



PARTICIPANT INFORMATION SHEET

– Children –

Title	Reducing Asthma-Related Hospitalisation and Mortality – Phase 3
HREC Reference Number	HREC/17/WCHN/185
Project Sponsor	Asthma Australia / Fay Fuller Foundation
Principal Investigator(s)	Ms Zoe Kopsaftis, The Queen Elizabeth Hospital, SA Dr Antony Veale, The Queen Elizabeth Hospital, SA
Associate Investigator(s)	Ms Binh Truong, The Queen Elizabeth Hospital, SA
Study Location	The Queen Elizabeth Hospital (TQEH), SA

1. Introduction

You are invited to join in this study which is looking at reducing the number of times people who have asthma have to go to hospital because they can't breathe. We chose you because you went to the hospital for your asthma not long ago or your local doctor is part of this study. Your name, the name of your Mum or Dad or the person who looks after you, your address and phone number was given to us by one of the doctors at the hospital you went to.

This document tells you about the study and explains what you will need to do if you decide to join in. Knowing what you need to do will help you to decide if you want to take part in this study.

Please read this carefully. If there is anything that you don't understand or want to know more about speak with your parents, your carer or a relative. If you still have questions after speaking with them, please phone or email the study staff whose details are provided on the last page of this document.

It is up to you whether or not you join in this study; if you don't want to take part, you don't have to. If you decide you want to take part your parents or the person who cares for you needs to sign the form which was sent with this document. If your parents sign the form, this tells the study staff that you and your parents have understood what you read and agree to take part in the study. You have agreed for the study staff to collect your information from the hospital and to ask your parents or family doctor some questions about your health.

You can keep this information sheet and a copy of the form that your parents sign.

2. Why is this study being done?

Lots of people in Australia have asthma and one in nine people in South Australia have asthma. Many people with asthma have to go to hospital because they can't breathe; 37 500 hospital visits each year are due to asthma. Australians make more hospital visits for asthma

than other countries in the world and South Australians make more hospital visits for asthma than people in other parts of Australia.

The reason for doing this study is to find out whether there are differences between people who need to go into hospital for their asthma and people who don't need to go into hospital for their asthma. We want to know more about these two groups of people, what their asthma is like and how they look after themselves. We are hoping to use what this study finds to help people with asthma stay out of the hospital as much as possible and to help the doctors and hospitals better care for people with asthma.

Because South Australians make more hospital visits for asthma than people with asthma in the other States, this study will look at people with asthma of all ages in South Australia, New South Wales and Queensland to see whether where they live has an effect on whether they need to go to the hospital for their asthma.

If people have visited one of the hospitals listed below for their asthma, we are asking them to join in this study.

- The Queen Elizabeth Hospital, Adelaide SA
- Royal Adelaide Hospital, Adelaide SA
- Women's and Children's Hospital Adelaide SA
- Concord Repatriation Hospital, Sydney NSW
- John Hunter Hospital, Newcastle NSW
- Nepean Hospital, Sydney NSW
- The Prince Charles Hospital, Brisbane QLD
- Lady Cilento Children's Hospital, Brisbane QLD
- Chandlers Hill Surgery (GP site in SA)
- Grow Medical Sherwood; Grow Medical Highgate Hill (GP sites QLD)
- Maxim Street Family Medical Practice (GP site NSW)

We want to study about 72 people with asthma in South Australia, 72 people with asthma in NSW and 72 people with asthma in QLD. Some of these people will have visited the hospital for their asthma and had to stay overnight, some will have visited and then gone home and some will have had problems breathing but not needed to go to hospital. The study wants to find out whether there are differences between the three States and differences between people who have to stay in hospital for a long time for their asthma, people who stay in hospital a short time or who don't go to hospital at all for their asthma.

This study is being organised by a group of researchers at The Queen Elizabeth Hospital in Adelaide. They have been given money by Asthma Australia to do this project.

3. If I take part in the study, what do I have to do?

You have been given this information about the study because you have recently been to one of the hospitals listed above for your asthma. If you read this information and you would like to take part in the study, you can let your parents or someone who looks after you know and they can sign the form that says you both agree to take part in the study. Once your parents or the person who looks after you has agreed and posted back the signed form, we will contact them to talk more about it.

If you both agree to join in the study, we will get some information about you from the hospital or GP practice that you went to. This information will be things like your height and weight, where you were born, where your parents are from, what year you are in at school, what asthma tests you've had, what causes your asthma, what drugs you take for your asthma, whether you have an asthma action plan, whether you've been to hospital for asthma before and what happened when most recently went to the hospital. Most of the information will be in your file at the hospital but, if we are missing anything, we will also talk to your Mum or Dad. We will ask them about how often you go to see your family doctor, if

your doctor has written down what to do if your asthma gets bad, and how you feel about using your asthma medications. We think we'll need to speak to your parents or carer for roughly one hour. If we still need more information we may also talk to your family or asthma doctor. The information we collect will be the same for everyone who takes part in the study.

Being in this study is your choice so you or the person looking after you will not get any money or reward. If you agree to be in the study but change your mind later on, you can let us know and we will stop collecting information about you.

4. Do I have to take part in this study?

It is up to you whether or not you want to take join in this study; you can say yes or no. If you say yes, your Mum, Dad or someone who looks after you should sign the form which was sent with this document and post it back to us in the envelope we've provided. If you say yes but later decide you don't want to help with the study anymore, you can let us know at any time. Whatever you decide, it will not change the way you are looked after in the hospital or by your family doctor.

5. What do I get for joining in this study?

You will not receive anything for joining in this project but we hope that the information we find will help other people with asthma live a better life and help doctors and hospitals better care for people with asthma.

6. Are there any risks involved in taking part in the study?

Nothing bad will happen to you if you agree to take part in this study. Some of the questions that we ask your parents or the person looking after you might make them think about the past and this may make them sad. They do not need to answer any questions that make them feel sad. If they become upset and need to talk to someone about it, we can help them find someone who is trained to help people who feel sad and this service will be provided for free.

7. What if I decide I don't want to do be in the study anymore?

If you agree to take part in this study but later change your mind, you can leave the study at any time. If you decide to leave, study staff will not collect any more information about you. Any information we collected before you left the study will be kept and will be part of the end results.

8. What happens when the study ends?

This part of the study will be finished by June 2020 and the entire project should be finished by June 2020. If you want to know what we find out from this study, please let one of the study staff know.

9. What will happen to information the study collects about me?

If you say yes to taking part in this study, you are saying yes to the study team gathering some information about you and your asthma from the hospital, talking to your Mum, Dad or someone who looks after you and maybe even speaking to your family or asthma doctor.

The information we collect from the hospital or from talking to your parents or carer will only be used for this study or anywhere else that you agree to, unless it is required by the law. If

you tell study staff that you are taking drugs that weren't bought from the hospital, chemist or supermarket then we will have to tell one of the doctors at the hospital you recently visited for your asthma. He/she will ring you and give you information about people you can speak to who will help you to quit drugs.

Information which is collected during the study may be checked by study staff or someone else who is not involved in the study in any way to ensure it is right. When you agree to join in the study, you are also agreeing to let someone check this information.

Study staff may talk to other people about what the study has found. This sometimes happens when researchers find something interesting and want to share it with others. Any information we share with others will not include your name or exact details about you.

You are allowed to ask us if you would like to look at any of the study information collected about you. You are also allowed to tell us if any of the information we have about you is not correct, we can change it. The people who you can talk to about this are listed at the end of this document.

Only the people involved in the research study and who know the computer password will be able to look at your information. No one else can see your information. It will be kept protected for 15 years. Your information will only be given to other people if you let us or if we need to because of the law.

10. Injury & Compensation

If you, your Mum, Dad or someone who looks after you becomes upset because of the study, one of the study staff should be told as soon as possible. The study staff will help you or them find someone helpful to talk to.

11. Who is organising & providing money for this study?

This study is run by staff at The Queen Elizabeth Hospital in Adelaide. Money has been given to the study by Asthma Australia and the Fay Fuller Foundation. None of the study staff will receive any additional money because you agree to join in this study, they will only receive their normal pay.

12. Who has checked out the research project?

Any studies about people in Australia are checked by a group called the Human Research Ethics Committee or HREC for short. The HREC from The Women's and Children's Hospital in Adelaide has checked out this study and said that it could go ahead. The study must follow rules that protect the information and rights of those people who agree to take part.

13. Research Contacts

If you have any more questions about the study or any problems about joining the study, you can phone or email one of the study team:

Name	Ms Binh Truong
Position	Study Officer, The Queen Elizabeth Hospital
Telephone	(08) 8222 7053
Email	Binh.Truong@sa.gov.au

Name	Ms Zoe Kopsaftis
Position	Study Officer, The Queen Elizabeth Hospital
Telephone	(08) 8222 7886
Email	Zoe.Kopsaftis@sa.gov.au

14. Approving HREC & Complaints Contact

If you have any problems with the study and want to talk to someone who is not part of the study team, you may call or email:

HREC Name	Women's and Children's Health Network Human Research Ethics Committee
HREC Contact	Mr Luke Fraser
Telephone	(08) 8161 6521
Email	Luke.fraser2 @sa.gov.au