

## 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:

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Top End Health Service  
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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](mailto:ethics@menzies.edu.au)  
HREC number: 2023-4759

**NT Health Research Governance Officer**  
Phone: [08 8922 7764](tel:0889227764)  
Email: [nthealth.rgo@nt.gov.au](mailto: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.

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# 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."**



***Lactiplantibacillus Plantarum***,  
the 'good bacteria'

## 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 OR 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"**

## How will we know if probiotics work



**"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, you will need to sign a consent form. 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

# 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](http://www.menzies.edu.au)  
ABN: 70 413 542 847

My 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.

**“If unclear, please discuss with a team member before proceeding.”**



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

<p><b>1. To give my baby a probiotic or placebo for 7 consecutive days.</b></p>  <p><b>Probiotic:</b> Lactiplantibacillus plantarum plus fructo-oligosaccharides</p>	<p><b>2. To have our medical records accessed from birth until my baby's 1st birthday.</b></p>  <p><b>Includes:</b> Aboriginal medical health services, medical centers, clinics, hospitals and any other health records</p>	<p><b>3. To be contacted regularly via phone/email/social media.</b></p> 					
<p><b>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:</b></p> <table border="1"> <tr> <td data-bbox="87 1086 239 1276"> <p><u>Cord blood</u></p>  </td> <td data-bbox="311 1086 526 1276"> <p><u>Baby stool (poo)</u></p>  </td> <td data-bbox="598 1086 790 1276"> <p><u>Baby nose swab</u></p>  </td> <td data-bbox="837 1086 1212 1276"> <p><u>Baby blood</u></p>  </td> <td data-bbox="1276 1086 1540 1276"> <p><u>Mother's breast milk</u></p>  </td> </tr> </table>			<p><u>Cord blood</u></p> 	<p><u>Baby stool (poo)</u></p> 	<p><u>Baby nose swab</u></p> 	<p><u>Baby blood</u></p> 	<p><u>Mother's breast milk</u></p> 
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## Optional

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. Yes ☐ No ☐

I agree to be contacted for future clinical research studies at Menzies School of Health Research Yes ☐ No ☐

## Feedback

I would like updates and a copy of the research outcomes by post / email / social media? Yes ☐ No ☐

If Yes, contact details \_\_\_\_\_

<p>_____/_____/_____ Participant / legal care-giver of participant Signature Date</p>	<p>_____/_____/_____ Research staff Signature Date</p>
<p><b>I understand what I am signing. I will be given a copy to keep.</b></p>	<p><b>I have verbally explained the project to the participant. I believe the explanation was understood.</b></p>
<p>_____/_____/_____ Interpreter / witness signature (N/A if not applicable) Date</p>	