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Informed Consent Procedure

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1.0 Introduction / Background

Participation in a clinical trial generally requires written informed consent from participants. The process for obtaining consent firstly involves providing a potential participant (their legal Guardian or Person Responsible) written and verbal information including the opportunity to ask questions regarding a clinical trial or research project to ensure they are informed of all aspects that are relevant to their decision to participate. The discussion(s) is then followed by the participant voluntarily signing the consent documentation. This must be completed before the participant can take part in any study procedures as detailed in the ethically approved protocol.

"In obtaining and documenting informed consent, the investigator should comply with applicable regulatory requirement(s) and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki" according to the International Council for Harmonisation (ICH) Good Clinical Practice (GCP).

The National Statement of Ethical Conduct in the National Statement of Ethical Conduct in Human Research also outlines the Australian consenting requirements including general requirements, qualifiers and waivers for consent.

Under Part 5 of the NSW Guardianship Act 1987, clinical trials which seek to involve a person aged 16 years or older with decision making disability must be approved by the Guardianship Division of the NSW Civil and Administrative Tribunal (NCAT). NCAT must also decide whether consent to the treatment proposed during the trial is to be given by a person responsible, by NCAT itself or both.

2.0 Objective

To describe the standards expected in relation to informed consent for clinical trials. This is not intended as consent training and clinical trials team members not experienced in taking consent should seek training and support from the Clinical Trials Support Unit (CTSU) and refer to the GCP and the National Statement of Ethical Conduct in Human Research requirements.

3.0 Scope

This SOP applies to all staff involved in clinical trials at South West Sydney Local Health District (SWSLHD) & the Ingham Institute.

4.0 Ownership and Responsibility

The Principal Investigator (PI) retains overall responsibility for ensuring a participant's consent has been obtained in the correct manner before entry into the clinical trial. For clinical trials being conducted under the Therapeutic Goods Act involving an unapproved therapeutic goods under the Clinical Trial Application (CTA) or Clinical Trial Notification (CTN) Scheme, if responsibility for taking informed consent is delegated, it must be to a medical doctor or delegate with the appropriate training, experience and knowledge to enable them to explain fully the implications of participating in the study to the potential participant.

The Delegation of Responsibilities Log (electronic Delegation of Responsibilities or FM_007 Delegation of Responsibilities Log) must be completed by the PI prior to any duty being undertaken.

SWSLHD and the Ingham Institute use Veeva SiteVault electronic Investigator Site File (eISF) which includes an eConsent platform. This has been approved in accordance with NSW Health and SWSLHD Policies.

5.0 Associated Documents

SOP_CTSU_02 Investigator Responsibilities
SOP_CTSU_ 09 Investigator Site File and Essential Documents
SOP_CTSU_13 Recruiting Clinical Trial Participants
FM_001 Source Data Location
FM_003 Subject Identification Log
FM_005 Record Management Form
FM_006 Protocol Specific Training Log
FM_007 Delegation of Responsibilities Log
Veeva SiteVault Validation Documents

6.0 Procedure

6.1 How to Delegate Responsibility for Informed Consent

The Principal Investigator (PI) for a clinical trial can delegate the duty for the informed consent process on the Delegation of Responsibilities Log (electronic Delegation of Responsibilities or FM_007 Delegation of Responsibilities Log). In the case where the PI is also the participants treating physician, from an ethical standpoint, it is preferred that the process for seeking written informed consent from the participant is delegated to a non-treating colleague, to avoid the perception of coercion. The following criteria must first be met:

- The delegate is prepared to take on this additional responsibility and feels confident to take informed consent in line with professional, SWSLHD and/or Ingham Institute policy.
- They must have a comprehensive understanding of the clinical trial, potential pharmacological interactions, treatment toxicities (or adverse impacts of non-medication interventions) and the associated disease area. The delegate should be fully aware of the risks and potential benefits of a participant taking part in the clinical trial. The delegate will be adequately trained with relevant experience and should have received appropriate protocol training for the clinical trial. In pharmacological clinical trials, the person consenting to the participant should be medically qualified. All training must be documented in the Individual Training Log (electronic Training Materials Log or FM_006 Protocol Specific Training Log).
- All personnel who have been delegated the responsibilities of obtaining written informed consent must have been approved through the Research Governance Office (RGO) using the Site Specific Application (SSA) in REGIS. The following must be in place before undertaking this duty:
  - A current copy of their signed and dated CV in the Investigator Site File (ISF) or eISF
  - A current GCP training certificate
  - Must have completed the study-specific Study Delegation of Responsibilities Log, either electronically or in paper format which has been authorised by the PI
  - Completed protocol and other relevant training (documented)
- An effective line of communication is maintained back to the PI who is ultimately the person responsible for the participant's care and for ensuring that they or their legally acceptable representative have fully understood what they are consenting to.
- The PI is also responsible for supervising any staff to whom they have delegated study responsibilities.
- Any other research personnel involved in giving information during the informed consent process should document this in the participant's medical records.

6.2 The Consent Process

- The potential participant should be provided with the current version of the Participant Information & Consent Form (PICF) as approved by the Human Research Ethics Committee (HREC) and the RGO.
- The consenting process usually will occur in person, however depending on the study it also may occur over the tele-health platform or over the telephone. The principles of informed consent must be followed at all times.
- Where the potential participant is seriously ill, it is critical that obtaining written informed consent does not delay or impede the start of standard medical care.
- Clinical trial sites should make every effort to enrol participants from Cultural and Linguistically Diverse (CALD) backgrounds using available resources. This may include translated PICFs and documents, the Interpreter services and/or the Aboriginal Liaison Officer.
- The consent conversation should also reflect language the participant can understand which should not only be scientifically accurate but should also be sensitive to their social and cultural context. Consumer engagement is encouraged to ensure that the social and cultural context is addressed in the PICF and consenting process.
- Participants or their legally acceptable representatives should be given adequate time, to read the PICF and to discuss it with any family, friends, GP (if applicable) before agreeing to participate. The participant must not be coerced to participate in the study.
- Once all questions have been addressed, participants should sign and personally date the PICF which should then be countersigned by the person obtaining consent. If the consent is conducted over a tele-health platform or on the telephone, an explanation of the reason for this type of visit, if it was recorded, a method that the PICF was sent to the participant for review and signature should be clearly documented in their medical records. Depending on the level of risk involved with the study the HREC may require more stringent proof of the process whereby participants are adequately informed.
- A copy of the PICF should be given to the participant, the original filed in the (e) ISF. Where the participant is also a patient, a clear explanation of the consent process should be documented in their medical records so that other clinicians involved in their care are aware of their participation. NB: An Alert must be added to the electronic medical record for all clinical trial participants including the PIs details for all SWSLHD patients.

- Original consent forms may be destroyed after they have been uploaded and certified. The process for risk-based Quality Control (QC) checks for certified copies before destruction of the originals should ensure that the copy is of sufficient quality for the intended purpose and should include the following attestation by the person certifying the copy. Refer to SOP_CTSU_09 Investigator Site File & Essential Documents for more details

6.3 eConsent

- SWSLHD and the Ingham Institute have implemented an eConsent platform in Veeva SiteVault (eISF) to be utilised across clinical trials. Sponsor platforms are discouraged as these require the appropriate cybersecurity and privacy approvals be granted as per NSW Health policies. There will be costs associated with the cybersecurity and privacy approval and there will be a training cost for all SWSLHD or Ingham Institute staff members if the Sponsor will not accept Veeva SiteVault e-Consent.
- The PI or delegate will build the PICF in Veeva SiteVault. For instructions, please see https://sites.veevavault.help/gr/econsent/consenting/
- The Lead HREC will document in the application form that SWSLHD or Ingham Institute sites will be utilising an eConsent platform utilising the approved version of the PICF.
- The HREC-approved version of the PICF will be created in Veeva SiteVault by the delegated study team member using the eConsent editor in Veeva SiteVault.
- The site-specific version is submitted to the RGO for review and approval. eConsent versions will be submitted and approved by the RGO process. The eConsent process will be performed consistent with the study protocol and HREC application.
- Only approved versions of the eConsent are available to be sent to participant by study team members delegated consenting responsibilities by the PI.
- Upon the participant's agreement to participate in the consenting process, the delegated study team member will enter the participants information into Veeva SiteVault to enable that participant to access the eConsent through MyVeeva for Patients, the eConsent application. If that patient does not already have a MyVeeva for Patients account, when they receive the email to access the eConsent documents, they will be required to set up a MyVeeva account with a username and password.
- Participants will review the informed consent form and complete two-factor authentication to sign the ePICF. This may occur in-person or a remote setting.
- The PI or Delegate will ensure that all questions that the participant has are answered prior to the participant signing the ePICF.
- Following that participant's eSignature (validated Part 11) the eConsent will be automatically filed into SiteVault with a task for the delegated site staff to countersign.
- The participant-signed eConsent document will be available immediately to the participant through their MyVeeva for Patients account and made accessible for the duration of the study.
- The participant can access the MyVeeva for Patient website at any time to gain access to the signed PICF.

6.4 E-Consent Onsite

You can create and scan an in-person consent code to have participants or other signatories complete eConsent forms in person using a site's device. A participant or signatory can scan the QR code or go to the web address shown onscreen to access MyVeeva for Patients. This in-person consenting functionality bypasses the invitation email and makes it easier to have participants and signatories complete eConsent forms at the office or another location where they may not have their own device.

If a patient doesn't have contact information in SiteVault or isn't registered for a MyVeeva for Patients account, they must sign during an in-person consenting session and hand-draw their signature in place of dual-factor authentication.

6.5 Requirement for an impartial 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 consent process was followed, the information in the PICF was 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 National Statement and GCP Guidelines do not require the Interpreter to sign the consent form as specified in PD2017_044. For this reason, the Interpreter and the PI/delegate should document the process for consenting the participant in the participant's medical records.

6.5 Consent Involving Children or Young People

Prior consent of a parent or legal guardian is required for children. For older children; NSW Health policy states that a child aged between 14 years and <18 years may consent to their own treatment provided they adequately understand and appreciate the nature and consequences of the operation, intervention, 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 Assent document.

The child or young person will sign the Assent 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 clinical

trial. If a child or adolescent turns 18 whilst on a trial, they should be asked to provide their consent to confirm their willingness to continue.

6.6 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 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 Trial Facts Sheet . In addition, the National Statement (Sections 4.4.5 to 4.4.14) should be followed.

6.7 Participants in Isolation

It is encouraged that eConsent is utilised for participants in isolation but this is not always possible. In this case the PI/delegate will provide a copy of the PICF to the participant directly and discuss the clinical trial with them. The participant will be given the opportunity to ask questions and consider participating in the study. They will be advised that participation is voluntary, and they can withdraw at any time. If the participant is willing to take part in the clinical trial, they will sign the consent form. A photo of the signed and dated consent page will be taken and used as source documentation. The photo will be uploaded to participant's electronic medical records and filed in the eISF in the source document folder. A copy of the photo will be emailed to the participant where possible or a copy given to them.

6.8 Patients in isolation or unable to give consent but with Person Responsible present

For participants who are unable to consent due to isolation or other medical conditions, HREC approval may allow for a Person Responsible to provide consent if NSW Civil Administrative Tribunal (NCAT) guidelines are followed. The NCAT process must be approved prior to participants entering the trial. Below is the standard process utilised under NCAT approval:

For patients in isolation who are unable to give consent but with a Person Responsible present in the hospital, the PI will provide a copy of the PICF to the Person Responsible and discuss the clinical trial with them. The Person Responsible will be given the opportunity to ask questions and consider whether the patient should participate. The Person Responsible will be advised that participation is voluntary, the patient can be withdrawn at any time and that if they decide that the participant does not take part, they will receive alternative treatments. If the Person Responsible is willing to consent to the participant being involved

in the clinical trial, they will sign the PICF. A copy will be provided to the Person Responsible. When the patient has sufficiently recovered, the PICF will be provided to them and if the patient is willing to continue participation in the clinical trial, the PI and the patient will sign the consent form. In the event the patient is not willing to consent, the Sponsor will be notified that the data cannot be used and the patient will be withdrawn.

6.9 Patients in isolation or unable to give consent but with a Person Responsible available off site

For participants who are unable to consent due to isolation or other medical conditions, the HREC approval may allow for a Person Responsible who is available off-site to provide consent if NCAT Guidelines are followed. The NCAT process must be approved prior to participants entering the trial. Below is the standard process utilised under NCAT approval:

The PI will contact the Person Responsible via telephone and discuss the clinical trial with them. A copy of the PICF will be sent via Veeva SiteVault e-Consent or emailed to the Person Responsible and they will be given the opportunity to ask questions and consider whether the patient should participate. The Person Responsible will be advised that participation is voluntary, the patient can be withdrawn at any time and that if they decide not to participate, they will receive alternative treatments. The PI will arrange a video or tele-health with the Person Responsible once they have had time to review the information. The Person Responsible must be willing to consent to the patient being involved in the clinical trial. The video or tele-conference will be recorded and used as evidence of the informed consent process. An electronic copy will be uploaded to the patient's electronic medical records where possible. For paper medical records, the consent process should be described in detail and information given as to how to access the video or tele-conference. The same information will be stored in the (e)ISF. A copy will be emailed to the Person Responsible if e-Consent is not being used. When the patient has sufficiently recovered the PICF will be provided to them and if the patient is willing to continue participation in the clinical trial, the PI and the patient will sign the consent form. In the event the patient is not willing to consent, the Sponsor will be notified that the data cannot be used and the patient will be withdrawn.

6.10 Maintaining consent

The informed consent process does not end once the consent form has been signed. The practice of giving information about the trial to participants should be an ongoing process performed by all members of the research team for the duration of the clinical trial.

The PICF provided to participants should be revised if important new information becomes available that may impact 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 clinical trial. If approved by an HREC, the re-consent may be obtained by tele-health or telephone. This would be particularly relevant when the new information needs to be provided to participants 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.

Tele-Health or Telephone re-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 e-Consent platform, post or email
- See Section 6.3 for e-Consent platform
- The PI or delegate discusses the amendment over the tele-health portal or telephone and if the participant agrees to continue, signs and sends the PICF back to the site
- The PI 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 clearly and accurately in the participant's medical records

6.11 Documentation of Informed Consent

The process of informed consent must be documented in the medical notes by the consenting PI/Delegate. A template for documenting consent can be found in the SWSLHD electronic medical records. Informed Consent Documentation should include the following:

- In line with ICH GCP E6 (R2) Attributable, Legible, Contemporaneous, Original, Accurate and Complete (ALOCAC)
- The participant's name and hospital number must be documented
- Clinical trial name
- Version number and date of PICF and language of the PICF if appropriate
- Date PICF(s) given to the participant, including details if emailed/mailed prior to visit
- A statement by the PI/Delegate confirming that the 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
- Ensure that documentation in the medical records that the patient has met all inclusion criteria and none of the exclusion criteria as documented in the approved study protocol
- Rationale for why remote Consent was used
- If an interpreter is used, documentation from the Interpreter is required to confirm the

main elements of the consent conversation. Interpreters should have accreditation from SWSLHD or, depending on the study, be approved for use by the SWSLHD Human Research Ethics Committee.

7.0 References

ICH GCP (E6R2): Good Clinical Practice Guidelines - Annotated by the TGA

Declaration of Helsinki 2013

National Statement on Ethical Conduct in Human Research 2018

NSW Guardianship Act 1987 (as amended)

Australian 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)

Veeva SiteVault Validation document

8.0 Amendment History

Version	Date	Amended by	Details of Amendment
1.0	1 October 2020	Kelsey Dobell-Brown	Due to operational changes and accreditation requirements, inclusive of changing the naming convention of GCP to SOP_CTSU
2.0	30 September 2022	Meg Ford	Review of V1.0 to update any superseded links and processes

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