PATIENT INFORMATION STATEMENT

Queensland Government

Project Title **Peripherally inserted central catheter Innovation to reduce Infections & Clots**

HREC Number _____

Investigator _____

Protocol Version Number: V3.0 Version Date: 12/08/2020

Thank you for taking the time to read this **Information Statement and Consent Form**. We would like to ask you to participate in a research project that is explained below.

It is ok to say no

What is an Information Statement?

These pages tell you about the research project. It explains to you clearly and openly all the steps and procedures of the project. The information is to help you decide whether or not you would like the patient for whom you are the substitute decision maker to take part in the research. Please read this Information Statement carefully.

Before you decide if you want the patient to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

Important things to know

- It is your choice whether or not to take part in the research. You do not have to agree if you do not want to.
- If you decide you do not want to take part, it will not affect the treatment and care you receive through *(Insert Hospital Here)*

If you would like to take part in the research project, please sign the consent form provided by the Researcher. By signing the consent form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to taking part in the project

We will give you a copy of this information and consent form to keep.

1. What is the research project about?

Peripherally Inserted Central Catheters (PICCs) are plastic tubes which are inserted through veins in the arm or leg, into the heart, so people can receive medical treatment (e.g., medicines, fluid). Sometimes PICCs stop working due to because of blood clots and infections.

New types of PICCs have been developed, that may help prevent blood clots and infections. Within this trial we are comparing:

- A plain plastic PICC;
- A slippery PICC, that may stop blood clots attaching; and
- An anti-septic PICC, that is coated with a cleaning solution that may prevent infections.

It is important that we test these devices, to establish if these newer PICCs reduce complications, such as blood clots and infection.

The plain plastic and slippery PICCs are currently used in Australian hospitals, including this hospital. The anti-septic PICC is not currently available in Australia, but has been used in the United States for the past 2 years.

2. Who is funding the research project?

This trial has received funding from the Australian Government's National Health and Medical Research Council.

3. Compensation

This document in no way limits your rights at law from any damage that might arise from negligence on the part of investigators.

Why is the patient being asked to take part?

- You have been asked to take part because you require a PICC, so you can receive treatment.

What does the patient need to do in this research project?

- Information about your medical condition, device and blood test results will be recorded from the hospital chart by a research nurse or assistant.

- Research nurses will visit you weekly during their hospital stay and/or during outpatient clinic visits to collect information on the device. Outpatient contact will be made weekly by either phone or SMS (depending on your preference). For participant convenience some device outcome responses may be provided by prepaid mail correspondence.

- Follow up will continue for 8 weeks or until the PICC is removed (whichever occurs first).

- To test how your blood is responding to having the PICC in place a blood test may be collected via the PICC on insertion and once during PICC dwell or PICC removal (no additional needle-sticks).

- On removal, the PICC may be collected and will be tested in the laboratory for signs of infection and blood clots developing Similarly, blood/specimens which are already collected by your doctors and nurses (for QLD Pathology) may be checked.

- Photographs/video-footage may be taken of the device during participation in this study. These photographs/video-tapes are for research purposes and may be used in conference/ seminar presentations to demonstrate how these PICCs work. We will not include images of your face/identifying features, and we will not give people your name.

- We would like to keep the anonymous information we collect for other research into vascular access, blood clots and infection, and that may occur in the future.

Can the patient withdraw from the project?
Yes, you are free to withdraw your consent and to discontinue participation, by telling the research nurse and/ or completing the revocation of consent form. A decision not to participate or to withdraw participation will not affect the treatment you receive.

4. What if I wish to withdraw from the research project?
Your decision whether or not to participate will not prejudice your future relations with *(Insert Hospital Here).* If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time. The decision to withdraw from the study will not affect your routine medical treatment or your relationship with the people treating you.

5. What are the possible benefits for the patient and other people in the future?

It is not expected that the research will result in any personal benefit to the individual. We do expect that it will benefit patients in the future to support clinicians in make good decisions.

6. <u>Alternative Treatment</u>

The treating doctors and nurses will choose the PICC type to be inserted.

7. What are the possible risks, side-effects, discomforts and/or inconveniences?

All PICCs are associated with some risks. Above and beyond this, in rare cases patients may experience reactions to the PICC products the anti-septic solution. This is a commonly used in healthcare – it is found in skin cleanser, hand wash and mouth wash. If you experience any itchiness, redness, swelling, blistering or other reaction, please notify your treating nurse immediately. Regular checks will be conducted as per normal practice to ensure any reactions are identified quickly, and appropriately managed.

8. What will be done to make sure my information is confidential?

- Data collected during this study will be treated confidentially. The research nurse and assistants will store data using a unique research number.
- The information will be safely stored at the hospital and/or within Griffith University.
- Combined patient results of this study will be presented in scientific journals and conferences. However, the patient for who you are substitute decision maker will not be referred to by name and personal identification information will not be revealed in any publication or presentation.
- Research records will be destroyed 15 years after the study.
  Research data may be accessed by auditors, ethics committee or regulatory authorities however patient names and other identifying information will not be used.

9. Who should I contact for more information?

If you would like more information about the project or if you need to speak to a member of the research team in an emergency please contact: **TBA***

Name: <insert name>

Contact telephone: <insert contact phone number>

Email: <insert email>

HREC Information:

The Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC) has approved this study. If you have any concerns and/or complaints about the project, the way it is being conducted or your child's rights as a research participant, and would like to speak to someone independent of the project, please contact the HREC Co-ordinator on:
3069 7002 or email CHQETHICS@health.qld.gov.au

Local Governance Contact Information:

Name: <insert name>

Contact telephone: <insert contact phone number>

Email: <insert email>

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CHILDREN'S HEALTH QUEENSLAND
PARTICIPANT CONSENT FORM

Queensland Government

Title	**Peripherally inserted central catheter Innovation to reduce Infections & Clots**
Protocol Number	V3.0
Coordinating Principal Investigator/ Principal Investigator	*Dr Amanda Ullman (Principal Investigator)*

Declaration by Patient:

I have read the Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the research project without affecting your future health care.

I understand that I will be given a signed copy of this document to keep.

I agree that a blood sample may be taken from the PICC upon insertion and removal and that this will not require any additional needle pricks. These tests will be used to look for early signs of blood clots. The PICC itself may also be collected to assess for blood clots and early signs of infection. ☐

I agree that the device may be photographed by one of the members of the research team. These images may be taken if time permits and suitable equipment is available. This may be used in future conference/seminar presentations for research purposes. I understand that although the image will be shown, names will not be used. ☐

I also agree for the information collected and blood tests/ catheter (collected by the research nurse or the treating clinician) to be kept in an anonymous format for future research studies by the investigators on vascular access, blood clots and infection topics. ☐

I would like a copy of the research results to be sent to me at the end of this study. ☐

If the PICC remains in place for outpatient care, I (circle) consent / do not consent *to weekly phone call or SMS follow-up.*

*Email or postal address for report to be sent:*_____

_____

Name of Participant (please print) _____

Signature of Participant _____ Date _____

Declaration by Study Doctor/Senior Researcher

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____