Participant Information Sheet

Study title:	**The PLUSS Trial 2-year Assessment**		
Locality:	Liggins Institute	Ethics committee ref.:	17/CEN/203
Lead investigator:	Dr Chris McKinlay (New Zealand) Dr Omar Kamlin (Australia)	Contact phone number:	0274725099

Your child is invited to take part in the PLUSS Trial 2-year Assessment. This Participant Information Sheet will help you decide if you would like your child to take part. It explains why we are doing this research and what is involved. Please ask us if something is not clear or if you would like more information. Before you decide, you may also want to discuss the study with other people, such as family, whānau, friends, or your healthcare providers. Your child's participation is entirely voluntary (your choice). If you agree for your child to take part, you will be asked to sign a Consent Form.

This document is 4 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

The PLUSS Trial, including this 2-Year Assessment, has ethical approval from the Central Health and Disability Ethics Committee 17/CEN/203.

WHY IS MY CHILD BEING ASKED TO TAKE PART IN THIS STUDY?

Your child was born extremely preterm (before 28 weeks' gestation) and after birth you enrolled them in the PLUSS Trial (Preventing Lung Disease Using Surfactant + Steroid). The PLUSS Trial is investigating if giving a small amount of steroid medicine, called budesonide, directly into the lungs with surfactant (a natural lung fluid needed for breathing) helps prevent preterm lung disease and improves early lung growth. We would now like to assess if this treatment has any benefits on health and development at 2-3 years of age.

WHAT IS THE PURPOSE OF THE STUDY?

To fully understand the effects of budesonide in surfactant in preterm babies it is important that we follow up the children in this study to assess their health, growth, behaviour and development in early childhood. This information will be important in determining how budesonide should be used in the future.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

All children born very preterm are eligible for a medical and developmental check at 2-3 years of age. A paediatrician will measure your child's growth and assess their movement and reflexes. A developmental assessor will use a series of interactive games and activities to assess your child's development in thinking, language and coordination. This is part of routine care. It usually takes 1.5-2 hours to complete.

We are seeking your permission to collect this information, or if this assessment has not been completed, to allow a member of the research team to undertake the same clinical assessment. In addition, we will ask you to complete some questionnaires about your child's general health, risk of asthma, emotional-behavioural development and the home environment. These questionnaires can be filled out online or on paper, and will take up to 25 minutes to complete.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

We will provide you with a summary of your child's growth and development, and many parents find this reassuring. If we discover any areas of concern, we will discuss this with you and help you decide if any further help is needed. The information we gather in this study may help other very preterm babies in the future.

WHO PAYS FOR THE STUDY?

This research is being conducted by a collaborative group of clinical researchers in Australia and New Zealand. Funding is being sought from the National Health and Medical Research Council (NHMRC), Australia. You will not incur any costs by taking part in this study. We will cover the costs of your travel to and from the visit.

WHAT IF SOMETHING GOES WRONG?

If your child was injured in this study, which is very 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 funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that if your child takes part in this study, his or her cover won't be affected.

WHAT ARE MY RIGHTS?

Participation in this study is voluntary. If you join the study but change your mind you can withdraw your child at any time and your child's usual medical care will not be affected. With your consent, data collected prior to your withdrawal will be used in study analysis.

You and your child's privacy will be protected. Study data will be de-identified and any identifiable data, such as name or address, will be held securely, accessible only to the immediate research team. Project reports will not identify any individual participants. You may request to view your child's study data at any time.

WHAT HAPPENS AFTER THE STUDY?

When the study is completed, we will write to you outlining the main findings of the study. You will be able to find out which study group your baby was in after they have completed the 2-year Assessment. Hard copy records will be kept securely for 25 years and will be accessible only to the study investigators. De-identified electronic records will be permanently and securely archived. We may contact you in the future about enrolling your child in later follow-up studies to investigate the longer-term effects of the study treatment into childhood. De-identified study data may be made available to other researchers for approved future research.

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 Chris McKinlay, Lead Investigator, NZ
Phone: +64 274725099
Email: c.mckinlay@auckland.ac.nz

Dr Omar Kamlin, Principal Investigator, Australia
Phone: +61 3 83453763
Email: omar.kamlin@thewomens.org.au

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

If there is a specific Māori issue/concern please contact: Leigh Henderson, Chair CMDHB Māori Research Review Committee, +64 9 2629562, x3162

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 - *The PLUSS Trial: 2-year Assessment*

PARENT / CAREGIVER STATEMENT

I have read and I understand the Participant Information Sheet.		
I have had time to consider whether to allow my child to take part.		
I have had the opportunity to ask questions and I am satisfied with the answers I have been given.		
I have had the opportunity to use whānau/ family or other support to help me understand the study.		
I understand that the participation of my child in this study is my choice and that he/she may withdraw from the study at any time and this will not affect his/her continuing health care.		
I understand that any information collected about my child through the study will be kept confidential and that no material that could identify me or my child will be used in any study reports.		
I know who to contact if I have any questions about the study in general.		
I understand the compensation provisions for the study.		
I consent to the investigators accessing my child's medical records for study purposes only.		
I wish to be notified of the results of this research when they are available If yes, I prefer to be notified by ☐ email or ☐ post (tick one)	Yes ☐	No ☐
If I decide to withdraw my child from the study, I agree that the information collected up to the point when I withdraw may continue to be processed.	Yes ☐	No ☐
You may contact me in the future to ask about my child participating in further aspects of the study.	Yes ☐	No ☐

Declaration by participant:
I hereby consent to my child taking take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:
I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it. I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____