



PARTICIPANT INFORMATION & CONSENT FORM

– Adults –

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 you recently presented to the Emergency Department with asthma, were admitted to hospital or are a patient with asthma at a participating GP practice. This letter has been sent to you from the medical staff at the medical institution caring for you, 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 (contact details for the researchers are detailed at the end of this document). Before deciding whether or not to take part, you might 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:

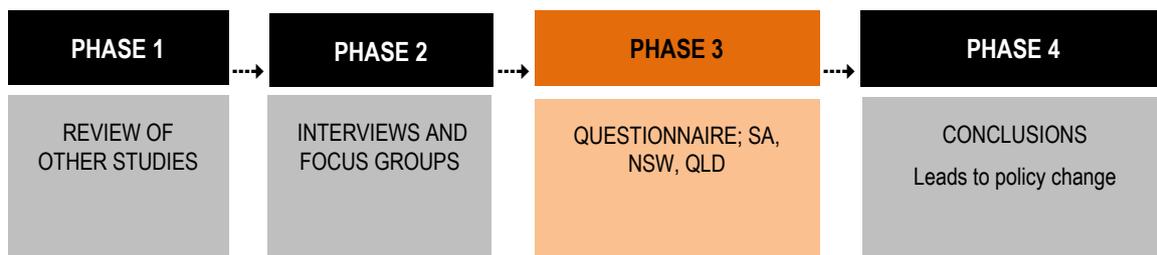
- Understand what you have read
- Consent to take part in the research project
- Consent to be involved in the research described
- Consent to the use of your personal and health information as described.

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 hospitalisation 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 who have not been hospitalised for asthma. 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 to 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.

Participants for this study have been targeted because they have visited one of the hospitals or GP practices listed below 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 hospitals listed above, another third will be those from the same hospitals who were seen in the emergency department but not admitted and the final third will be people with asthma from one of the GP community practices listed above, 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).

This study has been initiated by researchers of the Clinical Practice Unit, The Queen Elizabeth Hospital, SA and sponsored through 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 have visited one of the hospitals or GP practices listed above for your asthma. If, after reading this information form, you are comfortable agreeing to participate in this study please complete the consent section 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.

If you choose to consent to participate in this study, the researchers will be collecting demographic, occupational data, smoking, substance and alcohol use, asthma history and self-management processes, medication compliance, environmental and occupational exposure to triggers, results of respiratory tests, whether an asthma action plan exists, details on hospital admissions over the previous 24 months, details about the most recent ED presentation and inpatient treatment (if any), discharge plan details and subsequent admission up to 90 days after study event from your medical records. data and medical information from your medical records at one of the listed hospitals or GP practices in SA, NSW or QLD. Researchers will be collecting information about your medical history, any health professionals you have seen for your asthma, and how you manage your asthma. Most of this information will be available from your hospital or GP medical records. Researchers will phone you to ask about any information they could not source from your hospital or GP records such as height and weight, age, allergies, asthma triggers such as smoking, and other health conditions. The researchers may also ask you how often you visit your GP for an asthma review, whether you have an asthma action plan, or how confident you are in using your prescribed inhalers. This phone call should take around one hour but may be shorter or longer depending on the information the researchers still need to collect. The researchers may also contact your GP or Specialist to fill in any information gaps.

All the information the researchers are collecting for this study will be based on a standardised questionnaire so all participants are asked the same things. If any information is not applicable or does not exist such as 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 do not wish to answer certain questions, 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 your time on the phone.

If you decide to take part and 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 routine care, your relationship with professional staff or your relationship with the SA Health, its institutions, Asthma Australia, or the Fay Fuller Foundation.

If you do decide to take part, please sign the Consent Form below and return it to us in the enclosed 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, though the researchers will retain the original copy.

5. What are the possible benefits of taking part?

There will be no direct benefit to you from participating 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 taking part in this study. However some of the questions the researchers ask over the phone may trigger memories of 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. 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 from you, 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.

9. What will happen to information about me?

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

Your 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 to one of the researchers that you have used recreational drugs in the past, the researcher is obliged to inform the Study Investigator of the hospital which you attended for your asthma emergency. The investigator will phone you at a later date and provide you with information about relevant local counselling or quitting services. Information about your use of recreational drugs will be recorded for the purpose of the study and will remain confidential, it will not be documented on your 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.

The results of this research project may be published and/or presented in a variety of forums (i.e. journals, conferences, media). In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

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

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 third 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, SA 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

– Adults–

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Associate Investigator(s)	Ms Binh Truong, The Queen Elizabeth Hospital, SA
Study Location	The Queen Elizabeth Hospital (TQEH), SA

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 I may not 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 my 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 medical records will be accessed and my General Practitioner and/or Specialist may be contacted.
12. I understand that the personal information I provide 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	
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.**