PARENT/GUARDIAN INFORMATION STATEMENT

Project Title	**Preventing adverse events during paediatric cancer treatment: A multi-site hybrid randomised controlled trial of catheter lock solutions**
HREC Number:	HREC/22/QCHQ/81744
Coordinating Principal Investigator:	Professor Amanda Ullman
Local Principal Investigator:	TBC
Local Investigators:	TBC

Thank you for taking the time to read this **Parent/Guardian Information Statement and Consent Form**. We would like to ask your child 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 your child to take part in the research. Please read this Information Statement carefully.

Before you decide if you want your child 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 your child can take part in the research. You do not have to agree if you do not want to.
- If you decide you do not want your child to take part, it will not affect the treatment and care your child receives through <enter hospital here>

If you would like your child 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 your child 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?

Central venous lines are a plastic or silicone tube, linking a child's bloodstream with treatment. Central lines are used to administer chemotherapy, immunotherapy and supportive therapies across cancer care – most children with cancer need a central line for their treatment. To help keep central lines working, nursing staff 'lock' the catheter with a solution of either normal saline (sterile salty water) or heparin (a medication that is designed to prevent blood clots) whenever the line isn't being used. These 'locks' are a routine intervention that can dwell in the tubing between therapies (between 6 hours up to 8 weeks), providing a fluid-based 'lock' to prevent blood moving back into the tubing.

Unfortunately, despite this care, central lines can be associated with some complications. Bloodstream infections are caused by bacteria and fungi growing inside the line. Blood clots can also form in the veins around the central line tip. Occlusion occurs when the tube becomes blocked due to medications, blood clots, or tip positioning.

Tetrasodium-EDTA (T-EDTA) is now available in Australia. It is proposed as a viable new lock solution, as bacteria and blood clots cannot clump together in the solution. T-EDTA is a new version of the older medication (EDTA), that we use in blood collection tubes. EDTA has been safely used in health care, for example to treat lead poisoning and the treatment of cardiac disease, and T-EDTA has been safely used overseas to lock central lines. KiteLock™ is approved for use in both Australia and New Zealand. EDTA is commonly found in everyday items such as shampoo, mouthwash and some foods.

Children that participate in the study will be randomly allocated to either:

- Normal Saline,
- Heparin or
- T-EDTA.

Importantly, families and health care providers don't get to choose which one your child will receive.

The allocated fluid will be used to 'lock' your child's central line whenever it isn't being used for more then 6 hours. You will know which of the 'locks' your child is receiving.

A research nurse will visit in person, or contact you (via phone or text if not in hospital) twice a week to check on your child's wellbeing, to see how the central line is performing, to assess for infection or occlusion and to see what medications have been administered. This will continue for a period of 3 months or until the central line is removed (whichever occurs first). You will not be required to attend the hospital for any additional tests outside your routine cares.

Your child's study involvement will be temporarily or permanently stopped if your child is transferred or admitted to a hospital that is not part of the trial. Your child may continue participating in the trial once they return to a participating hospital. Whilst in a non-trial healthcare facility they will receive the standard care locking solution at that site.

<Remove/edit this paragraph to make site specific> For families In Queensland/ Victoria, there may be instances where you receive care during the project at more than one participating hospital (Queensland Children's Hospital, Sunshine Coast University Hospital or Gold Coast University Hospital)/ (Monash Children's Hospital and the Royal Children's Hospital). In this event, the research nurses at each site will communicate with each other and share the data that has been collected and access their electronic medical record so that your child can remain on the trial and continue receive the intervention.

We would like to make contact with your family in the future (1 and 5 years) to see how your child's health and quality of life is long term. You can refuse this future follow up, while still being part of the study.

2. Who is funding the research project?

This project is funded by Cancer Council Queensland.

3. Compensation

- You will not be paid to participate in this project. All care will be provided at routine appointments by your normal healthcare providers.
- Indemnity insurance is provided by the University of Queensland for all participants in the study in the unlikely event of injury or harm. You are free to review these documents.

4. Will I have to pay for anything?

There will be no cost to you to participate in the research. There are no costs associated with receiving clinical services or intervention through the public health system, all study interventions will be provided free of charge.

5. Who can take part in this study?

Your child is being asked to take part in this study because they are:

- ✓ Under the age of 18
- ✓ Have an oncological or malignant haematological condition
- ✓ Have a central line

6. What if I wish to withdraw from the research project?

Your decision whether or not for your child to participate will not prejudice their future relations with the children's hospital. If you decide for your child to participate, you are free to withdraw consent and to discontinue participation at any time. The decision to withdraw from the study will not affect their routine medical treatment or their relationship with the people treating them. If you withdraw from the study, we will ask you if we can use the data collected to that point. If we cannot/ are unable to gain your consent to use the information, it will be excluded from our results.

7. What are the possible benefits for my child and other people in the future?

You or your child may not benefit directly from participating in this study. Conclusions drawn from this study may help guide future treatment decisions for your child and other children with a central line. If you would like, we can share the results of the study with you when it is done.

8. Alternative Clinical Pathway / Options

If you decide not to participate, the solution used to lock your child's central line will be at the discretion of your treating team.

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

Unfortunately, despite the care provided for your child, central line associated complications may still arise. There is also a small risk of adverse reaction or allergy to Heparin or T-EDTA. Heparin can cause bleeding if other risk factors for bleeding are present, such as renal impairment or interaction with other drugs. T-EDTA can cause an unpleasant taste, tingling lips and pain on port needle removal. There have only been a handful of these events reported worldwide. These will be managed by your treating clinicians in collaboration with the research team.

10. What will be done to make sure my child's information is confidential?

We treat your child's medical information in strict confidence. Any data that is collected for this project will be deidentified using a study number instead of their name or any other personal information.
To ensure that we comply with ethical guidelines, the information we collect may be accessed by the ethics committee, auditors or regulatory authorities. The results of this study may be published in a health journal however no identifying data will be used. Hard-copy documents (for example consent forms) will be stored onsite in a locked area. Electronic data (for example the medications your child receives, any complications that occur) will be de-identified on a password protected electronic database available only to research staff. Data will be held for 15 years after completion/ publication/ discontinuation of the study AND the child turns 18. Information collected in this trial may be stored and used by the researchers for future research projects. You can choose to allow or refuse the future use of any information.

11. 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 local research team please contact:

Name: **Insert local details here

Contact telephone:

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
UQ Ethics Information: This study adheres to the Guidelines of the ethical review process of The University of Queensland and the National Statement on Ethical Conduct in Human Research. Whilst you are free to discuss your participation in this study with the researcher, if you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Coordinator on +617 3365 3924 / +617 3443 1656 or email humanethics@research.uq.edu.au
Local Governance Contact Information: Local RGO information to be added at individual sites

Preventing adverse events during paediatric cancer treatment: A multi-site hybrid randomised controlled trial of catheter lock solutions.

Coordinating Principal Investigator *Professor Amanda Ullman*
Local Principal Investigator *TBC*

Declaration by Parent/Guardian

I have read the Parent/Guardian 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 my child participating in this research project as described and understand that I am free to withdraw them at any time during the research project without affecting their future health care.
I understand that the staff from other participating sites will access the participants trial information and hospital record if they receive care in more then one participating hospital (Queensland and Victoria only).
I understand that I will be given a signed copy of this document to keep.

- I consent to being contacted in the future by the study team for additional information **yes/ no**
- I would like a copy of the results at the end of the study **yes/ no**

Email address for results and/or follow up:

Name of Child (please print) _____

Name of Parent/Guardian (please print) _____

Signature of Parent/Guardian _____ Date _____

Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9*) a witness* to informed consent is required*

Name of Witness* to
Parent/Guardian's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

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 parent/guardian has understood that explanation.

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

Signature _____ Date _____