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HEALTH+MEDICAL RESEARCH

Informed consent

Standard Operating Procedure



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1. Purpose

To describe the process for obtaining and maintaining informed consent from a potential clinical trial participant or their legally acceptable representative. To ensure that sites conducting clinical trials take appropriate account of the Guidelines for Good Clinical Practice based on sponsor requirements¹.

2. Scope

All clinical trials (except Teletrials)² conducted at NSW Public Health Organisations.

3. Applicable to

The Principal Investigator (PI) and all other staff involved in the process of clinical trial consent.

4. Definitions

Refer to SOP-G-01: Glossary of terms.

5. Background

Informed consent is a process of information exchange that culminates in a potential trial participant (or their legally acceptable representative) confirming willingness to participate in a study. For clinical trials, informed consent is documented using a written, signed and dated participant information sheet and consent form (PICF)*.

** The National Statement enables an HREC to approve trials that deviate from the traditional consent process. This may include a consent to continue approach (e.g. for some trials conducted in the emergency setting) or an opt-out approach. Where deemed legally and ethically defensible by the HREC, a consent waiver may also be granted.*

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 is undertaken.

Staff obtaining consent must:

- be appropriately qualified, experienced and trained*

- be aware of the limits of their knowledge and confident that they are fully competent to take on the role.
- have agreed to take on the role.

** Clinical trial consent is normally obtained by medically qualified staff. However, it may be acceptable for non-medical staff to obtain consent if approved by the HREC and permitted by local policy. In this instance, documented arrangements should be in place for the availability of medical staff for any medical input during the consent process.*

For therapeutic good trials, staff obtaining consent should be thoroughly familiar with the investigational product and have a comprehensive understanding of potential pharmacological interactions/treatment toxicities and the disease area. All staff should be competent to assess the capacity of potential participants to provide their consent.

The consent process

The potential participant should be provided with the current version of the PICF and should be given adequate time to read the information and discuss with others. PICFs may be provided to potential participants in advance of their visit. In this instance, participants should be instructed to read the PICF, but not to sign, and to come to the visit with any questions they may have. Where an electronic version of the PICF is emailed before a visit*, it should be sent in a portable document format (PDF) format to ensure no changes are made to the form. Once all questions have been addressed, participants should sign and personally date the PICF which should then be countersigned by the person obtaining consent. A copy of the PICF should be given to the participant, the original filed in the Investigator Site File and where the participant is also a patient, in their medical records so that other clinicians involved in their care are aware of their participation.

**HREC may approve trials with no face to face visits with trial staff. In these trials, the consent process may be completed by other means (e.g. mail, telephone or electronic consent).*

Electronic consent

Electronic methods for seeking, confirming and documenting informed consent are increasingly being adopted by trial sponsors. However, the option to provide written consent should normally be available to

¹ All trials must comply with the principles of GCP (Section 2 of ICH GCP (E6 R2) or Clause 4 of ISO 14155) however sponsors submitting data to regulatory authorities will normally require full compliance with ICH GCP (E6 R2) or ISO 14155 GCP Guidelines.

² NSW Health have published an annotated version of these SOPs for sites utilising a Teletrials model.

potential participants to avoid selection bias and discrimination against those who do not wish to use an electronic device.

Pre-screening and trial-specific screening

Pre-screening of medical records, databases or clinic lists in order to identify potential participants may only be undertaken by those involved in the clinical care of those patients. This would include research nurses and trial coordinators employed by the organisation.

Trial-specific screening activities (e.g. blood tests or scans) may only commence once consent has been obtained.

The requirement for a witness

Where the person giving consent is unable to read, is physically unable to sign or mark the document, or where a translator is being used for non-English speaking participants, they 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.

In cases where translation is required, a professional interpreter should be accessed to facilitate the process in accordance with NSW Health Policy Directive PD2017_044. The interpreter should be asked to sign and date the relevant section of the consent form.

Consent involving children and young people

Prior consent of a parent or legal guardian is required for children*. For older children, NSW Health policy (PD 2005_406) states that a child aged 14 years and above may consent to their own treatment provided they adequately understand and appreciate the nature and consequences of the operation, procedure or treatment. However, for clinical trials, it is usual practice to also obtain the consent of the parent or guardian up until the age of 18 years whilst also encouraging a child or adolescent to co-sign the consent form if they agree to take part and have sufficient maturity and understanding of what is proposed to provide their consent. Where possible, children and adolescents should agree to their participation in the trial. If a child or adolescent turns 18 whilst on a trial, they should be asked to provide their consent to confirm willingness to continue.

Consent involving incapacitated adults

Under Part 5 of the Guardianship Act 1987, studies that are *deemed under the Act to be clinical trials* that

seek to involve persons of 16 years of age or older with decision making disabilities, must be approved by the NSW *Civil and Administrative Tribunal* (NCAT) as described in NCAT Clinical Trials Fact Sheet (as amended). In addition, the National Statement (Sections 4.4.5 to 4.4.14) should be followed.

Maintaining consent

The PICF provided to participants should be revised if important new information becomes available that may impact on the participants' continued consent. Participants may withdraw their consent at any time without giving a reason. Participants should be re-consented promptly to confirm their willingness to continue in the trial. If approved by an ethics committee, the re-consent may be obtained by telephone. This would be particularly relevant when the new information needs to be provided to patients before the next scheduled visit (or no additional visits are planned) and the process of bringing participants back to the site specifically for re-consent is considered unduly burdensome.

Telephone consent should be conducted using the following process:

- The participant is contacted and advised that there has been a change in the PICF
- The PICF is sent to the participant by post or email.
- If relevant (e.g. new safety information) the PI or delegate discusses the amendment over the phone and if the patient agrees to continue, signs and send the PICF back to the site
- The investigator or delegate countersigns and dates the consent form (date of their signature rather than the date the participant signed) files a copy and sends a copy back to the participant.
- The re-consent is documented in the participant's records.

The investigator (usually in liaison with the sponsor) may determine that the information in an updated PICF is only relevant to a particular participant or a subset of participants. The justification for not re-consenting participants should be documented.

6. Procedure

Principal Investigator (PI)

Ensure individuals delegated the task of obtaining consent are competent to undertake the role and named on the trial-specific Delegation Log and supervise all individuals involved.

Ensure individuals consenting participants follow the process approved by the HREC.

Ensure each delegated staff member has the relevant training (including GCP training).

Ensure consent is obtained before any trial-specific procedures are performed and where appropriate, participants are contacted and re-consented promptly when new versions of the PICF become available.

PI's delegate

Undertake the consent process in accordance with the ethics approval and GCP, ensuring that only the current and approved consent documents are used.

Be satisfied that all questions are satisfactorily answered and potential participants have the capacity to give their consent, that they have had sufficient time to read the information provided and to discuss it with others.

File a copy of the PICF in the medical records (or participant file for healthy volunteer studies) and document the process of consent including:

- The data he version number of the PICF used
- Evidence that adequate time was given and all significant questions or issues addressed
- Where relevant, the use of a witness or interpreter.

7. References

[ICH GCP \(E6 R2\): Good Clinical Practice Guidelines – Annotated by the TGA](#)

[National Statement on Ethical Conduct in Human Research \(2018\)](#), as amended

[NSW Guardianship Act 1987](#) (as amended)

[Australia High Court: Rogers v. Whitaker. Aust Law J 1993; 67: 47-55](#)

[NSW Policy Directive \(PD2017_044\): Interpreters – Standard Procedures for Working with Health Care Interpreters](#)

[NSW Policy Directive \(PD2005_406\): Consent to Medical Treatment - Patient Information](#)

[TransCelerate E-consent implementation Guidance \(2017\)](#)

8. Associated documents

None