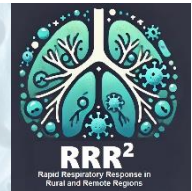


# Project Information Sheet: Parent/Guardian



<b>Scientific title of study</b>	RRR <sup>2</sup> : Rapid Respiratory Response in Rural and Remote Regions - an observational study of bronchiectasis using ground-breaking tools
<b>Lay Title of study</b>	RRR <sup>2</sup> : Rapid Respiratory Response in Rural and Remote Regions
<b>Principal Investigator</b>	Dr Thomas Goddard
<b>Institution</b>	Women's and Children's Hospital
<b>Phone Number</b>	(08) 8161 7234 or (08) 8161 7000 (24-hr emergency)

## Introduction

We invite you and your child to take part in this research study. Please read this sheet carefully and ask any questions. Participation is voluntary.

## Why are we doing this study?

Lung infections are a major health issue for children in rural and remote areas, especially in First Nations communities. These infections can lead to a serious condition called bronchiectasis, where the lungs can become permanently damaged.

Currently, doctors use tests that take a long time to identify what is causing these infections. This delay can mean children are treated with antibiotics that might not work for their specific infection. We want to help improve this.

This study aims to:

1. **Find faster ways to identify the germs causing lung infections** by studying samples like mucus (or spit) that your child already gives during routine care.
2. **Help doctors give better, more targeted treatments** to reduce the need for children to travel to big hospitals for care and reduce infection severity. This includes advising and giving the right medication for the specific infection.
3. **Improve the long-term health of children** by preventing serious lung damage caused by delayed treatment.

## Who is conducting the study?

This study is being conducted by a team of doctors and researchers at the Women's and Children's Hospital in Adelaide, led by Dr. Thomas Goddard.

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## Who has approved the study?

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All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). These committees carefully review studies before they begin to ensure they respect the rights, culture, and wellbeing of all participants.

This study has been reviewed and approved by the following ethics committees:

- **Women’s and Children’s Health Network Human Research Ethics Committee (WCHN-HREC)**
- **Aboriginal Health Research Ethics Committee (AHREC)**
- **NT Health and Menzies School of Health Research Human Research Ethics Committee (NT-HREC)** – under the National Mutual Acceptance (NMA) scheme

In addition, the following hospitals have each granted approval for the study to be conducted at their sites:

- **Women’s and Children’s Hospital** (South Australia)
- **Alice Springs Hospital** (Northern Territory)
- **Mount Gambier and Districts Health Service** (South Australia)

## Who is funding the study?

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This study is funded through a **Women’s and Children’s Hospital Foundation Boom Research Grant**. The Foundation provides funding to support research that improves the health and wellbeing of children and their families.

## Why is my child being asked to join the study?

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Your child is being asked because they are being treated for bronchiectasis or a related lung condition, such as a chronic wet cough. By studying their samples, we can better understand the germs causing infections and develop faster and more accurate ways to diagnose and treat them.

## How many children will be part of this study?

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A total of **115 children** aged between 0-18 years will be involved in this study:

- **50 children** from the Women’s and Children’s Hospital in Adelaide
- **50 children** from Alice Springs Hospital
- **15 children** from Mount Gambier and Districts Health Service

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## What will happen if my child takes part?

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If you agree for your child to participate:

1. We will use samples (like mucus or spit) that are **already collected** as part of your child's routine care.
2. These samples will be sent to a lab, where researchers will study the germs causing the infection.
3. There will be **no extra procedures** or tests required for this study.

## How long will it take?

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We are only using samples from your child's regular doctor visits or hospital admissions, so there's no extra time needed for this study.

## Does it hurt?

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No. We are just using a portion of the mucus (or spit) samples already provided to your child's doctor.

## What are the risks?

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There are no physical risks to your child because the study uses samples already collected during their regular care.

## What are the benefits?

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Your child might not directly benefit from this study. However:

- The results could help improve health care for children with lung infections in the future.
- If the new diagnostic methods we are testing are successful, they might lead to faster and better treatments for your child and others.

## What happens to the mucus/spit after it is collected?

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We will study the germs in your child's mucus/spit sample by looking at their DNA using **DNA sequencing technologies**. This means we can read the germs' DNA to find out:

- What germs are present in the lungs
- Whether the germs have anything in their DNA that might affect how doctors treat or get rid of them

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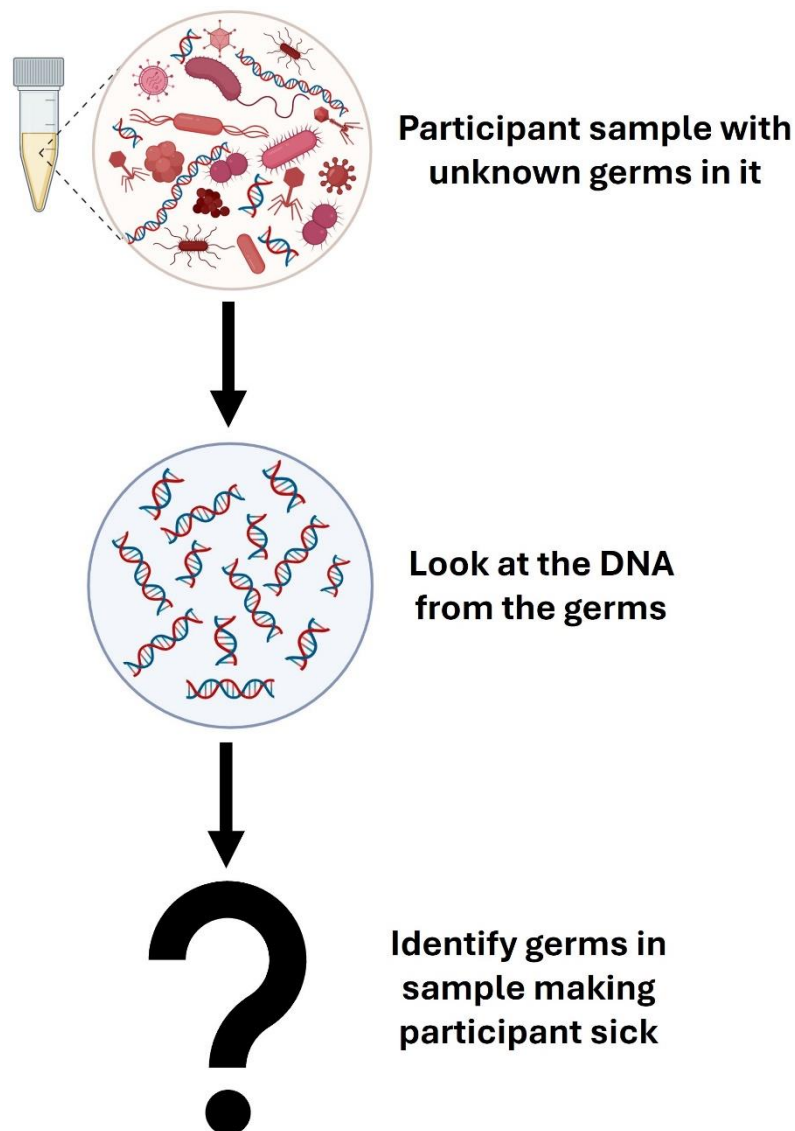
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To make this possible, the research team will bring a mobile laboratory to remote regions. This means the DNA of the germs can be extracted and studied on site, giving us a clear picture of which germs are in the lungs and making children sick. Doing this on site helps us quickly see which germs are present and avoids delays that might happen if samples had to be sent far away.

We will only look at the DNA of the germs in the sample. We will not study your child's DNA.



Once your child's sample has been analysed, you will be given the option in the consent form to allow the research team to safely store any remaining de-identified sample in a secure freezer until the project is completed. This storage allows researchers to perform additional analyses if needed to better understand the germs.

At the end of the study, any leftover mucus/spit sample or extracted DNA will be disposed of respectfully and safely.

## How will results be communicated?

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The information we learn from the samples will be combined with results from all children in the study. This helps us see patterns and trends in lung health across different regions.

**We will not make any results public before they have been shared with Elders and community leaders first and approval has been received.**

We will not provide individual test results for your child. Instead, families and communities will be updated about the overall findings in ways that are clear and accessible. These include:

- Newsletters that can be sent to families directly (by email or post).
- By visiting our project website: <https://fame.flinders.edu.au/rrr2/>

In addition, the results of this project will be written up for scientific publications and shared at conferences in Australia and internationally. These findings will always be presented in a way that protects the privacy of children and families involved.

This approach ensures families are kept informed, while also respecting cultural protocols and contributing to improvements in children's health more broadly.

In the consent form, you will have the option to let us know if you would like to receive project updates and results directly (by email or post).

## Will the researchers use any other information?

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Yes. As part of this study, information about your child's health will be accessed from their electronic medical records. This includes clinical notes, test results, treatments, and hospital visits that are relevant to the research. All data will be de-identified, it will not be able to be tracked back to your child. All information will be handled confidentially in accordance with relevant privacy and ethical guidelines.

The information we will use includes:

- Basic details: Gender, age, date and time of sample collection, and primary language (as an indicator of place of origin)
- Lung health: Lung function test results (such as FEV1) and imaging results (for example, CT scans showing bronchiectasis)
- Treatments and test history: Records of antibiotics your child has had and reports from past respiratory cultures.
- Blood test results: Including *Strongyloides stercoralis* (Threadworm) serology, specific IgE, Aspergillus precipitins, C-reactive protein (CRP), and white blood cell count.

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## Who will see my child's samples and data?

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Any samples or information collected from your child will be kept strictly confidential. When your child's mucus/spit sample is tested, their name will not appear on it. Instead, it will be given a unique study code made up of random numbers. This process is called de-identification. It means that no one analysing the sample will know it belongs to your child.

The research team will be able to use and access the samples for the study, but they will only see the de-identified code, not your child's personal details. Only your child's treating doctor will know which code is linked to your child.

## Who will look after my child's samples and data?

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Your child's mucus/spit sample will be stored securely in a locked freezer at either the hospital where the sample was collected or at Flinders University in Adelaide. Access to these facilities will be restricted to trained researchers only.

The DNA data generated from your child's sample will first be securely stored on the **Pawsey Supercomputing Centre's** computer system for short-term storage (up to five years). Pawsey is a national research facility that provides highly secure data storage for Australian research projects. After this period, the data will be transferred to the **National Centre for Indigenous Genomics (NCIG)** for long-term storage.

Both Pawsey and NCIG carefully safeguard all information and will only provide access to approved members of the research team in its de-identified form. NCIG operates under First Nations governance, ensuring that data are managed according to strict ethical and cultural standards.

Any de-identified ancillary data collected for the study (such as clinical, demographic, or laboratory information) will be securely stored on **Flinders University's REDCap system**, a password-protected and encrypted database used for health research. Access to this system is limited to authorised research team members only.

When the study is finished, any leftover mucus/spit sample or extracted DNA will be disposed of respectfully and safely. The DNA data and any other de-identified information collected about your child's health will be stored securely for 30 years (as required for this type of research) and will then be permanently deleted.

## What about future research?

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The data generated from the DNA sequencing of the mucus samples may be useful for other approved research studies in the future. This would allow researchers to build on the findings of this study and continue improving our understanding of children's lung health, without needing to collect new samples.

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It is entirely you and your child's choice whether the de-identified data generated from this study is used in future research. If you would prefer that your child's de-identified data is only used for this study, you can choose this in the consent form.

Any future research would be reviewed and approved by relevant ethics committees, research governance committees, and the Australian Alliance for Indigenous Genomics to ensure that any future research has a focus on community benefit to ensure that it is not only scientifically rigorous and appropriate, but also culturally sensitive and appropriate.

## Will I or my child be paid for taking part?

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No, there is no payment for participating in this study. However, there are also no costs to you or your child.

## Do we have to take part?

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No. Taking part in this study is completely you and your child's choice. If you decide not to participate, your child's medical care will not be affected in any way.

You can also change your mind at any time. Your child can withdraw from the study without any consequences.

If you decide to withdraw, just let a member of the research team know, or phone or email the Principal Investigator (see the '*Who can I contact for more information?*' section).

## What happens if we change our mind?

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You and your child can stop participating at any time by letting a member of the research team know. There will be no consequences, and your child's care will continue as normal. If you decide to withdraw, you will be asked to complete a **Withdrawal from Study Form**, which gives you the option to explain the reason for withdrawal if you wish.

If you withdraw, no further information or samples will be collected from your child. However, there may be a point at which your child's de-identified data can no longer be withdrawn. This is because, in scientific research, once results have been analysed, removing data would change those results and make them unreliable. For example, this may occur if your child's data has already been included in analyses used for publications or conference presentations.

Any future analyses that have not yet been conducted will exclude your child's de-identified data if you choose to withdraw.

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### If you withdraw from the study:

- Any mucus/spit sample will be disposed of respectfully and safely.
- Any de-identified sequencing data generated will be deleted by the **National Centre for Indigenous Genomics**.
- Any other de-identified research data collected will be deleted from **Flinders University's** secure Research Electronic Data Capture (**REDCap**) database.

## What happens next?

If you agree for your child to participate:

1. You will be asked to sign a consent form.
2. You will get a copy of this information sheet and the signed consent form for your records.

Thank you for considering being part of this important research study. Together, we can help improve care for children with lung infections.

## Who can I contact for more information?

If you have any **questions** or want **more information**, please contact:

Name	Phone Number	Email	Role
Dr. Thomas Goddard	(08) 8161 7234	<a href="mailto:tom.goddard@sa.gov.au">tom.goddard@sa.gov.au</a>	Principal Investigator

If you have any **concerns or complaints** about the study, you can contact:

Location	Name	Phone Number	Email
South Australia	<b>Jade Jordan-Hall</b> (WCHN HREC Ethics Officer)	(08) 8161 6521	<a href="mailto:HealthWCHNResearch@sa.gov.au">HealthWCHNResearch@sa.gov.au</a>
South Australia	Aboriginal Health Research Ethics Committee	(08) 8273 7200	<a href="mailto:research@ahcsa.org.au">research@ahcsa.org.au</a>
Northern Territory	NT Health and Menzies School of Health Research Human Research Ethics Committee	(08) 8946 8600	<a href="mailto:NTHREC@menzies.edu.au">NTHREC@menzies.edu.au</a>

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