Participant Information Sheet

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| **Study Title** | Effect of **R**etinopathy **O**f **P**rematurity screening on cerebral and somatic (splanchnic) regional **ox**ygenation and cardiovascular stability in neonates (**ROP-Ox**) |
| **Locality** | Wellington Regional Hospital Neonatal Intensive Care Unit |
| **Coordinating Investigator** | Dr Angus Goodson |
| **Contact Number** | 0211998263 |
| **Ethics Reference** |  18/NTB/10 |

# 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 and your baby has been identified as being at risk of developing Retinopathy of Prematurity (ROP). Your baby will undergo screening for this condition.

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**

Retinopathy of Prematurity (ROP) is the abnormal development of blood vessels in the eye. ROP can occur in premature babies, mainly affecting those born before 31 weeks gestation or with a birthweight under 1300 grams. Not all of these babies will be affected but all at risk babies are routinely checked by an ophthalmologist whilst still in the neonatal unit.

The retina lines the inside of the eye. It receives rays of light and sends images to the brain where they are converted into what we see. As the eye develops, tiny blood vessels grow throughout the retina. The blood vessels start developing at 16 weeks of pregnancy and complete growing approximately one month after birth.



With ROP, these blood vessels may grow in the wrong direction or stop growing too early. The blood vessels are very fragile and there is a high risk of blood leaking from them. This bleeding can result in scarring and damage to the retina. If there are abnormal blood vessels they can be effectively treated with lasers which is why screening is so important.

Your baby’s eyes will be examined by a specialist eye doctor known as an ophthalmologist. In order for the ophthalmologist to be able to properly examine the retina, eye drops are needed to enlarge the pupils. These drops are given approximately one hour before the screening.

The screening for ROP can result in some babies showing signs of stress. There is also some evidence that ROP screening can cause disruption to your baby’s ability to handle feeds for a short period and may make them more vulnerable to developing infections related to the gastrointestinal tract. For this reason, feeding is paused at the time of screening.

This study aims to better understand the underlying changes that lead to these effects and determine whether they are related to changes in blood flow to the gastrointestinal tract. This study further seeks to identify during which stage of the ROP screening process these changes occur.

The early detection of ROP is vital in protecting the future vision of premature neonates. This study aims to contribute to ensuring that the screening process is as safe as possible.

This study is for observation only. What this means is that only your doctors will decide whether your baby needs screening for ROP and this study will not affect their decision making in any way.

# Who we are looking for?

We are looking for babies on the neonatal intensive care unit in Wellington Hospital, who are being screened for retinopathy of prematurity because they meet the criteria.

# Why we might not consider including your baby in the study:

If your baby is considered critically unwell or the clinical staff caring for the baby feel that involvement in the study may adversely effect your baby then we would not consider enrolling 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 ROP screening using the following equipment:

 ***Oxygen levels in the brain and gastrointestinal tract***

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 2 locations; forehead and lower abdomen. 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***

We use neonatal size soft blood pressure cuffs to take intermittent blood pressure recordings

***USS Doppler***

A doppler is a non-invasive measurement of blood flow in the arteries supplying the intestines using an ultrasound machine.

# Study Timeline

Start of Study

Eye Drops

Eye Exam

End of Study

NIRS

Heart Rate and PaO2

Blood Pressure

1 hr

1 hr\*

3 h

Coeliac

Doppler

Coeliac

Doppler

Coeliac

Doppler

Blood Pressure

Blood Pressure

# The total expected time of the study is approximately 5 hours

# If at any time the doctors or nurses caring for your baby feel that the additional monitoring is causing your baby stress or distress, it will be discontinued.

# Confidentiality of health information:

If you choose to participate in the study, the 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 screening
* Breathing support (if any)
* The medication your baby is receiving
* Position of your baby (e.g. lying on back, side, etc)
* Presence of a patent ductus arteriosus

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 your baby turns 16. 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 premature babies at risk of retinopathy of prematurity.

# 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.

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) is used safely in both term and preterm babies for research around the world, it is increasingly introduced into clinical practice.

. Ultrasound is a non-invasive imaging technique that involves placing a probe on the surface of the skin. There should be no significant pain or discomfort associated with the procedure.

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.

# If at any time the doctors or nurses caring for your baby feel that the additional monitoring is causing your baby stress or distress, it will be discontinued.

# 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.

***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).

Ph 043855999 ext 5956

Email : wcs@ccdhb.org.z

Hours 8:00am – 4:30pm

Other Contacts: Cheryl Goodyear – Manager Maori – HHS Extn 4074

# 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. Angus Goodson (Coordinating Investigator)

Tel: 0211998263

# 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