الجامعة الإسلامية العالمية ماليزيا
INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA
يونيفرسيتي إسلام انتارابغسا ملسيا
Garden of Knowledge and Virtue

[Informed Consent Form for _____]

This informed consent form is to whom we are inviting to participate in research titled "Mathematical Formula versus Direct Measurement for Insertion of Peripherally Inserted Central Catheter (PICC) in Neonates".

Principal investigator:
1) **Dr Muhd Alwi bin Muhd Helmi (MMC 63272)**
2) **Dr Syamila Huda binti Jusili (MMC 63107)**

Co-researchers:
1) **Prof Hans Van Rostenberghe (MMC 31042)**
2) **Syed Abdul Khaliq Bin Syed Abd (MMC 45397)**
3) **Adam Mat Ali (MMC 57814)**
4) **Assoc Prof Noraida Ramli (MMC 32514)**
5) **Dr Nor Rosidah Ibrahim (MMC 35070)**
6) **Prof Ariffin Nasir (MMC 31850)**

International Islamic University Malaya (IIUM)

Mathematical Formula versus Direct Measurement for Insertion of Peripherally Inserted Central Catheter (PICC) in Neonates

This Informed Consent Form has two parts:
- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

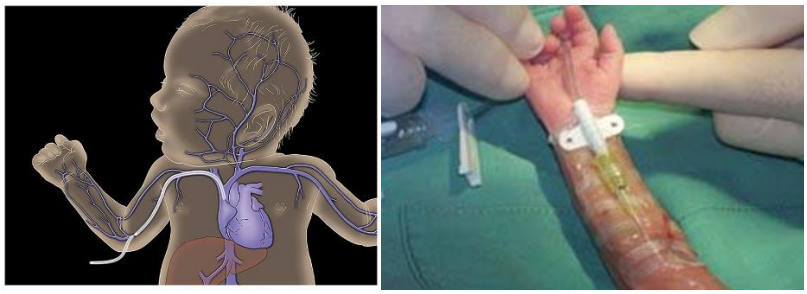
Introduction
I am Dr. Muhd Alwi Muhd Helmi working for the Islamic International University Malaysia (IIUM). We are doing research on Mathematical Formula versus Direct Measurement for Insertion of Peripherally Inserted Central Catheter (PICC) in Neonates. I am going to give you information and invite you and your child to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.

Purpose of the research
PICC in a long catheter or tube inserted into the blood vessel on the hand and leg of your baby where the tip of the catheter end near the entrance into your baby's heart (figure 1). The PICC is important and necessary for the care of your child in NICU. It is used to deliver nutrient and some medications that cannot be administered through a regular short catheter or branula (figure 2). Compared to branula, PICC has multiple advantages. For instance, a correctly placed PICC can last longer up to 4 weeks without the

need for replacement, less risk of skin injury due to medication sipped out of the catheter (extravasation) and can be used to administer irritating and more concentrated medication. However, PICC can also cause few complications. For example, infection, formation of blood clots and injury to the internal organ such as lung and heart. Most of these complications arise from a incorrectly placed PICC. Therefore, it is important to make sure a PICC is placed correctly.

There are 2 ways to determine the length of PICC to be inserted in a baby. These methods are by mathematical formula using the baby's body weight and length (**mathematical formula**) OR by directly measuring the distance between the insertion site and the chest bone or the umbilicus (**direct measurement)**. There is currently no research done to determine which of the 2 methods is the best. We are conducting this research to compare the effectiveness of the 2 methods of insertion.



Rajah 1: PICC yang dimasukkan dari hujung tangan dan penghujungnya berakhir berhampiran dengan jantung.[1,2]

Rajah 2: tiub intravena pendek atau branula yang dimasukkan pada belakang tangan bayi[3]

Type of Research Intervention
Babies who fulfilled all the criteria will be assigned randomly into either two groups. Group A will be the group who will have PICC inserted use mathematical formula. Group B will have PICC inserted using direct measurement.

Participant Selection
Participants of the study are neonates admitted in NICU that require PICC within the study the period.

Voluntary Participation
Your child's participation in this research is on voluntary basis. You have the right to refuse or withdraw from the study at any time without any penalty or medical disadvantages. Your child's participation can also be dismissed and terminated by the doctors involved in this research without your consent.

If you decide to withdraw from the study, the doctor involved or a research staff may discuss with you regarding any medical issues pertaining to your baby's or your withdrawal of participation.

Procedures
All PICC will be inserted by well-trained medical officer working in NICUs with at least one year experiences in PICC insertion. The site of insertion will depend on the availability of suitable blood vessel in the area and will be decided by the doctor performing the procedure.

The information recorded is confidential, your child's name is not being included on the forms, only a number will identify your child, and no one else except Dr Muhd Alwi Muhd Helmi will have access to your child information.

Duration
The study will be conducted in Neonatal Intensive Care Unit (NICU) at Hospital USM, Kubang Kerian Kelantan, Hospital Alor Setar, and SASMEC. The study is planned to be conducted in the period between 1st November 2020 to 1st March 2021.

Risks
No additional risks to your child are expected from participation to this study. Besides the different method of PICC insertion, no other than the routine care is involved in the study procedures. The babies are under the care of the doctors involved in the study.

Benefits
Study procedures will be provided at no cost to you or your child. You may receive information about your child's health from any physical examination/ analysis done in this study. We hope that the outcome and information regarding this research will beneficial to future patients.

Reimbursements
You will not receive any compensation for your child's participation in this study.

Confidentiality
Your child's medical information will be kept confidential by the study doctor and staff and will not be made publicly available unless disclosure is required by law. Data obtained from this study that does not identify you or your child will be published for knowledge purposes. All the data will be analyze collectively without revealing any individual data.

Your child's original medical records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying clinical trial procedures and/or data. Your child's medical information may be held and processed on a computer.

By signing this consent form, you authorize the record review, information storage and data transfer described above.

Sharing the Results
Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. If you wish, the knowledge that we get from this research will be shared with you before it is made widely available to the public. Each participant will receive a summary of the results upon request by emailing to us at muhdalwi@iium.edu.my.

Right to Refuse or Withdraw
Your child does not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Who to Contact
If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following:

Dr Muhd Alwi bin Muhd Helmi (MMC 63272)
Department of Paediatrics,
Kulliyyah of Medicine,
International Islamic University Malaysia,
Kuantan, Pahang.
011-11333010
muhdalwi@iium.edu.my

This proposal has been reviewed and approved by IIUM Research Ethics Committee, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IIUM Research Ethics Committee:

IIUM Research Ethics Committee
Research Management Centre (Kuantan),
Level 1, Admin Building (OCD),
International Islamic University Malaysia,
Jalan Sultan Haji Ahmad Shah,
25200 Kuantan, Pahang.
(+603) 6421 6421

Reference

1. McCay AS, Elliott EC, Walden M. PICC Placement in the Neonate. New England Journal of Medicine. 2014;370(11):e17.
2. Osborn D. Peripherally Inserted Central Catheter, RPA Newborn Care Guidelines

Royal Prince Alfred Hospital 2009. Available from: https://www.slhd.nsw.gov.au/rpa/neonatal/html/docs/cvl.pdf.
3. Sangam SL. Quality improvement measures for early detection of severe intravenous infiltration in infants. BMJ Open Quality. 2019;8(2):e000407.

Part II: Certificate of Consent

My child have been invited to participate in research titled "Mathematical Formula versus Direct Measurement for Insertion of Peripherally Inserted Central Catheter (PICC) in Neonates".

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study

Name of Participant _____

IC number _____

Signature of Researcher/ person taking the consent _____ **Date** _____

If illiterate [1]

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Thumb print of participant

Name of witness _____

IC number _____

Signature of witness _____ **Date** _____

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. _____
2. _____
3. _____

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of Researcher/ person taking the consent _____

IC number _____

Signature of Researcher/ person taking the consent _____ **Date** _____

[1] A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.