Informed Consent Form for Parents/Guardians of Subjects

Peripherally inserted central venous catheter insertion site and complication rates in neonates: a randomized controlled trial **Principle Investigator: Dr. Harish Amin**

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CONSENT FORM

TITLE: Peripherally inserted central venous catheter insertion site and complication rates in neonates: a randomized controlled trial

SPONSOR: Section of Neonatology, Department of Pediatrics, University of Calgary

INVESTIGATORS: Dr. Amuchou Soraisham, Dr. Sumesh Thomas, Kim Pearson, Norma Oliver, Dr. Harish Amin.

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your child's participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form for your records.

BACKGROUND

Peripherally inserted central venous catheters (PICC lines) are a type of intravenous access that is used to provide sick newborns nutrition and medications through their veins. PICC lines are inserted into the big veins that are present in babies' arms or legs. Sometimes problems can happen from the PICC line. Some examples of common problems are bleeding, line infiltration (fluid leakage around the line), blood clots, or infection. More serious problems could be fluid in or around the heart, lungs or chest wall.

Currently the PICC line is inserted in the place the doctor or nurse prefers. However, some people think that putting the PICC line in the arm or leg increases the chance of a problem happening. Other people think that the location doesn't matter. We would like to test whether there are any differences in the PICC insertion success and the number of problems between PICC lines inserted in the arms versus legs.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of the study is to compare the success rate for PICC insertion and the complication rate resulting in early removal between PICCs inserted in the arms and those inserted in the legs.

WHAT WOULD MY CHILD HAVE TO DO?

The decision to insert a PICC is made by your baby's treating team and the procedure will be done regardless of whether your baby is in the study or not.
If you agree to allow your baby to participate in this study, your baby will be randomly put into one of two groups, receiving the PICC in either their arm or leg.

- PICCs will be inserted under sterile conditions by certified health care providers as they normally would.
- A maximum of two attempts will be allowed in the designated arm or leg, after which any further attempts will be considered in the other location if the inserter is confident of success.
- After the PICC line is inserted, the correct position will be confirmed by x-ray, and repeat x-rays will be taken if the PICC needs to be adjusted. This would happen if your baby got a PICC line, whether you decide to be in the study or not.
- Normally PICC lines will be removed when your baby no longer needs one, or earlier if they develop complications. If the nurse or doctor is worried about a complication such as a blood clot, the PICC line will be removed and an ultrasound will be done to examine your baby for the complication.

During the study period your baby will receive the same care that s/he would otherwise receive had you chosen not to participate in this study. Your baby's information will be coded and kept confidential.

WHAT ARE THE RISKS?

The potential complications associated with PICC insertions in babies include bleeding, infiltration (fluid leakage), blockage of the line, blood clots, infection, irregular heart beat and/or very rarely tearing could occur in the heart allowing fluid into the heart or around it and lungs

We do not expect any other complications to occur, but there is a very rare chance another complication could occur that we did not expect.

ARE THERE ANY BENEFITS FOR MY CHILD?

If you agree for your child to participate in this study there may or may not be a direct medical benefit to them. The information we get from this study may help us to provide better clinical care in the future for patients who need a PICC.

DOES MY CHILD HAVE TO PARTICIPATE?

Participation in this study is entirely voluntary and you may withdraw your baby from the study at any time without jeopardizing his or her medical care. Also, the researchers can withdraw your baby from the study at any time that the researcher feels it is in the child's best interest.
Refusal or discontinuation of your baby's participation in this study will involve no penalty or any alteration of the level of medical care your baby receives. On the other hand, your baby's participation in the study will not entitle him/her to receive any extra medical care than usual. You will be provided with any new information that could affect your willingness to let your baby participate in this study.

WILL WE BE PAID FOR PARTICIPATING, OR DO WE HAVE TO PAY FOR ANYTHING?

You/your baby will not be paid for participating in this study. Also, you do not have to pay for anything related to this study.

WILL MY CHILD'S RECORDS BE KEPT PRIVATE?

Several steps have been taken to ensure the protection of your baby's privacy. Collected information will be stored on a password protected computer in a locked office, with access limited to the study team. If the results of the study are published, neither your baby's name nor any information that discloses his/her identity will be released. Your child's identity will not be disclosed to any person, except for the purposes described above and in the event of a medical emergency or if required by law.

Authorized representatives from the University of Calgary and the Conjoint Health Research Ethics Board may look at your child's identifiable medical/clinical study records held at Foothills Medical Centre and Alberta Children's Hospital for quality assurance purposes. Data collected during your child's time in this research study will be de-identified and will be held in a database for future use by other researchers. Any future use of this research data is required to undergo review by a Research Ethics Board.

IF MY CHILD SUFFERS A RESEARCH-RELATED INJURY, WILL WE BE COMPENSATED?

In the event that your child suffers injury as a result of participating in this research, no compensation will be provided to you by the Department of Pediatrics, the University of Calgary, Alberta Health Services or the Researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your child's participation in the research project and agree to participation. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw your child from the study at any time without jeopardizing their health care. If you have further questions concerning matters related to this research, please contact:

Dr. Amuchou Soraisham (403) 944-1087
or
Dr. Sumesh Thomas (403) 944-1939
or
Dr. Harish Amin (403) 955-7513

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair of the Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

Parent/Guardian's Name	Signature and Date
Child's Name	Signature and Date
Investigator/Delegate's Name	Signature and Date
Witness' Name	Signature and Date

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.
A signed copy of this consent form has been given to you to keep for your records and reference.