Participant Information Sheet

Study Title	Near Infrared spectroscopy for Monitoring brain Oxygenation in Premature infants (NIMO-Prem)
Locality	Wellington Regional Hospital Neonatal Intensive Care Unit
Coordinating Investigator	Dr. Maria Saito-Benz
Contact Number	021570609
Ethics Reference	16/NTA/209

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 may be born preterm (less than 30 weeks gestation) in Wellington Hospital.

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:
Thanks to advancement in modern medicine babies who are born extremely premature (<30 weeks gestation) and with very low birth weight (<1000g) today have a good chance of survival with good long-term outcomes. However, a proportion of these vulnerable babies sadly suffer from serious long-term neurological complications, including cerebral palsy, visual and hearing impairment.

For healthy brain development ensuring adequate supply of blood and oxygen to the brain is essential. In this study, we hope to understand the optimal levels of oxygen

and blood supply to the brain of premature babies, and what factors may affect or help stabilise them.

This study is part of a PhD project at the University of Otago, Wellington, and is carried out in collaboration with the Texas Children's Hospital, US.

Who we are looking for?
We are looking for babies who are born less than 30 weeks gestation and with birth weight less than 1000g.

Why we might not consider including your baby in the study:
If your baby is born after 30 weeks of gestation or weighs more 1000g at the time of birth we will not include him/her in the study. Equally, if your baby is very unwell shortly after birth, or has any condition that may affect measurements taken as part of the study then we may consider not including him/her in the study.

What does the study involve?
If you choose to participate in this study, your baby will have following investigations. All of the investigations are non-invasive and this means that no pain will be inflicted to your baby by taking part in the study. Some of the investigations described will be part of your baby's routine clinical care. If so, we will simply be sharing information that is already collected.

Oxygen levels in the brain
Near-infrared spectroscopy (NIRS) is a non-invasive device that allows us to monitor the oxygen level in the brain. A small and soft NIRS probe containing a LED light will be placed on the forehead for the first 3 days of life.

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, and one probe will be placed on a hand or a foot for the first 3 days of life.

Blood pressure / carbon dioxide level
If your baby is born premature blood pressure and carbon dioxide level will be monitored as part of routine clinical care. We will simply record these measurements if your baby takes part in the study.

Urine test
Urine sample will be collected by placing a cotton wool or gauze in the nappy once a day for the first 3 days. It will then be analysed to look for any evidence of stress in the brain.

Heart scans
Ultrasound scan of the heart (also known as 'echocardiography') is a routine investigation for many premature babies on the first day of life. If, for whatever reasons, this scan is not indicated in your baby, we would like to carry it out as a one-off investigation by the bedside.

Brain scans

As part of routine clinical care, your baby will receive screening ultrasound scan of the brain at 1 week and 1 month of age to look for any complications of prematurity. If he/she takes part in the study, additional daily ultrasound scans will be performed in the first 3 days of life. When your baby is at 'term-equivalent age' (i.e. around their due date) we will also perform MRI of the brain to look for more subtle abnormalities which are not easily detected by ultrasound alone. This MRI scan will be done without any form of sedation, i.e. your baby will simply have a feed just before the scan and will be wrapped in a blanket for comfort so that he/she will hopefully be settled for the duration of the scan.

Neurodevelopmental follow-up assessment
Some premature babies will receive a formal neurodevelopmental assessment as part of routine care in order to screen for any neurological complications after going home. If your baby is not eligible for this service, we would like to visit you and your baby at home when your baby is between 1 and 2 years of age and perform this assessment.

With your permission, we would like to share any relevant clinical information obtained as part of this study with your doctors and other health professionals. This is so that such information can be used to optimise your baby's clinical care.

Confidentiality of health information:
If you choose to participate in the study, a number of relevant health information will be collected from mother and baby's medical records. 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 anyone outside of the research team. All study records will be kept securely and electronically in a databank until your child is 16 years of age.

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 is an observational study, there is no direct benefit to you or your baby by taking part. However, it is possible that additional clinical information gathered during this study (e.g. from the heart and brain scans or the follow-up neurodevelopmental assessment) may help optimise your baby's clinical care.

Risks of the study:
All investigations in this study are non-invasive. This means that there will be no pain inflicted on your baby if you choose to participate. None of the tests performed as part of this study are known to pose any risk to your baby's health.

There will be additional handling of your baby if you choose to take part in the study. Any disturbance to your baby will be kept to minimum by making sure that all investigations are carried out by skilled practitioners with experience in performing them.

How many babies are we recruiting?

A total of 120 babies will be recruited into the study between two centres (Wellington Hospital and Texas Children's Hospital) over the next 2 years. The size of the study has been calculated by a biostatistician and reflects the minimum number of participants required to answer relevant research questions with confidence (using a statistical analysis called the Receiver Operating Characteristics curve).

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:
If you or your baby were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive further funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

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
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Dr. Max Berry (co-investigator)
Email: max.berry@otago.ac.nz

A/Prof. Shieak Tzeng (co-investigator)
Email: shieak.tzeng@otago.ac.nz

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