



CHILDHOOD ASTHMA PREVENTION STUDY (CAPS) 8 YEAR FOLLOW-UP INFORMATION STATEMENT FOR PARENTS

Thank you for your participation in the Childhood Asthma Prevention Study (CAPS) over the last 8 years. Now that your child is eight we would like to repeat the assessment procedures that your child had previously. These include the skin prick tests, a blood test, the health and symptoms questionnaire, and a home visit. In addition, we would like to perform a further breathing test to measure the twitchiness of the airway. Using the results of these tests and questionnaires we hope to find out if the CAPS interventions have been successful in preventing asthma.

In addition, on this occasion, we would also like to make some quick and simple measurements related to the heart health of each child. Heart disease in adult life remains a major health problem in Australia, and recent information has suggested that diet and growth in the first two years of life can be important in determining the risk of heart disease in adulthood. This would require a couple of additional tests which are all painless and safe, such as an ultrasound of the main blood vessel in the neck, using the same ultrasound equipment as is used on mothers to study their growing babies. In order to understand more about your child's growth, we would like to measure the height, weight, and waist of both his or her parents.

What does the assessment involve?

Health and symptoms questions: Your child will be examined by a nurse and you will be asked some questions about his/her health.

Skin prick tests: Most of the CAPS children would have been tested to these common allergens previously. This test causes minimal discomfort and is safe. A few small drops of allergen are placed on your child's arm. The skin is pricked lightly through the droplet. If your child is allergic, this will cause a small itchy bump (like a mosquito bite) which will usually disappear within 15 to 30 minutes.

Blood tests: We will collect a blood specimen from your child. This test will be performed by a person experienced in collecting blood from children. An EMLA patch (anaesthetic patch) will be supplied to you to put on the child's arm 1 hour before the assessment. The patch will numb the area so it is not painful. A 15 ml sample (three teaspoons) of blood will then be taken. There is a slight possibility of mild bruising at the site after collection but the bruising will disappear after 1 to 2 days. The blood will be analysed to measure factors related to allergy, asthma and diet.

Breathing tests: Your child may have had these tests done at the 5 year assessment. To assess lung function we will ask your child to breathe normally through a mouthpiece for 2 minutes. The mouthpiece is connected to an oscillator, which creates a gentle vibration in the air. Your child will breathe normally for a while then take in a deep breath before returning to normal breathing for the rest of the test. During the test we will ask your child to hold his/her hands over his/her cheeks. We will also ask your child to take a big breath and blow out hard through a tube. This is to measure his/her breathing capacity. Finally, we will also ask your child to blow, two or three times, into a bag through a tube. This is a bit like blowing up a balloon. The air in the bag will be analysed to give information about inflammation in the airways.

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Breathing test to find out if your child has twitchy or irritable airways. Your child will inhale a small quantity of methacholine, a substance like one that occurs naturally in the body, and we will measure its effect on breathing capacity. The test may cause some wheezing or chest tightness (usually in people with asthma) but these symptoms, if they occur, are relieved within ten minutes by two puffs of Ventolin™.

Blood vessel tests: To find out how healthy your child's blood vessels are, we would do an ultrasound of the main blood vessels in the neck while your child is lying comfortably on a bed in a quiet room. This is painless and takes approximately 5 minutes. We would then measure your child's pulse at the wrist using a probe that rests on your child's skin, to measure the waveform of the pulse in a very detailed way. This test also only takes 5-10 minutes.

Home visit As on previous occasions, we will ask to visit you and your child at home on one occasion, at a time that is convenient for you. During this visit we will ask some questions and make some observations about the home environment and collect some dust from your child's bed for measuring allergen levels. During this visit we will also repeat the test of breathing capacity both before and after the inhalation of 2 puffs of Ventolin. Ventolin is the puffer commonly used by children with asthma.

Parent's height, weight and waster measurement: At either the clinic or the home visit we would like to make these measurements on both parents. If this is not possible for one or other parent, we will provide you with instruction about how to do this yourself and ask if you could give us the results.

Does my child have to participate in the assessment?

Participation in CAPS is voluntary and if you decide for your child not to take part in certain procedure or if you decide to withdraw at any time this will not affect your child's care.

Will anyone else know the results of my tests?

All of the study results are kept confidential, and only the research nurses will know the results of your tests. Data obtained from these tests will be stored in a computer database that is password protected and any written copy will be kept in a locked filing cabinet. When the study is finished, a report will be written for a medical journal, but individual people will not be identified in this report. Data will be stored for at least 15 years after which they will be destroyed.

Will the assessment benefit me or my child?

We hope that this study will improve our ability to tell whether we have successfully prevented asthma or not. It may have benefited your child in some way, but we will not be able to tell this until we have analysed the results of all the children and until the last child turns 8.

What if there is a problem?

If you have a problem getting to the hospital, or keeping your appointment, please call Kitty Ng on 1 300 65 88 32 for the cost of a local call. This number will divert to the mobile but all you pay for is a local call.

The Chief Investigator for this Project is Dr Guy Marks of Liverpool Hospital and the Woolcock Institute of Medical Research. He can be contacted on 9828 4813 or via the switchboard at Liverpool Hospital on 9828 3000.

Complaints may be directed to the Ethics Secretariat, South Western Sydney Area Health Service, Locked Bag 7017, LIVERPOOL BC, NSW, 1871 (phone 9828 5727, fax 9828 5962, email: jennie.grech@swsahs.nsw.gov.au).



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Affix label here
 Label to include
 ID, name, date of birth

PARENTAL (OR GUARDIAN) CONSENT FORM

I, agree to permit, who is aged years, to participate as a participant in the study described in the Parental Information Sheet attached to this form.

I acknowledge that I have read the Information Sheet, which explains the aims and the nature of the study and the possible risks, and the statement has been explained to me to my satisfaction.

Before signing this Consent Form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm my child might suffer as a result of participation and I have received satisfactory answers.

I understand that I can withdraw my child from the study at any time without prejudice to my or my child's relationship to the Liverpool Hospital.

I agree that research data gathered from the results of the study may be published provided that neither my child nor I can be identified.

I understand that if I have any questions relating to my child's participation in this research, I may contact Kitty Ng on telephone 1 300 65 88 32, who will be happy to answer them.
 I acknowledge receipt of a copy of this Consent Form and the Information Sheet.

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Signature of parent (or guardian)

Signature of investigator

Please PRINT name

Please PRINT name

Date

Date

CAPS

Signature of parent (or guardian)

Signature of investigator

Please PRINT name

Please PRINT name

Date

Date