Participant Information Sheet/Consent Form - Parent/Guardian

Title	*WA Paediatric Bronchiectasis Cohort Study*
Project Sponsor	*Telethon Kids Institute*
Coordinating Principal Investigator	*A/Professor Andre Schultz*
Location	*Perth Children's Hospital*

1 Introduction

This is an invitation for the child in your care to take part in this research project, "WA Paediatric Bronchiectasis Cohort Study". This study is looking at children with bronchiectasis in Western Australia and aims to understand how this lung condition develops during childhood. To do this, we also need information about the lung function of healthy children. We are looking to recruit healthy children who will provide a control group for the children with bronchiectasis.

This *Participant Information Sheet* tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want your child to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether your child can take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you do not wish for your child to take part, they do not have to. They will receive the best possible care whether or not they take part.

If you decide you want your child to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read.
- Consent to your child taking part in the research project.
- Consent to your child having tests for research that are described.
- Consent to the use of your child's personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Bronchiectasis is a condition where the breathing tubes of the lungs are damaged, widened, and thickened. Children with bronchiectasis often experience wet cough and are prone to respiratory infections. This can result in difficulties with breathing and the need for medications and hospital visits.

The disease processes in bronchiectasis are poorly understood, which means that there are limited disease specific treatment options. With this project we would like to gain knowledge into the disease mechanisms of childhood bronchiectasis in order to identify targets for treatment.

In this study, we are looking to recruit children and adolescents who do not have any history of respiratory illness or breathing problems. By collecting data from these children, we will be able to compare the results with those children who have bronchiectasis. By looking at any differences between these groups, we can begin to identify what is causing some of the breathing issues we are seeing in children with bronchiectasis.

3 What does participation in this research involve?

If you choose for your child to participate in this study, we will ask you and your child to visit Perth Children's Hospital (PCH) once every 6 months, over a 5-year follow-up period. Each research visit will take about one hour in total. At each visit, we will ask your child to perform some lung function tests. These tests are described in more detail below. We will organise a time that suits your schedule for these visits.

Throughout the study duration, there will be no lifestyle, dietary or other restrictions for your child. Your child should continue to take their usual medications (if any).

After the initial 5-year period, we may extend the research until your child turns 18. If this is the case, we will re-contact you and provide you with an updated information sheet. If you choose to continue participating, we would go through the consenting process again. There is no obligation to continue the research past the initial 5-year period.

Lung function tests

Multiple Breath Washout (MBW): This test can tell us how evenly gases mix in your child's lungs. It can also tell us how well air is moving in the smaller airways located in the outer parts of your child's lung. Your child will be asked to breathe normally into a mouthpiece while wearing a nose clip for a few minutes at a time. We will use 100% oxygen (gas) to temporarily washout (or, dilute) the air that is normally in your child's lungs. We will then measure how quickly your child breathes out the gas from their lungs. These gases do not taste or feel different to normal air, but they may make the mouth feel a bit dry. This test requires at least two trials of several minutes each to be performed. The total time to complete this test can take up to 30 minutes.

Plethysmography: This test accurately measures how much air your child can hold in their lungs. Your child will sit in the lung function room body box that is completely see through and looks like a phone booth with the door closed. Your child will then be asked to breathe or pant into a mouthpiece with a nose clip on. This test takes approximately 5-10 minutes to perform.

Spirometry: This test measures how much air your child breathes in and out. Your child will be asked to wear a nose clip and to breathe normally through a mouthpiece. After a couple of normal breaths in and out, your child will be asked to breathe in as much air as they can at a moderate pace and then slowly exhale all of this air. This process lasts for about 1-2 minutes and will be repeated 3 times to get accurate measurements which match each other.

Table 1: Summary of planned investigations

Modality	Baseline	Recurrent	Frequency
Age and Demographics	√	-	-
Height, weight, body mass index (BMI)	√	√	6 monthly
Multiple Breath Washout	√	√	6 monthly
Plethysmography	√	√	6 monthly
Spirometry	√	√	6 monthly

Costs and reimbursement

There are no costs associated with participating in this research project, nor will you or your child be paid. You may be reimbursed for any reasonable travel, parking and other expenses associated with the research project visit, up to $25 per visit.

4 Does my child have to take part in this research project?

Participation in any research project is voluntary. If you do not wish for your child to take part, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw them from the project at any stage.

5 What are the possible benefits of taking part?

We anticipate this study yielding benefits for the greater Bronchiectasis community, particularly with tailoring the care and research in early bronchiectasis management to improve lung health in future generations. Your healthy child will be helping improve the outcomes for children with bronchiectasis. We are also able to provide you with feedback about your child's lung function results.

6 What are the possible risks and disadvantages of taking part?

While this research does not involve any interventional treatment, the research tests and assessments may reveal clinically relevant results.

There are no risks associated with the lung function tests. The gas used in the MBW test (oxygen) may make the mouth a little dry. If your child suffers from claustrophobia (a fear of small spaces) the body box may make them feel anxious. If your child suffers from claustrophobia, or don't want to do the test for any reason, they will not have to do this test.

7 What if I would like to withdraw my child from this research project?

Your child can stop taking part in the project at any time; you just need to notify a member of the research team. You do not need to tell us the reason why. If you decide to withdraw from the study, you can request for your child's data to be destroyed. Otherwise, if nothing is specified, all data collected up until the date of withdrawal, will be kept and used for analysis.

8 What will happen to information about my child?

Participant records will be held securely on site within Telethon Kids Institute until 7 years post study closure or until subjects reach 25 years of age.

By signing the consent form, you consent to the study doctor and relevant research staff collecting and using personal information about your child for the research project. Any information obtained in connection with this research project that can identify your child will remain confidential. Any form of data collected will be de-identified and assigned a re-identifiable study ID.

Confidentiality and Security

Any information obtained for the purpose of this research project and for the future research that can identify the participant will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law. Some of the staff working on this study are employed by the Telethon Kids Institute and are not employed by the government of Western Australia. These staff are working with the approval of the Child and Adolescent Health Service (CAHS). All staff working on this project will follow all the required policies and procedures and will safeguard the confidentiality of participant information.

For hard copy participant files, these are kept in a locked filing cabinet within Telethon Kids Institute. For any electronic data, this is stored within a restricted network drive and within password protected databases.

Information about your child may be obtained from their health records held at this and other health services, for the purpose of this research. By signing the consent form, you agree to the research team accessing health records if they are relevant to participation in this research project.

It is anticipated that the results of this research project will be published and/or presented and shared in a variety of forums. This includes publications in journals, presentations at conferences and to consumers within the consumer reference group. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified, except with your permission.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about your child. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your child's information.

9 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Child and Adolescent Health Service (CAHS) HREC. This research has been funded by the National Health and Medical Research Council (NHMRC).

10 Further information and who to contact:

If you would like any further information about this study, please do not hesitate to contact one of the research team. They are very happy to answer your questions.

Name	**Contact Number**
Ms Alana Harper – Project Coordinator	08 6319 1617
Dr. Kathryn Ramsey	08 6319 1374
A/Prof Andre Schultz	08 6456 0217

You can also send an email enquiry to: BXResearch@telethonkids.org.au

If you have any concerns or complaints regarding this study, you can contact the Executive Director of Medical Services at PCH by calling 08 6456 2222. Your concerns will be brought to the attention of the Ethics Committee who is monitoring the study.

Consent Form – Parent/Guardian

Title	*WA Paediatric Bronchiectasis Cohort Study*
Project Sponsor	*Telethon Kids Institute*
Coordinating Principal Investigator	*A/Professor Andre Schultz*
Location	*Perth Children's Hospital*

Declaration by Parent/Guardian

- I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participating in this research project as described and understand that I am free to withdraw them at any time during the project without affecting future health care.
- I understand that some of the staff working on this project are employed by Telethon Kids Institute and are not employed by the government of Western Australia. These staff are working with the approval of the Child and Adolescent Health Service (CAHS). All staff working on this project will follow the required policies and procedures and will safeguard the confidentiality of participant information.
- I understand that I will be given a signed copy of this document to keep.

OPTIONAL CONSENT

☐ I do	☐ I do not	Consent to the storage of my / my child's lung function data for use in future ethically approved research projects (related to this project/disease)
☐ I do	☐ I do not	Consent to being contacted for future ethically approved research.

Name of Child/Mature Minor _____

Signature of Child _____ **Date** _____
(optional)

Signature of Mature Minor: _____ **Date:** _____

Name of Parent (please print) _____

Signature of Parent _____ **Date** _____

Declaration by Study Doctor/Senior Researcher†

- I have given a verbal explanation of the research project, its procedures and risks and I believe that the parent/guardian has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ **Date** _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Form for Withdrawal of Participation – Parent/Guardian

Title	*WA Paediatric Bronchiectasis Cohort Study*
Project Sponsor	*Telethon Kids Institute*
Coordinating Principal Investigator	*A/Professor Andre Schultz*
Location	*Perth Children's Hospital*

Declaration by Parent/Guardian

I wish to withdraw my child/myself from participation in the above research project and understand that such withdrawal will not affect their routine treatment, relationship with those providing treatment or relationship with *Perth Children's Hospital.*

Please indicate below if you would like any data collected as part of your child's involvement in this study to be destroyed:

☐ *Yes, please destroy my/my child's data.*

☐ *No, please retain my/my child's data for future analysis.*

Name of Child/Mature Minor _____

(please print)

Signature of Mature Minor _____ **Date**

Name of Parent/Guardian _____

(please print)

Signature of Parent/Guardian _____ **Date**

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the parent/guardian of the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher†
(please print) _____

Signature _____ **Date** _____

† A senior member of the research team must provide the explanation of, and information concerning, withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.