Peninsula Health

OPERATION / PROCEDURE CONSENT

(Refer to PH Consent to Treatment Policy)

UR NUMBER .....

SURNAME .....

GIVEN NAMES .....

DATE OF BIRTH .....

Please fill in if no Patient Label available

App.18/05/2021 Print Code:13491

PHF552800U

DOCTOR / PROCEDURALIST

Operations / Procedures proposed (to be documented by Doctor/Proceduralist):

PERCUTANEOUS NEEDLE APONEUROTOMY WITH VAPOCOOLANT SPRAY ANALGESIA

I, Doctor / Proceduralist I. SETH have informed and explained to the

☑ Patient ☐ Responsible Person ☐ Guardian

☑ The nature and effect of the proposed operation / procedure

☑ The material complications and risks as documented below:

RISK - INFECTION, PAIN, BLEEDING, NEUROVASCULAR INJURY, TENDON RUPTURE

REOCCURENCE

I have also supplied the patient with relevant printed information from:

	Yes
• EIDO Healthcare brochures (Peninsula Health Intranet), or	☐
• Relevant Patient Information Brochure	☐

Doctor / Proceduralist Signature	Print Name	Date and Time
	I.SETH	

PATIENT / RESPONSIBLE PERSON / GUARDIAN

I, ...

☑ Patient ☐ Responsible Person ☐ Guardian

confirm that the above information has been provided to me and I understand and give consent for:

the proposed operation / procedure and other operations / procedures found urgently necessary during the operation, including the anaesthetic and / or blood product transfusion. I have also had the opportunity to ask questions and receive relevant information. I understand that no guarantee is given that the procedure will be performed by a particular surgeon / proceduralist. I understand I may withdraw consent, in writing at any time.

Signature	Print Name	Date and Time

CONFIRMATION OF CONSENT

(Where there is doubt about the validity of previously provided consent - see section 5.1 of the PH Consent to Treatment Policy)

Signature Patient / Responsible Person / Guardian	Print Name	Date and time

Signature Doctor	Print Name	Date and time

OPERATION / PROCEDURE CONSENT

MR/552800

18/05/2021 Print Code:13491 LUW

Procedure	**SOP 09 - Participant Informed Consent Process and Documentation Standard Operating Procedure for Clinical Trials**
Peninsula Care Goal	**Effective**

1. Target Audience and Setting

This SOP applies to all relevant employees including, but not limited to, visiting health professionals, contractors, consultants 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. This SOP must be read in conjunction with individual trial unit SOPs, as well as Peninsula Health's Research Governance Framework, Research Ethics and Governance Policy and Responsible Conduct of Research Policy.

Refer to Standard Operating Procedures for Clinical Trials for the full suite of SOPs relating to the conduct of clinical trials at Peninsula Health.

For teletrials, addition requirements are detailed in National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia SOP 09.

2. 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 SOP.

3. Definitions

See **Standard Operating Procedures for Clinical Trials** for a full list of definitions.

4. Precautions/Contraindications

Not applicable.

5. Equipment

Not applicable.

6. Standard Requirements

Not applicable.

7. Procedure

7.1 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
- Refer to 'How to talk to potential clinical trial participants' available from the Australian Clinical Trials Website

7.2 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. However, at their discretion, the PI can delegate the duty for obtaining consent to a suitably qualified Associate Investigator as described in SOP 02 – Responsibilities of the Research Team, SOP 03 - 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 Site Authorisation letter, 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 reviewing HREC's written approval and authorisation from Office from Research before these may be used to obtain consent or continued consent from any participant.

7.3 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 reviewing HREC approved/Site authorised Participant Information and other approved media. This can be provided in the format specified within the approved protocol (such as in person, by telehealth or by telephone and email or weblink)
- Potential participants should be made aware of their healthcare rights and/or provided with the Clinical Trial Participant Welcome Pack (available from the Office for Research)
- 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 amount of time required will depend on the complexity of the trial and the individual/family needs. 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
- Additional supports should be offered based on an individual's needs (for example Aboriginal Hospital Liaison Officer Service, Interpreter Services, etc). 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 and Dental qualified persons 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 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 or are attesting to a translation of the Participant Information

provided (see also ICH GCP Section 4.8.9). 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 participant's medical record to indicate that person is participating in research as part of their medical care
- Participants may withdraw their consent at any time without giving a reason.

7.4 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 contact the reviewing HREC and Office for Research to obtain ethical approval and site authorisation for these changes and to discuss the need, or immediacy of need, to inform existing participants
- The PI will ensure that all currently enrolled participants are re-contacted in a timely manner with the relevant new information as approved by the reviewing HREC and authorised by the Office for Research. 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, continued consent may be obtained verbally and recorded in the participant's medical records and Source Documents
- 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 medical records and the SMF/ISF.

7.5 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 Site Authorisation, the Investigator may apply under the Medical Treatment Planning and Decisions Act 2016 (Vic), 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. Refer to Peninsula Health's Medical Treatment, Decisions and Consent Policy

7.6 Informed Consent via Telephone or Telehealth
- 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 in the participant's medical record, and/or Source Document, stating (as an example): "The protocol was discussed with [participant's name] via telephone on [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.

7.7 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

- For multi-site trials, the Master PICF is supplied by the Sponsor or CPI. Any necessary national or local adaptation are made as required for submission to the reviewing HREC and Peninsula Health Office for Research
- The process of informed consent must be documented in the participant's medical record, in accordance with the Clinical Documentation Policy. The documentation must include the following:
  - Date
  - Identification that the visit was for "Research"
  - Research study title and/or HREC number
  - Visit number /identification information
  - 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.
  - Full consent/re-consent process information (for consent visits)
  - Summary of procedures undertaken at visit
  - Information collected/ decisions made at visit, including adverse events
  - Clinically Relevant observations
  - Name of staff member(s) conducting the visit/collecting the information, signature, date, contact number (phone/pager)
  - Use of witness, if required
  - Use of an interpreter, if needed.
- Once the PICF is signed and dated by both participant and the Investigator, the original PICF is kept in the SMF/ISF or participant folder if SMF/ISF is digital, a copy is provided to the participant, and to Health Information Services (HIS) to upload to the participant's Digitised Medical Record (DMR).
- Where consent has been obtained by telehealth or telephone, once the PICF is signed and dated by both the participant and the Investigator (and any other person present for example an interpreter), the participant is to tick the statement identifying that consent was obtained by telehealth or telephone with the name of the Investigator. Similarly, the Investigator is to tick the statement identifying that consent was obtained by telehealth or telephone with the name of the participant. The participant's PICF is kept in the SMF/ISF, a copy is provided to the participant,

and to Health Information Services (HIS) to upload to the participant's Digitised Medical Record (DMR).

8. Key Aligned or Related Documentation

- Peninsula Care Clinical Governance Framework
- Research Governance Framework
- Research Ethics and Governance Policy
- Responsible Conduct of Research Policy

9. Related Legislation and References

- Alfred Health (2024). Research – Research Participant Informed Consent Process and Documentation Guideline.
- Commonwealth Department of Health. Clinical Trials Project Reference Group (2020). National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia - Based on the International Council for Harmonisation Guideline for Good clinical practice ICH E6 (R2).
- Department of Health. Australian Commission on Safety and Quality in Health Care (2022). The National Clinical Trials Governance Framework and user guide for health service organisations conducting clinical trials.
- National Health and Medical Research Council (2018). Australian Code for the Responsible Conduct of Research.
- National Health and Medical Research Council (2018). Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders.
- National Health and Medical Research Council (2018). Keeping research on track II. A companion document to Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders.
- National Health and Medical Research Council (2023). National Statement on Ethical Conduct in Human Research.
- National Health and Medical Research Council (2016). Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods.
- Northern Health (2024). Research - Standard Operating Procedures for Clinical Trials.
- Therapeutic Goods Administration (2021) Australian Clinical Trial Handbook – Guidance on conducting clinical trials in Australia using 'unapproved' therapeutic goods.

10. Evaluation and Compliance

Feedback systems like incident reports, complaints, performance indicators, and specific audits are used to evaluate compliance.

11. Authors

Director of Research, Peninsula Health
Manager, Office for Research, Peninsula Health
Quality Coordinator, Office for Research, Peninsula Health
Clinical Research Nurse, Academic Unit, Peninsula Health
This Standard Operating Procedure has been adapted from the National Standard Operating Procedures for Clinical Trials, Including Teletrials, in Australia.

The authors wish to acknowledge the Standard Operating Procedures of the Northern Health Research Development Unit and Alfred Health Ethics and Research Governance Office from which parts of this document were based.

12. Keywords

Not applicable.

Document governance	
Supporting Policy:	Research Governance Framework
Approving Body /Committee	Research Operations Committee
Executive Sponsor:	Executive Director Medical Services
Document Owner:	Office for Research
Approved by:	As above
Date Approved by approving committee or body:	19 November 2024