PARENT INFORMATION SHEET

Principle investigators:

Professor Jeroen Douwes - Centre for Public Health Research, Massey University

Professor Julian Crane - Wellington Asthma Research Group, University of Otago, Wellington

Dr Patrick Biggs - Institute of Vet, Animal & Biomedical Sciences, Massey University

Dr Thorsten Villiers Stanley - Department of Paediatrics and Child Health, University of Otago, Wellington

Dr Collin Brooks - Centre for Public Health Research, Massey University

Professor Graham LeGros - Malaghan Institute of Medical Research, Victoria University

Professor Neil Pearce - London School of Hygiene and Tropical Medicine, UK

Dr David Murdoch - Pathology, University of Otago, Christchurch

Professor Monica Innes Asher - Paediatrics, University of Auckland

Professor Peter Gibson - Airway Research Centre, Respiratory and Sleep Medicine, Hunter Hospital, Newcastle, Australia

What is this study about?

We would like to invite you and your child to participate in a research project that will assess the role of airway bacteria in the development of childhood asthma. Previous studies of airway bacteria suggest that changes in the types of bacteria may lead to chronic lung diseases later in life. This study will investigate the differences in the airway bacteria of asthmatic children with low lung function and asthmatic children with normal lung function. Participants will then be compared to a control group of non-asthmatic children with normal lung function.

We would therefore like to invite your child as one of 160 asthmatic and 80 non-asthmatic children to take part in this study which will help find the role of bacteria in the airway. This study will provide important new knowledge to help us and other asthma researchers to develop effective strategies to prevent asthma and contribute to improved treatment options for all asthmatics.

What will my participation involve?

Phase I: *All participants*

Participation in the screening phase of the study consists of two steps:

Step I - Parents fill out the screening questionnaire. This survey may take 5-10 minutes to complete.

Step II - Child undergoes a non-invasive lung function test. This may take 20 minutes to complete and includes the inhalation of Ventolin (salbutamol).

Based on the responses to the questionnaire, we will then contact selected participants and ask them to take part in some further tests at our study centre. Please note only a few participants will be selected for phase II and complete the phase II tests.

Centre for Public Health Research

Massey University – Wellington Campus

PO Box 756
Wellington, 6140
New Zealand

Administration
+64 (0)4 979 3106

Direct Fax
+04 802-7120

Courier Address
Block 3, Level D
Entrance B, Wallace Street
Wellington, 6021
New Zealand

Internet
publichealth.massey.ac.nz

Facebook
@CPHRMassey

Jean Feary Mckenzie
0800 080 078
asthma@massey.ac.nz

Christoph Martens
+64 (0)4 979 3173
c.martens@massey.ac.nz

Dr Collin Brooks
+64 (0)4 979 3093
c.r.brooks@massey.ac.nz

Phase II: *Selected participants*

Once Phase I is completed, and we have your child's completed confidential questionnaire and lung function results, **we will invite 160 asthmatic and 80 non-asthmatic participants for a further assessment at our study centre.** We will also ask participants to fill out a more comprehensive questionnaire that may take up to 15-20 minutes to complete. Please note that we will exclude those who no longer have asthma symptoms (based on the screening questionnaire). The tests may take up to one-and-a-half hour and can be done at a time that is convenient for you and your child. The visit will involve:

An exhaled NO (FeNO) test to assess airway inflammation, which involves blowing into a specialised machine for several seconds.

A skin prick allergy test on the arm. To do this, we apply small drops of liquid on the skin of the forearm and then administer a small prick (this is almost painless, and just enough to break the skin) onto each drop of allergen to see if there is an allergic reaction. Trained personnel will conduct the test. Some topical forearm itching may occur with a positive skin prick test. Apart from an insect bite-like reaction (if the test is positive) adverse reactions to skin prick testing are extremely rare. Using our skin prick test technique, no serious (systemic) allergic reactions have been reported despite extensive use in large groups of children.

A lung function test involves blowing into a specialised machine as hard as the participant can for a few seconds. The results of the lung function test are available immediately after the test is completed. It may provoke a short period of slight breathlessness, although generally this test will cause no discomfort.

An airway hypersensitivity and sputum induction test involves breathing a fine mist of a saline solution (similar to sea water). After some time (up to 11.5 min) of inhaling the saline, your child will start coughing and we encourage this. We want to obtain coughing products (sputum) in order to analyse its content. The sputum induction procedure may cause mild irritation to the back of your child's throat and also has the potential to cause a small drop in your child's lung function. If this occurs, we will ask them to inhale some salbutamol (a common asthma medication that opens up the airways). Your child's breathing will be observed carefully throughout this procedure and after each inhalation period (30 seconds up to 11.5 min) to ensure your child's safety. Trained personnel will administer this test and a doctor and/or nurse will be there. If for any other reason they want to stop the test, this is possible at any time.

A blood sample will be collected from your child's arm, and will be used to assess levels of proteins associated with airway inflammation. Blood collection may be slightly uncomfortable, and may result in a temporary bruise.

A nicotine hair test will be carried out on a sample of participant's hair obtained by cutting 10-50 mg of hair from the participant's scalp as close as possible to the skin. This provides information on nicotine intake and exposure to environmental tobacco smoke over a long period of time.

Stool sample collection: We will provide your child with a stool collection kit to collect a stool sample before the first visit, which they can freeze until they come in for their visit.

Phase III: *Asthmatic participants*

Sputum induction tests will be repeated after about 3 months in all asthmatics. We will follow the same safety procedures regarding your child's lung function as in the initial tests.

Who pays for the study?

This study is funded by the Health Research Council. Participation in our study will not incur any costs to your child. As a token of appreciation for participating in this study we will give a koha (or gift) of $25 to each participant taking part in Phase II. This will also help account for local travel costs.

What will happen with my personal information?

We will treat all information from the questionnaires and collected during the appointment as strictly confidential. The data from the questionnaires and tests will be seen by named researchers only. During and after completion all questionnaires will be stored in locked filing cabinets.

In the case of unexpected or "abnormal" results, we would like your permission to send your child's results to their general practitioner (GP) as they may be useful for their future medical care. We would not send your child's GP any other results from the study. The results of the study will be published in scientific journals and a summary of the results will be provided to all study participants. **No individual information or names will be published**. This project has been reviewed and approved by the Ethics Committees (Ref 16/NTB/64).

Biological samples disposal and storage:

Your child's blood samples will be disposed of by the pathology laboratory responsible following completion of analysis. We appreciate that you and your family may hold beliefs about a sacred and shared value for all or any tissue samples removed. The cultural issue associated with disposing and storing your child's samples should be discussed with your family/whānau as appropriate. Therefore, you may request that your samples are returned to you at this stage. There is a range of views held by Māori around these issues: some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose between having your samples disposed of securely or returned to you.

Future Unspecified Research:

As part of this study about the role of airway bacteria, you and your child also have the option to agree for your child's remaining collected data and samples to be used by the current research team in New Zealand for future unspecified research, and to answer any questions that may arise during the course of our study. Research will include further immunological, inflammatory, genetic, and epigenetic analysis. If you agree for the unspecified future research, your child will not need to have any additional tests.

- Your child's data and samples will be stored anonymously for up to 10 years and all future research will be subject to ethical review.
- Consenting for future unspecified research is OPTIONAL and you and/or your child can withdraw consent if you change your mind at anytime later. However, the research done on your child's remaining samples before you change your mind will not be reversed and if you consent for your child's remaining samples to be stored anonymously, you relinquish your right to withdraw consent in the future.

We will not contact you in the future regarding your child's stored biological samples. However, you can request information on the analysis of samples and information about future unspecified research at any time. Your decision regarding the consent for use of your child's tissue sample for unspecified future research will in no way affect the quality of your child's current or future clinical care. Please discuss any cultural issues associated with disposing and storing your child's samples with your family/whānau.

Your child's rights:

Your child has the right to:

- decline to participate
- decline to answer any of the questions
- stop the interview/tests at any time
- withdraw from the study or parts of the study at any time either verbally or in writing
- be given access to a summary of the study findings when it is completed

Compensation

If physical injury results from your child's participation in this study, you should visit a treatment provider to make a claim to ACC as soon as possible. ACC cover and entitlements are not automatic and your claim will be assessed by ACC in accordance with the Injury Prevention, Rehabilitation and Compensation Act 2001. If your claim is not accepted you should immediately contact the researcher. The researcher will initiate processes to ensure your child receives compensation equivalent to that to which they would have been entitled had ACC accepted your claim.

Thank you very much for your time in considering this study!

We hope that with your help we can find more innovative and safe approaches to reducing asthma in New Zealand.

For further information or to discuss any queries that you may have about the study, please contact our research team on:

0800 080 078

Email: asthma@massey.ac.nz

Centre for Public Health Research
Massey University- Wellington Campus
PO Box 756
Wellington 6014
Fax: (04) 802-7120
http://publichealth.massey.ac.nz
Facebook: @CPHRMassey