigator who must be a medical doctor with the appropriate training, experience and knowledge. Investigators obtaining informed consent must have valid International Conference on Harmonisation Good Clinical Practice (ICH GCP) training to enable them to explain the full implications of participating in the clinical trial to the clinical trial participant. Delegation by the principal investigator should be clinical trial specific, in accordance with ICH GCP and must be clearly documented on the clinical trial specific Delegation of Duties log, signed and dated by the principal investigator prior to informed consent being obtained.

1. Glossary of Terms

Please refer to (SITE)-SOP-Glossary of Terms (see Related Documents) for full supporting glossary of terms.

1. Procedure
2. Delegating Informed Consent

The principal investigator can delegate the duty of informed consent if the following is met:

* The sub-investigator is prepared to take on this additional responsibility and feels confident to take informed consent in line with professional and organisational guidelines.
* The sub-investigator has a comprehensive understanding of the clinical trial, potential pharmacological interactions/treatment toxicities, associated disease area, risks and potential benefits of taking part in the clinical trial.
* The sub-investigator is appropriately qualified, with relevant experience and completed appropriate protocol training. All training must be documented in the individual clinical trial training log (as outlined in (SITE)-SOP-03: Clinical Trial Training (see Related Documents).
* Delegation of duties is documented on the delegation of duties log only after the sub-investigator has completed protocol training, as outlined in (SITE) -SOP-04: Delegation of Duties (see Related Documents).
* An effective line of communication is maintained between sub-investigator and principal investigator. The principal investigator is ultimately responsible for the clinical trial participant’s care and the process of ensuring clinical trial participants or their legally acceptable representative have fully understood what they are consenting to.
* Any other study team member involved in giving information during the informed consent process should document this in the clinical trial participant’s medical record .

1. Obtaining Informed Consent

Patients who have been identified by their treating clinician as a potential clinical trial participant will be considered for clinical trial participation. A verbal explanation of the clinical trial and the patient informed consent form (PICF) will be given to the potential clinical trial participant, or their legally acceptable representative, along with any family, friends or general practitioner if applicable.

Potential clinical trial participants, or their legally acceptable representative should be given adequate time to read the PICF and to discuss with any family, friends or general practitioner if applicable, prior to agreeing to participate in the clinical trial. The potential clinical trial participant should not be coerced to participate in the clinical trial. The potential clinical trial participant should be given adequate time to ask questions throughout the discussion, and their questions adequately answered before proceeding.

The PICF must be voluntarily signed prior to any clinical trial procedures being undertaken.

On some occasions, the investigator may request that the PICF is sent to a potential clinical trial participant before their visit. In this circumstance the investigator must ensure he/she has discussed the clinical trial with the potential clinical trial participant prior to the PICF being sent.

The PICF may be mailed or emailed to the potential clinical trial participant. If emailed, the PICF must be sent in a portable document format (PDF) format to ensure no changes to the form are made.

Where the PICF has been provided by email or mailed the following information/instructions must also be provided:

* Thoroughly read PICF, but do not sign.
* Write any questions down and bring to next appointment.

Prior to the informed consenting process beginning, the investigator must ensure:

* The relevant (SITE) study team is notified of the potential clinical trial participant and the eligibility criteria has been discussed with the (SITE) study team.
* Once the potential clinical trial participant or their legally acceptable representative has had time to read the PICF and has had any questions regarding their participation answered, the investigator obtaining informed consent will ask the potential clinical trial participant to sign and personally date the appropriate section(s) of the hard copy PICF.
* The PICF must also be signed and personally dated by the investigator.
* Both the clinical trial participant and the investigator should clearly print their full name.
* If a witness is required (as outlined in section 6.5), the witness will be asked to sign and personally date the witness section of the PICF.
* It must be clearly understood by the person obtaining the consent and the person acting as the witness as to the requirements of the witness, and to what they are witnessing, prior to the informed consent process beginning.
* Once all parties have signed the PICF, the clinical trial participant will receive a copy of the signed and dated PICF.
* The original signed PICF will be filed in the participant folder and a copy must also be scanned into the clinical trial participant’s eMR.
* Clinical trial participants will be provided with SITE study team contact details for use during the course of their trial participation.

Additional Requirements for Informed Consent for teletrial participants:

* The consent process will be outlined in the trial specific Supervision Plan.
* If delegated, the local sub-investigator will consent the participant following the procedure above.
* If the process is not delegated to the local sub-investigator, the PI will undertake informed consent process via video conference. In addition to the documentation requirements for consent as outlined in Section 6.3, the following processes must be recorded in the patient’s medical record:
  + Process of consent documented in medical record at the time of consent “The protocol was discussed with [Participant’s name] via video conference today [DD/MMM/YYYY]. 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.
  + Signing of consent documented in the medical record on the date the original consent is received and signed “The original PICF signed by patient XX on [DD/MMM/YYYY], was received in hard copy and signed by me the consenting clinician, dated today [DD/MMM/YYYY].
* The original PICF will be filed according to the trial specific supervision plan.

1. Informed Consent Documentation

The process of informed consent must be documented in the eMR by the investigator obtaining consent. The (SITE) study team member should also document the process in the eMR. The investigator and study team member’s documentation should include the following:

* Patient name and unit record (UR) number.
* Version number and date of PICF.
* Date PICF(s) given to clinical trial participant, including details if emailed/mailed prior to visit.
* A statement by the investigator obtaining informed consent confirming that the clinical trial participant has had full opportunity to read the PICF and ask questions (questions/issues raised should also be documented) and that all questions have been adequately addressed.
* Date PICF was signed and dated by the clinical trial participant.
* Use of witness.
* Use of interpreter.

Teletrials:

* If consent is delegated to the sub-investigator, the Informed consent process is to be documented by the sub-investigator at the satellite site.
* If the consent is undertaken by the PI via telehealth, the process will be documented by the PI at the Primary Site.

1. Re-consent

The informed consent process does not cease once the consent form has been signed. The practice of giving information about the clinical trial to the clinical trial participant should be an on-going process performed by all members of the study team (as appropriate). During the clinical trial, important new information may become available; if this occurs the PICF may need to be revised. If the updated information significantly changes the protocol resulting in change to clinical trial participant visit requirements or side effects associated with the treatment, these changes may be relevant to the clinical trial participant’s willingness to continue to participate. In these circumstances the clinical trial participant or their legally acceptable representative will be asked to re-consent to an amended ethical and governance approved PICF in order to continue their involvement in the clinical trial. The consenting process must be documented (as outlined in section 6.3).

The principal investigator will determine if PICF amendments require the clinical trial participant to re-consent in the PICF ethical submission.

Where the principal investigator determines that the new information provided in the revised PICF does not have any relevance to a specific clinical trial participant, the clinical trial participant does not need to be informed of the new PICF, nor will be required to sign it.

1. Clinical Trial Participants who are Unable to Read

When a clinical trial participant is unable to read, an impartial witness must be present during the entire consenting process:

* The PICF and any other written information will be provided to the clinical trial participant or their legally acceptable representative.
* The entire PICF will be read to the clinical trial participant.
* The investigator will explain all aspects of the clinical trial and will confirm their understanding.
* The clinical trial participant will, if agreeable, sign and personally date the PICF.
* The impartial witness will sign and personally date the PICF.

By signing the PICF, the witness attests to information in the PICF and any other written information being accurately explained to the clinical trial participant or their legally acceptable representative. They also confirm that the informed consent was freely given by the clinical trial participant or their legally acceptable representative.

1. Consent of Non English Speaking Clinical Trial Participants

The National Statement on Ethical Conduct in Human Research states that when obtaining consent from a patient, the “…information must be presented in ways suitable to each participant.” (National Health and Medical Research Council et al, 2007, sec. 2.2.3) This is further clarified by describing how information regarding the trial must take into account “the need for accurate and reliable translation (written and/or oral) into a participant’s first language or dialect.” (NHMRC et al, 2007, sec. 5.2.16)

On occasions a non-English speaking individual may participate in a clinical trial. For all trials coordinated by (SITE), the utilisation of an ethically approved (English) written PICF’s will be used. No other hard copy translation of the PICF will be utilised. When a potential patient is non-English speaking an oral translation of the PICF will be read verbatim to the potential clinical trial participant, using an independent interpreter as outlined in (SITE) Policy 1.1.

The use of an interpreter in the informed consent process must be clearly documented in the clinical trial participant eMR (as outlined in section 6.3). The name of the interpreter and the relationship between the interpreter and the clinical trial participant should be noted in the eMR.

1. Informed Consent of a Young Person

On occasion, an individual under the age of 18 years (young person) may participate in a clinical trial. Each clinical trial specific protocol will identify the age range of the clinical trial participant; subject to ethical approval (approving Human Research Ethics Committee (HREC) must be authorised to approve age range).

Specific consent of a young person’s participation in a clinical trial should be obtained from the young person whenever he or she has the capacity to make this decision and either:

* One parent, except when in the opinion of the HREC, the risks involved in the young person’s participation require the consent of both parents; or
* The guardian or other primary care giver, or any organisation required by law.

Informed consent for a young person must be clearly documented in the clinical trial participant eMR (as outlined in section 6.3), including details of the parental or guardian consent and the young person’s consent were obtained.

Clarification should be sought from the local HREC in circumstances of dispute.

1. Clinical Trial Participant with Cognitive Impairment, Intellectual Disabilities or Mental Illness

On occasion, an individual with a cognitive impairment, an intellectual disability or a mental illness may participate in a clinical trial.

When a potential clinical trial participant has any of these conditions, the investigator obtaining informed consent should, where the impairment, disability or illness is temporary or episodic, attempt to obtain consent at a time when the condition does not interfere with the clinical trial participant’s capacity to give consent.

Prior to obtaining informed consent from a clinical trial participant with a cognitive impairment, an intellectual disability or a mental illness, the principal investigator must inform the relevant HREC how they propose to determine the capacity of the clinical trial participant to consent to the clinical trial. This should include the following:

1. How the decision about the clinical trial participant’s capacity will be made.
2. Who will make the decision.
3. The criteria that will be used in making the decision.
4. The process of reviewing clinical trial participant’s capacity to consent and to participate in the clinical trial, throughout the duration of the clinical trial.

The informed consent process should be witnessed by:

* A person who has the capacity to understand the merits, risks and procedures of the clinical trial.
* A person who is independent of the study team (impartial witness).
* Where possible, a person who knows the clinical trial participant and is familiar with his/her condition.

The informed consent process should include discussions of the possibility that the clinical trial participant’s capacity to consent or to participate in the clinical trial may vary or be lost altogether. The clinical trial participant’s wishes about what should occur in those circumstances should be followed, unless changes in circumstances mean acting in accordance with those wishes to be contrary to the clinical trial participant’s best interest. These discussions must be clearly documented in the clinical trial participant eMR (as outlined in section 6.3).

Where consent has been given by the clinical trial participant’s legally acceptable representative, the investigator obtaining the informed consent should, as far as possible, explain to the clinical trial participant what the clinical trial is about and what participation involves. Should the clinical trial participant at any time during the clinical trial recover the capacity to consent, the investigator will offer the clinical trial participant opportunity to continue participation or to withdraw.

1. Clinical Trial Participants Highly Dependent on Medical Care

Consenting a clinical trial participant who is highly dependent on medical care should first be sought from the individual, when they are capable to give consent and it is practicable to approach them. During the consenting process, the investigator should ensure that stress or emotional factors that may impair the clinical trial participant’s understanding of the clinical trial or their decision to participate in the trial are minimised where possible. The dependency of the individual and their relatives on the treating clinician may also compromise the freedom of a decision to participate.

Where the investigator is also the treating clinician, it should be considered whether another investigator should make the initial approach/obtain the consent from the potential clinical trial participant or their legally acceptable representative.

When a clinical trial participant who is highly dependent on medical care is not capable of giving consent, or where it is not practicable to approach them, consent should be obtained by their legally acceptable representative.

In circumstances where neither the potential clinical trial participant nor their legally acceptable representative can consider the clinical trial, the HREC may (having taken into account, relevant jurisdictional law) approve the clinical trial participant’s involvement without prior consent, providing:

* There is no reason to believe that, if the potential clinical trial participant or their legally acceptable representative were informed of the clinical trial, he/ she would be unwilling to consent.
* The risks of harm to individuals are minimised.
* The clinical trial is not controversial.
* The clinical trial supports a reasonable possibility of benefit over standard care.
* Any risk or burden to the clinical trial participant is justified by its potential benefits.
* Inclusion in the clinical trial is not contrary to the interest of the clinical trial participant.

As soon as reasonably possible, the clinical trial participant or their legally acceptable representative will be informed of their inclusion into the clinical trial and of their option to withdraw from it without any change in the quality of their care.

1. Telephone Re-consent

The use of the telephone to re-consent a clinical trial participant may occur for clinical trials that have undergone appropriate ethical review and approval to use this method of re-consent. The principal investigator is required to review the amendment and determine if the individual clinical trial participant warrants re-consent.

Re-consent via telephone can be used in the following circumstances:

* Clinical trial participants who are in survival follow up.
* Clinical trial participants who in the course of their clinical care are not required to attend the clinic in what would be considered an appropriate time frame.

If ethical approval has been granted for a member of the (Site) study team to re-consent a clinical trial participant via telephone the principal investigator must delegate that person to do so on the delegation log.

A member of the study team will contact the clinical trial participant patient and inform them of the recent PICF amendment and the requirement for them to re-consent.

The PICF will then be sent to the clinical trial participant and adequate time will be provided for the clinical trial participant to review and discuss with their legally acceptable representative, along with any family, friends or general practitioner if applicable.

When the PICF amendment contains safety information updates an investigator is required to contact the clinical trial participant to discuss the changes in detail.

If the patient is agreeable they will sign and send the original PICF back to site. The responsible (SITE) study team member or the investigator will document the clinical trial participant’s willingness to re-consent in the eMR (as outlined in section 6.3).

When the signed original PICF is received at site the appropriate member of the study team will sign the PICF (as the date received at site), send a copy to the clinical trial participant and clearly document in the clinical trial participant eMR (as outlined in section 6.3).

1. Dissemination and Implementation

Approved SOPs will be disseminated electronically by (SITE). SOPs will be made available in hard copy format or electronically upon request. Any updates to the existing approved SOPs will be disseminated internally, and will be effective immediately.

1. Monitoring Compliance and Effectiveness

Compliance with this SOP will be monitored as part of the (SITE) monitoring and audit process. Any queries concerning the effectiveness of this SOP identified during the (SITE) monitoring process or through use will be addressed and may result in the requirement to update the SOP.

1. Review and Updating

This SOP will be reviewed every three years, or when changes to legislation or working practices that impact upon the content of this document. This SOP may be merged with another SOP if appropriate or removed entirely if it becomes redundant.

1. Reference(s)

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. (1996). Guideline for Good Clinical Practice E6(R1).

Australian Government: National Health and Medical Research Council; Australian Research Council; Australian Vice-Chancellors’ Committee. (2007). National Statement on Ethical Conduct in Human Research.

1. Related Documents

(SITE)-SOP-Glossary-of-Terms

(SITE)-SOP-03: Clinical Trial Training

(SITE)-SOP-04: Delegation of Duties

(SITE) Policy 1.1

Integrated addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)