PARTICIPANT INFORMATION & CONSENT FORM

– Parent/Guardian of Child–

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 take part in this research project, which is called Reducing Asthma-Related Hospitalisation and Mortality. You have been invited because your child recently had an asthma-related emergency department presentation, admission to a participating hospital, or is a patient with asthma at a participating GP practice. This letter has been sent to you from the medical staff caring for your child, who have access to your contact information.

This Participant Information and Consent Form tells you about the research project. It explains the processes involved in taking part. Knowing what is involved will help you decide if you want 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 (our contact details are listed at the end of this document). Before deciding whether or not to take part, you might also want to talk about it with a relative, friend or local health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

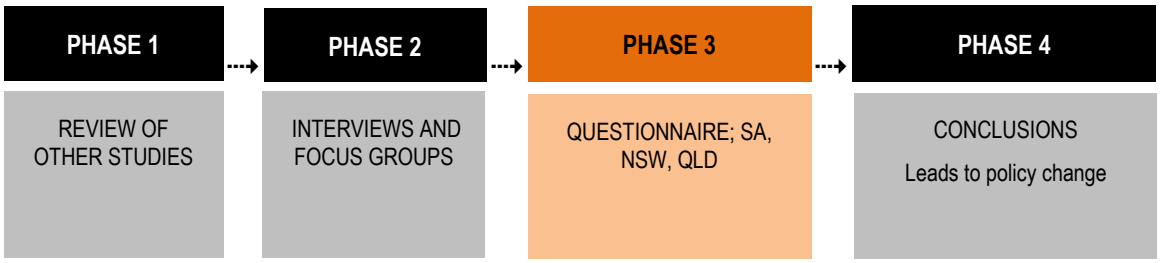
If you decide you want to take part in the research project, you will be asked to sign the consent section.
By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to be involved in the research described
• Consent to the use of your child's personal and health information as described.

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

2. What is the purpose of this research?

Asthma is a chronic respiratory disease affecting 1 in 9 South Australians, including children. Each year there are 37,500 asthma-related hospital admissions, which is high by international standards. South Australia (SA) records the highest asthma-related hospital rate per capita in the nation, as well as the highest number of deaths, although death due to asthma is a relatively uncommon event.

The purpose of this phase of the study (Phase 3) is to identify whether there are any differences between people who have been hospitalised for their asthma compared to those with asthma who have not. The researchers are interested in any differences in patient characteristics, asthma self-management strategies, asthma status, and local care practices. Findings from this study will help us improve current asthma care practices and tailor asthma management plans for people with asthma that have been identified with an increased risk for hospitalisation.



As SA records the highest asthma-related hospitalisation rate, this study will look at people with asthma of all ages in SA, New South Wales (NSW) and Queensland (QLD) to see whether location has any impact on whether they are admitted to hospital for their asthma or not.

Your child has been identified as a potential participant because they have visited one of the following hospitals or GP practices and their contact details have been kept on record:

- The Queen Elizabeth Hospital, SA
- Royal Adelaide Hospital, SA
- Women's and Children's Hospital, SA
- Concord Repatriation Hospital, NSW
- John Hunter Hospital, NSW
- Nepean Hospital, NSW
- The Prince Charles Hospital, QLD
- Lady Cilento Hospital, 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)

The researchers are looking to study approximately 72 people with asthma in metropolitan hospitals in SA, 72 in NSW and 72 in QLD. One third of these people with asthma will be those admitted to one of the above listed hospitals, another third will be those from the same hospitals who were seen in the emergency department but not admitted, and a final third will be people with asthma from one of the above listed GP practices, who have not visited a hospital within a 12 month period for their asthma. This will enable a comparison of differences between states (SA vs. NSW vs. QLD) and asthma groups (hospitalised vs. non-hospitalised vs. community).

For people with asthma aged 0-17 years (inclusive), the researchers will be contacting the parent or guardian for consent to access their child's medical information and to obtain some further information via telephone.

This study has been initiated by researchers of the Clinical Practice Unit, The Queen Elizabeth Hospital, and sponsored through grant-funding provided by Asthma Australia in conjunction with the Fay Fuller Foundation.

3. What does participation in this research involve?

You have been given this Participant Information Sheet with information about the study because you are a parent or guardian of a child who has visited one of the above listed hospitals or GP practices for his/her asthma. If, after reading this information form, you are comfortable agreeing to participate in this study you may provide your written consent at the end of this form and return it using the enclosed reply paid envelope. When the researchers receive this consent they will contact you by telephone to introduce themselves and discuss the project with you at this time.

If you choose to consent to participate in this study, the researchers will be collecting data from your child's medical records which are held at one of the listed hospitals or General Practices in SA, NSW or QLD. This data relates to your child's height and weight, where they were born, their parents cultural background, schooling details, what diagnostic tests they've had for asthma, what triggers their asthma, their medications, whether they've an asthma action plan, how their asthma is managed, whether they've been to hospital for asthma previously and information relating to their recent emergency department visit. Most of this information will be available from the hospital or GP medical records and the research team will be recording this directly from the hospital database. However, the researchers will also be contacting you via telephone to collect any data that couldn't be found in your child's medical records. For example, the researchers may ask you how often your child visits the General Practitioner for an asthma review or how confident you are in your child using their prescribed inhalers. The researchers expect this phone call should take around one hour but this may be shorter or longer depending on the information the researchers still need to collect. The researchers may also contact your child's listed GP or Specialist to answer any questions which remain unanswered.

All the information the researchers are collecting for this study will be based on a standardised written questionnaire, all participants are asked the same things. If any information does not apply to your child or does not exist (eg. smoking history or lung function test results) these will be left blank and the researchers will analyse the other information they were able to obtain. If you are uncomfortable answering certain questions relating to your child's health, you can refuse to answer, your right to do so will be respected by the research staff and you will not be required to provide a reason.

4. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. As participation is voluntary, you will not be paid for answering questions over the phone.

If you decide to participate in this study but later change your mind, you are free to withdraw from the project at any stage, even after consent has been provided.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your child's routine care, his/her or your relationship with professional staff or with the SA/NSW/QLD Health, its institutions, the Asthma Australia, or Fay Fuller Foundation.

If you do decide to take part, please sign the Consent Form below and return it to us in the supplied reply paid envelope. You may retain the Participant Information component of this form for your records. If you would like, the researchers may provide you with a copy of your

signed Consent Form via mail or email for your record also, although the researchers will retain the original copy.

5. What are the possible benefits of taking part?

There will be no direct benefit to you or your child from participation in this research.

The researchers hope the study will benefit the South Australian healthcare system and asthma community, by helping us to better understand why rates of asthma hospital admission for South Australia are the highest in the country compared to other states and territories.

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

The researchers do not anticipate any risk in you or your child taking part in this study. However, some of the questions the researchers ask over the phone may trigger past events that are stressful or upsetting. If you feel that some of the questions asked are stressful or upsetting, you do not have to answer those questions. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified personnel who are not members of the research team and this counselling will be provided free of charge.

7. What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time.

If you decide to leave the research project, the researchers will not collect additional information about your child, although information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results.

8. What happens when the research project ends?

It is anticipated that this component (Phase 3) of the study will be completed by June 2020. It is anticipated the entire study (Phases 1-4) will also be completed by June 2020.

If you wish to be advised of the results of this study please inform a member of the research team who contact details are provided below.

9. What will happen to information about my child?

By signing the consent form you consent to the research team collecting and using your child's personal information for the research project.

Your child's information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. If you indicate your child has been a recreational drug user in the past, the researcher is obliged to inform the Study Investigator of the hospital which your child attended for their most recent asthma emergency. The investigator will phone you at a later date and provide you with information about relevant local counselling or quitting services which you can pass onto your child. Information about your child's use of recreational drugs will be recorded for the purpose of the study and will remain confidential, it will not be documented on their hospital records by study staff.

Any information obtained during the research project is subject to inspection (for the purpose of verifying the procedures and the data) by the relevant research personnel, the institution, the human research ethics committee, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

All information collected will be de-identified and grouped in such a way that your child health data cannot be identified. The results of this research project may be published and/or presented in a variety ways, in scientific journals, at conferences, or through the media. Any information that is published or presented will not be identifiable.

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

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. All study documentation will be retained in a confidential, password protected file for 15 years in accordance with state and national guidelines. This file will only be accessible by the research team. It will be disclosed only with your permission, or as required by law. Therefore, sensitive personal information such as drug use will not be disclosed to any parties without your permission, or as required by law.

10. Injury & Compensation

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

11. Who is organising and funding the research?

This study is being conducted by researchers of The Queen Elizabeth Hospital, and has been funded by Asthma Australia and the Fay Fuller Foundation.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

12. 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 HREC of The Women's and Children's Health Network, SA.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

13. Research Contacts

If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact one of the research team:

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

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

14. Approving Ethics Committee & Complaints Contact

If you have any complaints about any aspect of the project, and wish to speak to someone independent of the research team, you may contact:

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

CONSENT FORM

– Parent/Guardian of Child –

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Declaration by Participant

1. I have read the Participant Information Sheet or someone has read it to me in a language that I understand. I understand it and agree to take part.
2. I understand the purposes, procedures and risks of the research described in the project.
3. I have had an opportunity to ask questions and I am satisfied with the answers I have received.
4. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.
5. I understand that I will be given a signed copy of this document to keep.
6. I understand that neither I nor my child will directly benefit by taking part in this study.
7. I understand that I can withdraw from the study at any stage and that this will not affect mine or my child's treatment or relationship with SA Health, its organisations, the Asthma Australia, or Fay Fuller Foundation.
8. I understand that there will be no payment to me for taking part in this study other than travel or car parking reimbursements.
9. I have had the opportunity to discuss taking part in this research project with a family member or friend.
10. I am aware that I should retain a copy of the Participant Information and signed Consent Form.
11. I understand that my child's medical records will be accessed and his/her General Practitioner or Specialist may be contacted.
12. I understand that the personal information I provide about my child will be kept confidential as explained in the information sheet except where there is a requirement by law for it to be divulged.

Name of Participant (please print) _____ Born: / /

Permission to participate granted by _____
(Parent / Guardian Name)

Signature _____ Date _____

Declaration by Researcher†

I have given a verbal explanation of the research project and its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† A member of the research team must provide an explanation of, and information concerning, the research project. ***Note: All parties signing the consent section must date their own signature.***