

Participant Information Sheet/Consent Form – Adolescent

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

1 Introduction

You have been invited to take part in this research project, “WA Paediatric Bronchiectasis Cohort Study”. It is a project hoping to let us learn more about how a lung condition called bronchiectasis develops during childhood. To do this, we also need information about the lung function of healthy children.

The next few pages will talk you through what the project involves. You can then be a part of the decision to take part if you like. Feel free to ask any questions about anything you don't understand or want to know more about.

Don't feel pressured to decide right away. You can take your time to think about it, talk to your parents or guardians, friends or even doctor.

Being a part of this project is voluntary. This means that if you don't want to take part, you don't have to. Whatever decision you make, you will still receive the best possible care through your usual clinical team.

You will be given a copy of this Participant information sheet to keep.

2 Why are we doing this research project?

Bronchiectasis is where the breathing tubes in the lungs get damaged and can cause those affected to be unwell. It can cause a cough that sounds wet, the coughing up of phlegm that can be yellow or green, or shortness of breath and tiredness.

There has been very limited research into the changes that occur over time in children and young adults with bronchiectasis. Therefore, there is a need to better understand the disease, how it affects lung

function and what causes sudden increases in symptoms or “flare-ups” (exacerbations) which often need a stay in hospital. This may enable us to help find the best treatments.

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 you, we will be able to compare the results from 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 would you need to do?

If you choose to participate in this study, we will ask you to visit Perth Children’s Hospital (PCH) once every 6 months, for 5 years. At each visit we will ask you to perform some breathing tests. These are described in more detail below.

Lung Function Tests

Multiple Breath Washout (MBW): This test tells us how evenly gases mix in your lungs and how well air moves to the smaller, outer airways. We will ask you to do normal breathing of 100% oxygen through a mouthpiece. The 100% oxygen does not taste or feel any different to normal air but may make the mouth feel a bit dry. This test requires at least two trials of a few minutes each, to be performed.

Plethysmography: This test measures how much air you can hold in your lungs. We will ask you to wear a nose clip and sit in a see-through box which looks like a phone booth, with the door closed. You will then be asked to breathe or pant into a mouthpiece. This test takes about 5-10 minutes to perform.

Spirometry: This test measures how much air you breathe in and out. We will ask you to wear a nose clip and breathe normally through a mouthpiece. After a couple of normal breaths, you will be asked to breathe in as much air as you can and then slowly exhale all the air. This process lasts for 1-2 minutes and will be repeated 3 times.

4 Do you have to take part in this project?

Being a part of this project is voluntary. This means that it is your choice to take part. If you don’t want to, then you don’t have to. This also means that if you agree but later change your mind, then that is okay too.

5 What are some possible benefits of taking part?

Although there may be no direct benefits in taking part in the study, we hope that the project will help with the care we can give to children with bronchiectasis in the future.

6 What are some possible risks of taking part?

There are no risks associated with the lung function tests in this study. The gas used in MBW may make your mouth feel a bit dry. If you suffer from claustrophobia (a fear of small spaces) the see-through body box may make you feel a bit anxious.

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

You can stop taking part in this 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 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 the results of this research project?

The results of this research will be published and/or presented and shared in a variety of ways including publications in journals, presentations at conferences and with consumers within the bronchiectasis consumer reference group. Any information that is shared is provided in such a way that you will not be able to be identified, except with your permission.

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.