#### What are the risks and benefits?

#### **Risks**

· There may be no direct benefits from the study

#### **Benefits**

- Giving probiotics can help grow or maintain the living good bacteria in your baby's tummy
- Probiotics could protect your baby from infections
- · Probiotics help to develop your baby's immunity
- The research will help us understand more about the benefits of giving probiotics to babies
- This study may improve the future lung health care of babies in the Northern Territory
- You will receive a \$20 gift voucher, a baby singlet, baby bib, waterbottle, carry bag and certificate of participation for your baby as a thank you at different study timepoints

# Did you know

Most adults with sick lungs had lots of chest infections when they were babies.

#### **Contact Details**

If you are unsure, have any questions or want more information about the study, please contact:

**Dr Tejal Shah**, Study Manager Menzies School of Health Research Ph: 0436 314 405

11. 0430 314 403

Email: ProKids@menzies.edu.au

**Dr Michael Binks,** Chief Investigator Menzies School of Health Research

Phone: 0423 194 728

Email: michael.binks@menzies.edu.au

Dr Peter Morris, Site Investigator

Top End Health Service Phone: 0428 910 254

Email: peter.morris@menzies.edu.au

This study is administered by Menzies School of Health Research and authorised by Northern Territory Health.

If you have concerns or complaints about your rights or the conduct of this study, please contact:

The **Human Research Ethics Committee** of the NT Department of Health & Menzies School of Health PO Box 41096, Casuarina NT 0811

Phone: (08) 8946 8600

Email: ethics@menzies.edu.au HREC number: 2023-4759

#### **NT Health Research Governance Officer**

Phone: <u>08 8922 7764</u>

Email: nthealth.rgo@nt.gov.au Reference number: 2024/2181





NT HEALTH

#### **Menzies School of Health Research (HQ)**

John Mathews Building (JMB), Building 58, Royal Darwin Hospital Campus, Northern Territory, Australia 0810.

Website: menzies.edu.au



# **Pro-Kids**

# Probiotics to reduce chest infections in First Nations babies



# "Protecting small lungs for healthy babies"

## PARTICIPANT INFORMATION SHEET

This is for you to keep.

Pro-Kids Study Participant Information and Consent Form\_V1.1\_25102024 for Study Protocol V1.1 Dated 25102024

### Why we care about chest infections?

- Chest infections are common in Aboriginal babies
- · Chest infections can make babies very sick
- Chest infections as a baby can make your lungs weak as an adult

### What are probiotics, what do they do?

- · Probiotics are 'good bacteria'
- Lactiplantibacillus plantarum is a probiotic
- It could protect your baby's tummy from germs
- It could strengthen your baby's immune system
- · It could prevent chest infections in your baby
- If you join this study, your baby will receive a supplement containing Lactiplantibacillus plantarum and fructo-oligosaccharides (sugars).
- We call this supplement LpFOS
- · LpFOS is ingested orally in water or breast milk
- · LpFOS is safe for babies

# What is the Pro-Kids study

"We want to know if giving probiotics to babies can improve immunity and stop chest infections."



Pro-Kids Study Participant Information and Consent Form V1.1\_25102024 for Study Protocol V1.1 Dated 25102024

### Can my baby join the Pro-Kids study?

Yes, if you are:

- Aged 18 years or over and having a baby of Aboriginal descent
- · A resident of a participating community
- · Willing to provide written consent in English

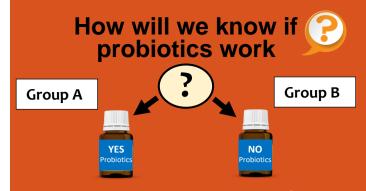
### What does the study involve?

- We will visit you and your baby 5 times starting between birth and your baby's 1<sup>st</sup> birthday
- · Your baby will receive:
  - 3mls of study medicine (in water or breast milk) every day for 7 days starting within 3 days of birth
  - Probiotics <u>OR</u> Placebo (No probiotics) (you will not know which one)

#### We will also collect:

- Information from your medical records to check your pregnancy health
- · Cord blood (birth) after birth
- Breast milk when your baby is age 7-13 days (finished the study medicine) and at age 1 month
- Baby's blood (via venepuncture, heel or finger prick) at 1, 4 and 7 months of age
- A nose swab from your baby at day 7-13, 1, 4 and 7 months of age
- A stool (poo) sample from your baby at birth, day 7-13, 1, 4 and 7 months of age
- Information from your baby's medical records will be collected between birth and 12 months of age to check for chest infections and other health conditions

"Your information will be kept private at all times"



"We will count the number of chest infections in each group"

## We will use the samples to check:

- How probiotics affects your baby's immune function and capacity to fight germs
- Microbes in your baby's nose and tummy to check how well probiotics works for your baby

# Before you join, <u>you will need to sign</u> <u>a consent form</u>. This means:

- · You understand why we are doing the study
- You understand the risks and benefits
- · You understand we will visit and contact you
- · You are happy for us to collect some samples
- · You are happy for us to check your medical records
- You agree to be a part of the study with your baby

You do not have to say "Yes"

If you say "Yes" you can still change your mind

Saying "No" will not affect you/your child's care

# Optional consent (you can say no):

- Permission to use your deidentified data and samples for future respiratory health research
- · Permission to contact you for any future studies
- Any future research will require new approval from the Human Research Ethics Committee

Page 2 of 3



# Pro-Kids Study CONSENT FORM

This form means you can say NO

Postal: PO 41096, Casuarina NT 0811, Australia Location: John Mathews Building (Bldg 58), Royal Darwin Hospital Campus, Rocklands Drv, Casuarina NT 0810 Ph: (08) 8946 8600

Fax: (08) 8946 8464 Website: www.menzies.edu.au ABN: 70 413 542 847

Мy	name is:	

The Pro-Kids study has been explained to me and I know what is involved. I have had the opportunity to ask questions about the study, I understand:

- It is OK to say NO and that, if I say YES, I can change my mind later.
- The possible risks, side effects and benefits being involved in the study.
- That my baby and I may not directly benefit by taking part in this study.
- All information collected about my baby and I will be kept confidential.

#### By signing this form, I give consent for myself or my child:

"If unclear, please discuss with a team member before proceeding."



To give my baby a probiotic or placebo for 7 consecutive days.



**2.** To have our **medical records** accessed from birth until my baby's 1st birthday.



**3.** To be **contacted** regularly via phone/email/social media.







**Probiotic:** Lactiplantibacillus plantarum plus fructooligosaccharides

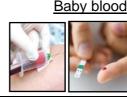
**Includes**: Aboriginal medical health services, medical centers, clinics, hospitals and any other health records

**4.** To have the following **samples collected** from me (breast milk only) and my baby over 5 study visits from birth for approximately 7 months:











Date

Mother's breast milk

#### **Optional**

	1 1		
I understand what I am signing. I will be given a copy to keep.	I have verbally explained the project to the participant. I believe the explanation was understood.		
Participant / legal care-giver of participant Date Signature	Research staff Signature	// Date	
Feedback I would like updates and a copy of the research outcomes by post / email / social media? If Yes, contact details			
I agree to be contacted for future clinical research studi	Yes 🗌 No 🗌		
I agree to have my own and/or my child's samples and information (NO identifying data) stored and used in future child respiratory health studies. You can say no and still join the study.			

Interpreter / witness signature (N/A if not applicable)