Study title:	*Microdrop administration of eye drops used for retinopathy eye test*		
Locality:	Southern, Canterbury, and Capital and Coast, District Health Boards	Central Health and Disability Ethics Committee ref.:	19/STH/114
Lead investigator:	David Reith	Contact phone number:	0279756150
Clinical Trial Name:	Microdrop administration of phenylephrine and cyclopentolate in neonates (MAPC-N)	Clinical Trial ref.:	ACTRN12619000795190p

Tēna koe,

Your baby is invited to take part in a study on eye drops (phenylephrine and cyclopentolate) used to dilate the pupils for the retinopathy of prematurity eye test. Whether or not your baby takes part is your choice. If you don't want your baby to take part, you don't have to give a reason, and it won't affect the care your baby receives. If you do want to take part now, but change your mind later, you can pull your baby out of the study at any time.

This Participant Information Sheet will help you decide if you'd like your baby to take part. It sets out why we are doing the study, what your baby's participation would involve, what the benefits and risks to your baby might be, and what will happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not your baby will participate in this study. Before you decide, feel free to talk about the study with other people, such as family, whānau, friends, or healthcare providers.

If you agree for your baby to take part in this study, you will be asked to sign the Consent Form on the last page of this document. After you sign the Consent Form, you will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

Phenylephrine and cyclopentolate are eye drops used during the retinopathy of prematurity eye check. Please talk to your nurse and/or doctor for further information about the reason for doing the eye check. The purpose of the eye drops is to dilate the pupil and make it possible to check all of the back of the eye (retina). We want to know whether giving less of these drops is as effective as giving higher doses. Giving weaker eye drops may reduce side

effects. It is unknown how weak to make these eye drops while still dilating the pupil enough for an eye examination.

If you agree that your baby can be part of this study, they will receive either low dose or ver low dose microdrop eye drops.

This study is being funded by CureKids, the University of Otago's School of Pharmacy, and School of Medicine. This study has been given ethical approval by the Southern Health and Disability Ethics Committee.

WHAT WILL MY BABY'S PARTICIPATION IN THE STUDY INVOLVE?

As part of routine procedure, it is recommended that your baby has an eye check to find out if they have retinopathy of prematurity (ROP). Your baby will be randomised to either the usual amount or weaker eye drops.

During the day of the retinopathy eye check, things that we will be measuring from your baby are:

- Pupil diameter: A digital camera will be used to take a photo of the pupil. We need to take 1 photo with the digital camera at the time of the eye test.
- Blood pressure: This is a routine measurement that you will be familiar with. A non-invasive blood pressure monitor (NIBP) will be used, and some babies can feel slight discomfort when having their blood pressure taken. We need to take 3 blood pressure measurements.
- Heart rate: This is a routine measurement that you will be familiar with. The heart rate will be measured using a small device that is in contact with the skin and is pain free. We need to take 3 heart rate measurements.

Data collected from medical notes:

- Feed tolerance: We will be looking in the medical notes to see if your baby has had any difficulty feeding for 24 hours before and for one week after the eye test.
- Lung support: We will be looking in the medical notes to see if your baby has had any change in lung (respiratory) support for 24 hours before, the day of, and the day after the eye test.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Some side effects of these medicines are increased blood pressure, increased heart rate, gastric reflux, increased risk of serious gut damage. By giving less medication, this may reduce the chance of side effects from happening.

If your baby is in this study, it is possible that the pupils might not dilate adequately. If after giving three lots of the lower dose medication and the medication does not work, we will then give the usual amount of medicine. This is the same as standard practice for this situation.

WHO PAYS FOR THE STUDY?

It does not cost you or your family/whānau to participate in this study.

WHAT IF SOMETHING GOES WRONG?

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

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

WHAT ARE MY RIGHTS?

Your baby's participation in this study is voluntary. If you choose for your baby not to be part of this study, your baby will still receive the usual treatment for retinopathy screening. There will be no cost to your family/whānau for participating in this study. Normal care will be provided by NICU staff during this study.

During the study, if any new information, positive or negative emerges during the study about the effects of these eye drops, you will be informed immediately.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

Once we have results from 150 babies, the results will be reviewed and a report will be written discussing results.

If you decide that your baby can be part of this study, a report on findings can be sent to you, at no cost. It is likely that this study will be completed by the end of 2020, and this is likely to be when the report is sent out to you (if you would like a copy).

All information collected about your baby will be kept confidential and only accessible by research staff. Your baby will be assigned a code to identify him/her and no identifiable information will be published. All information will be stored in a secure location for 10 years. If you would like to see any of the information collected, please ask your NICU nurse and one of the researchers can show you the information.

If you change your mind and don't want your baby to be part of the study, speak to any of the nurses in the NICU or your main neonatologist. The study investigators will then remove your baby from the study. Any data collected, up to the time you withdraw, will be included in this study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dr David Reith, Lead Investigator
david.reith@otago.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@hdc.org.nz

For Māori health support please contact: 0800 555 050

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone:	0800 4 ETHICS
Email:	hdecs@moh.govt.nz

Consent Form

Please tick to indicate you consent to the following

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.	Yes ☐	No ☐
I have been given sufficient time to consider whether or not my baby should participate in this study.	Yes ☐	No ☐
I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.	Yes ☐	No ☐
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes ☐	No ☐
I understand that taking part in this study is voluntary (my choice) and that I may withdraw my baby from the study at any time without this affecting their medical care.	Yes ☐	No ☐
If I decide to withdraw my baby from the study, I agree that the information collected about them up to the point when I withdraw may continue to be processed.	Yes ☐	No ☐
I consent to my GP or current provider being informed about my baby's participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	No ☐
I understand that my baby's participation in this study is confidential and that no material, which could identify my baby personally, will be used in any reports on this study.	Yes ☐	No ☐
I understand the compensation provisions in case of injury during the study.	Yes ☐	No ☐
I know who to contact if I have any questions about the study in general.	Yes ☐	No ☐
I understand my responsibilities as a parent/guardian of a study participant.	Yes ☐	No ☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:
I hereby consent for my baby to take part in this study.

Participant's name:

Signature: Date:

Relationship to participant:

Address for results:

Kia ora ☺

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant's parent/caregiver, and have answered the participant's questions about it.

I believe that the participant's parent/guardian understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date: