

JEPeM-USM

JAWATANKUASA ETIKA PENYELIDIKAN (MANUSIA) – JEPeM USM

UNIVERSITI SAINS MALAYSIA

 PARTICIPANT INFORMATION SHEET AND CONSENT FORM

 (RESEARCH PROJECT)

***The Participant Infomation and Consent Form*** *used in the Research Project must be according to these information formats. However, statements and phrases used only as a guide.*

* *Topic of the Research*
* *Introduction*
* *Purpose of the Study*
* *Participants Criteria*
* *Study Procedures*
* *Risks*
* *Reporting Health Experiences*
* *Participation in the Study*
* *Possible Benefits*
* *Questions*
* *Confidentiality*
* *Signatures*

 **ATTACHMENT A**

RESEARCH INFORMATION

*Research Title*  : Randomized Controlled Trial (RCT) comparing high versus standard dose

 of caffeine for apnoea in prematurity

*Name of Researcher*  : Dr Anis Munirah Mohd Kori (MMC No: 61637)

*Name of Co-Researcher* : Professor Dr. HansVan Rostenberghe(MMC No: 31842)

 Associate Professor Dr. Ariffin Nasir MMC 31850

 Dr Najib Majdi bin Yaacob MMC 41754

 Associate Professor Dr. Noraida Ramli MMC 32514

 Dr Rosidah Ibrahim MMC 35070

#### INTRODUCTION

**You and your baby is offered to voluntarily participate in a research in NICU, Hospital Universiti Sains Malaysia which involves premature babies 26 to 32 weeks gestational age who are in need of invasive or non invasive oxygen therapy and do not have any congenital defects**. They will be randomly divided into two groups of *‘high dose caffeine’ versus ‘standard dose caffeine’* where these caffeine doses are used to determine the optimum dose of caffeine for apnoea in prematurity without causing adverse effects. **For your information, caffeine is a standard medication that has been used worldwide to all premature baby less than 34 weeks to help them breathing**. Before you agree to participate in this research, it is important that you read and understand the contents of this form. If you agree to join this research, you will receive a copy of the form for your records.

#### PURPOSE OF THE STUDY

The purpose of this study is to compare the efficacy and safety of high versus standard dose of caffeine for apnoea in prematurity

There is a possibility that the information gathered in this study will be analysed by researchers in the future to validate the same research for medical or scientific purposes besides what is currently given.

#### PARTICIPANTS CRITERIA

The doctor responsible for this study or one of the research staff have discussed with you about the eligibility to participate in this study. It is very important that you are straightforward with the doctor or staff on your baby’s medical history. Your baby does not qualify if you do not fulfil all the eligibility requirements.

There are a few criteria to be eligible to join this study which are:

* Premature baby 26 to 32 week’s gestational age who is admitted in NICU, HUSM.
* Requiring invasive and non invasive ventilatory support

Your baby will not be eligible for this study if –

* The baby has *hydrops fetalis* or congenital defect
* The baby has serious neurological problem
* The baby has bowel problem

STUDY PROCEDURES

If you agree to participate in this study, if your premature baby 26 to 32 weeks gestational age that needs invasive or non invasive ventilation, they will be divided randomly into two groups of ‘High dose caffeine’ versus ‘Standard dose caffeine’ where these doses will be used to determine the optimum dose of caffeine for apnoea in prematurity. The baby will be monitored closely in intensive care unit throughout the caffeine usage. The parameters that will be monitored are oxygen in the blood, heart rate, weight. All the parameters monitored are standard monitoring to all premature baby in intensive care unit.

RISKS

If your baby participates in this study, your baby will face a risk of result in caffeine usage such as increased heart rate and any other side effects like bowel problem, feeding intolerance and diuresis effect. Previous studies have found that the risk of babies getting all the side effects is small. The side effects are reversible.The most common side effect is increased in heart rate and reversible when caffeine is witheld. If it is persistent or your baby has developed abnormal pattern of heart rate, caffeine will be withheld and your baby will be withdrew from the study.

If any important information is discovered during the period of this research which may change your decision to continue in this study, has to be informed as soon as possible

REPORTING HEALTH EXPERIENCES.

If your baby experience any injuries, harmful effects or any unusual health condition during this research, be sure to inform Dr. Anis Munirah Mohd Kori [Registration no. Malaysian Medical Council: MMC 61637] at <013 2076730> as soon as possible. You can make the call at any time to report such incidents. We will ensure NICU staff to always monitor your baby during the period of the research in NICU to avoid any unwanted complications.

#### PARTICIPATION IN THE STUDY

Participation is voluntary for this study. You have the right to withdraw from participating in this study or terminate your participation any time without any penalty or loss of benefits which you should receive.

Your baby's participation can also be terminated by the doctor involved without your consent. If your baby stops being involved in this study, the doctor or staff involved will discuss the medical issues related and the termination of your baby's participation.

#### POSSIBLE BENEFITS [Benefit to Individual, Community, University]

The procedure of this research will be given to you without any costs. You may receive information on your baby’s health during the period this research is conducted.

The result of this research is hoped to give benefits to other patients in the future. You and your baby will not receive any compensation for joining this research. However, any needs related to the research will be provided.

#### QUESTIONS

If you have any concerns or inquiries on the procedures of this study or your rights, please contact;

Dr Anis Munirah Mohd Kori No MPM 61637

Department of Paediatrics

Learning Institute: USM Health Campus

09 767 2354/3964 / 013-2076730

If you have any questions regarding the Ethical Approval or any issue / problem related to this study, please contact;

Mr. Mohd Bazlan Hafidz Mukrim

Secretary of Human Research Ethics Committee USM

Division of Research & Innovation (R&I)

USM Health Campus

Tel. No. : 09-767 2354 / 09-767 2362

Email : bazlan@usm.my or jepem@usm.my

#### CONFIDENTIALITY

Your baby’s medical information will be kept secret by the doctor and research staff. It will not be disclosed to public unless ordered by law.

Data obtained from this research does not identify individuals and may be published for the purpose of releasing new knowledge.

Your baby’s original medical records may be viewed by the researchers, Board of Ethics for this research and regulatory authorities for the purpose of verifying the procedures and/or data of the clinical research. The subjects’ medical records will be saved and processed in the computers.

By signing this consent form, you are allowing scrutiny of records, saving and transfer of data as elaborated above.

#### SIGNATURES

To take part in this study, you or your verified representative must sign and write the date on the signature page. (Refer to sample Patient Consent Form on Appendix S or Appendix P).

 APPENDIX S

Patient / Subject Consent Form

(Signature Page)

*Research Title:*  Randomized Controlled Trial (RCT) comparing betwen high versus standard

dose caffeine for apnoea in prematurity

*Researcher’s Name:* Dr Anis Munirah Mohd Kori

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

* I have read all of the information in this Patient Information and Consent Form including any information regarding the risk in this study and I have had time to think about it.
* All of my questions have been answered to my satisfaction.
* I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
* I may freely choose to stop being a part of this study at anytime.
* I have received a copy of this Participant Information and Consent Form to keep for myself.

Name of Guardian Short name and Patient ID

Patient’s IC number (New) IC number (old)

**Patient’s Signature** or verified representative **Date** (dd/MM/yy)

(Time if needed)

Name & Signature of Individual in charge Date (dd/MM/yy)

Of Discussion of Consent (Printed or typed)

Name of witness and signature Date (dd/MM/yy)

Note: i) All subjects/patients taking part in this research project are not protected by insurance.

 APPENDIX P

Consent Form to Publish Materials related to Patient/Subject

 (Page of Signature)

*Research Title:* Randomized Controlled Trial (RCT) comparing between high versus standard dose caffeine for apnoea in prematurity

*Researcher’s Name:* Dr Anis Munirah Mohd Kori

To participate in this research, you or your verified representative to sign this page.

By signing this page, I hereby understand the following:

* The materials will be published without including my baby’s name and every attempt will be made to ensure the anonymity of my baby’s name is not guaranteed. There is a possibility that anyone taking care of my baby in the hospital is able identify me.
* Materials will be published in weekly/monthly/ quarterly/biennial and will be spread wide globally. Most of these publications will reach medical doctors and also non-doctors including scientists and journal readers.
* The materials will also be attached on journal websites all over the world. Some of these websites are freely visited by everyone.
* The materials will also be used as local publications and delivered to many doctors and scientists around the world.
* The materials will also be used as book publications by journal publishers.
* The materials will not be used as commercials or as packaging material.

I also give my consent that the materials can be used as other publishings as requested by publishers with these criteria:

* The materials will not be used for commercialization packaging materials.
* The materials will not be used out of context – for example: Photo will not be used to illustrate an article not related to the subject of the photo.

Name of patient (Printed or Typed) Short name or Patient ID

Patient’s IC number Patient’s signature Date (dd/MM/yy)

Name & Signature of Individual in Charge Date (dd/MM/yy)

Of Discussion on Consent (Printed or typed)

Note: i) All subjects/patients taking part in this research project are not protected by insurance.