Participant Information Sheet

Study Title	Effect of elective blood transfusion on cerebral, hepatic and muscle regional oxygenation and cardiovascular stability in neonates (NIMO-AI)
Locality	Wellington Regional Hospital Neonatal Intensive Care Unit
Coordinating Investigator	Dr. Maria Saito-Benz
Contact Number	021570609
Ethics Reference	16/CEN/18

Introduction:
As the person responsible for your baby, you are invited to consider your baby's participation in this study. We are approaching you because your baby is currently an inpatient in the neonatal intensive care unit in Wellington Hospital, your baby has a condition called anaemia, and your doctors think that your baby may benefit from a non-urgent blood transfusion.

Thank you for taking time to read this information sheet. It contains detailed information about the study, and its purpose is to explain to you as openly and clearly as possible, the background and all the steps involved in the study. Please read all pages carefully, and feel free to ask questions about any of the information. You may wish to talk to your friends, family, whānau, or healthcare providers about the study.

Participation in this study is voluntary. Whether you wish to take part or not is entirely up to you, and you do not need to give a reason for your decision. You and your baby's medical care and relationship with the hospital will not be affected in any way by your decision.

If you agree for your baby to take part in this study, you will be asked to sign a consent form. By signing it you are telling us that you:

- Understand what you have read
- Consent your baby to take part in the study
- Consent to your baby participating in the study steps that are described
- Consent to the use of your baby's personal and health information as described

Purpose of the study:
Newborn babies in neonatal intensive care units are often treated with a non-urgent blood transfusion (often referred to as 'top-up' transfusion) for a medical condition called anaemia. Your baby has anaemia if your baby's haemoglobin count is lower than it should be. Haemoglobin is a type of protein within the red blood cells, and it plays an important role in carrying oxygen around the body so that different organs in the body have access to adequate oxygen.

Newborn babies are prone to developing anaemia for a number of reasons. If your baby was born pre-term, your baby's bone marrow may be more immature compared to that of a term baby. As a result your baby's bone marrow may not be able to keep up with production of red blood cells to meet the body's requirement. Whether your baby was born term or pre-term, if your baby's medical condition requires close monitoring in the way of frequent blood testing, it is also possible that your baby's bone marrow may not be able to keep up with the demand placed on it.

Anaemia can affect your baby's growth, breathing, and function of many organs including the heart and the brain. This is why your doctors may decide to treat your baby's anaemia with blood transfusion. Blood transfusion is the safest and most accepted way of treating anaemia in newborn babies worldwide. However, it is not without any risk. Although blood is carefully selected and thoroughly screened for in New Zealand, there is a small possibility that it may contain a rare infection or infection that has not been discovered yet. This is why doctors carefully weigh up the risks and benefits of blood transfusion and discuss these with you before deciding to give it to your baby.

At the moment there is no consensus worldwide on when to treat newborn babies with a blood transfusion. This is because it is not fully understood the severity of anaemia that would cause medium to long-term harm to them if left untreated. This is why different neonatal intensive care units at the moment adopt different policies on the timing of non-urgent blood transfusion.

The aim of this study is to try and understand how blood transfusion affects the oxygen level in different organs, and function of the heart and lungs. We hope that this study would help us better understand the mechanism by which blood transfusion benefits newborn babies, and would guide us to develop a more cohesive blood transfusion guideline in the future.

This study is for observation only. What this means is that only your doctors, after a discussion with you, will decide whether your baby will receive a blood transfusion. Whether your baby takes part or not in this study will not affect this decision-making.

Who we are looking for?
We are looking for babies on the neonatal intensive care unit in Wellington Hospital, who are being treated for anaemia with a non-urgent blood transfusion.

Why we might not consider including your baby in the study:
If your baby is considered critically unwell, is on a mechanical ventilator, or has other reasons to need an urgent blood transfusion then we will not include your baby in the study. Similarly, if your baby is being treated for an infection with broad-spectrum antibiotics, has a large ductus arteriosus affecting the function of the heart, or has excess fluid in the skin then we may not consider including your baby in the study.

What does the study involve?
If you choose to participate in this study, your baby will have physiological measurements taken before, during and after a blood transfusion using following equipment.

Oxygen levels in the brain, liver and muscle
Near-infrared spectroscopy (NIRS) is a non-invasive device that allows us to monitor the oxygen level in different organs. A small NIRS probe containing LED light emitters and light receivers will be placed on 3 locations; forehead, abdomen and calf (unless there is a medical reason to use thigh or upper arm). Location of liver in the abdomen will be determined using a portable ultrasound machine. The probes are soft and non-adherent, and will be kept in place using a soft elastic bandage or a Tegaderm dressing.

Peripheral saturation and pulse rate
Pulse oximeter is a non-invasive device frequently used in clinical practice to measure the peripheral oxygen saturation and pulse rate. A pulse oximeter probe also contains a LED light emitter and receiver, and one probe will be placed on a hand or a foot. If your baby already has a pulse oximeter on, we will need to place another probe for the purpose of the study.

Blood pressure
Human NIBP^{TM} blood pressure cuffs allow continuous monitoring of blood pressure non-invasively. Two soft blood pressure cuffs are placed on wrists, and each of them comes on alternately every 2 minutes to measure blood pressure.

Study timeline:

Time	Physiological measurements (duration)
Before transfusion*	• Peripheral saturation, pulse rate and blood pressure (12hrs) • Oxygen levels in the brain, liver and muscle (3hrs)
During transfusion	• Peripheral saturation, pulse rate and blood pressure (§) • Oxygen levels in the brain, liver and muscle (§)
Immediately after transfusion	• Peripheral saturation, pulse rate and blood pressure (12hrs) • Oxygen levels in the brain, liver and muscle (3hrs)
24hrs after transfusion*	• Peripheral saturation, pulse rate and blood pressure (12hrs) • Oxygen levels in the brain, liver and muscle (3hrs)
5 days after transfusion*	• Peripheral saturation, pulse rate and blood pressure (12hrs) • Oxygen levels in the brain, liver and muscle (3hrs)

** Your baby will be monitored overnight to minimise interference with daily routines such as cuddles and cares.*
§ Blood transfusion can be started as soon as the overnight measurements are completed provided that the clinical team is ready. It is usually given over 3 hours; however, your doctors will decide on the duration of blood transfusion.

Position of your baby during data recording
Ideally we would like your baby to be lying in the cot facing up. However, if there is a medical reason for your baby to be lying in other positions then we will simply record your baby's position instead.

Confidentiality of health information:
If you choose to participate in the study, following information on your baby will be collected as part of the study:

- Gestational and postnatal age
- Sex
- Ethnicity
- Birth weight and weight at the time of transfusion
- Blood results
- Breathing support (if any)
- Whether your baby is on any medication to support breathing (e.g. caffeine)
- Position of your baby
- Whether your baby spends more time asleep or awake during data recording

All information gathered as part of the study will be treated with confidence and no information that could identify you or your baby will be released to any person not associated directly with the study. All study records will be kept securely and electronically in a databank. All study records will be stored for a minimum of 10 years after the study is completed. This is a standard requirement by the New Zealand regulations.

The results of the study may eventually be published in medical journals or presented at professional meetings, but you and your baby will not be identified in any way.

Benefits of the study:
Because this study is for observation only, there is no direct benefit to your baby by taking part in this study. However, your participation may lead to an improvement in future treatment for newborn babies with anaemia.

Risks of the study:
All devices used to monitor babies in this study are non-invasive. This means that there will be no pain inflicted on your baby if you choose to participate. There is no known increased risk to the health of your baby by using any of the devices. Pulse oximeter is routine part of clinical care in the neonatal intensive care unit and it is used safely and widely in both term and preterm babies. Near-infrared spectroscopy (NIRS) and non-invasive blood pressure cuffs have been used safely in both term and preterm babies in research practice. NIRS is increasingly used in clinical practice in the neonatal intensive care units around the world.

It is possible that while measurements are being recorded you may find it difficult to take your baby out of a cot/incubator for a cuddle because of the probes being attached to your baby. Nursing staff will help you as much as possible so that you and your baby can continue having normal routines. We will also do most of our measurements overnight to minimise interference with daily routines.

Study results:
Once the study is completed we are more than happy to send you a summary of the study findings. Please indicate your preference in the consent form whether you wish to receive the summary.

Voluntary study participation and withdrawal:
Participation in this study is voluntary, and it is entirely your decision to participate or not in this study. If you decide to participate, you are free to withdraw your baby from the study at any stage, without explanation of why you have chosen to do so and without prejudice to you and your baby's current and future treatment.

Compensation:
In the unlikely event of a physical injury as the result of your baby's participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the Accident Compensation Act 2001. If you have any questions about ACC, please contact your nearest ACC office.

Study approval:
This study has been reviewed and approved by HDEC. If you wish to discuss the study with someone not directly involved, in particular in relation to policies, your rights as a participant, or should you wish to make a confidential complaint, you should contact Ethics Committee on 0800 4 ETHICS (0800 438 442) or hdecs@moh.govt.nz

Further information:
If you would like any further information about this study, please contact:

Dr. Maria Saito-Benz (Coordinating Investigator)
Tel: 021570609

Other contacts (support groups not involved in the study):
Independent Health and Disability Advocate:
Free Phone: 0800 555 050
Free Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

Māori cultural support contact:
Whanau Care is able to provide support to patients and whanau during their time in hospital and while taking part in this study. Whanau Care service at Wellington Hospital is located in atrium (level 2).
Phone: 04 806 0948
Email: wcs@ccdhb.org.nz