North West Lung Research Centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
M23 9LT
Tel. 0161 291 5036
Email: maasteam@manchester.ac.uk

Manchester Asthma and Allergy Study (MAAS)

Age 25 plus follow up

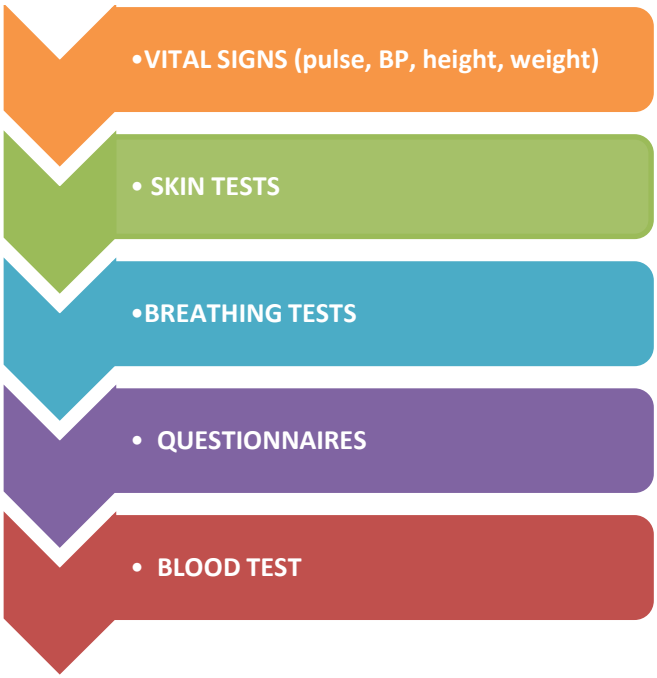
Participant Information Sheet (PIS)

- You are being invited to take part in a research study investigating the development of asthma and allergies.
- Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve.
- Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish.
- Please ask a member of the research team if there is anything that is not clear or if you would like more information.
- Your participation is entirely voluntary, so you do not have to take part if you do not want to.
- Thank you for taking the time to read this.

What would my involvement be?

- Taking part involves **1 visit** to the hospital **for up to 2 hours** and will be similar to previous appointments you have had over the years.
- If you agree to take part, you will be asked to sign a consent form. You do not have to consent to all aspects of the study - you can opt out of any of the tests. You will receive a copy of the consent form and this information sheet to keep.
- We would like you to do some breathing tests (that you may have done before), skin prick tests and a blood test. We will also ask you to complete some questionnaires.
- Your GP will be informed of any clinical results with your consent.
- With your consent, we would like to ask your GP for details of your medical and prescribing history.
- If you are on inhalers, you will be asked **not to take your inhalers for 4 hours before the test**, or 12 hours if you use long acting inhalers, if possible. You will also need to **refrain from using antihistamines for 72 hours**, if possible. We ask that you do not eat or drink anything (except plain water) for two hours before your visit.
- As previously, we would ask that you attend Wythenshawe Hospital for a Clinic Visit. Car Parking is free, travel expenses are available, and a small gift token will be given at the end of the visit. If this is not possible, we may be able to offer you a Home Visit, where we can complete some of the tests. If neither of these options are possible, we can offer an Online Visit (or postal).

The diagram below shows a brief outline of what will happen during the Clinic Visit if you choose to take part:



VITAL SIGNS

We would like to measure your blood pressure, pulse oximetry, heart rate, height and weight.

SKIN PRICK TESTS

Skin prick tests provide us very useful information about sensitisation that may lead to allergies and asthma. At this visit we would like to test you against airborne and food allergens (including house dust mite, cat, dog, grass, trees, mould, milk, egg, peanut, hazelnut, walnut, Brazil nut, cashew and peach). You may have some itchiness, redness and/or swelling at the site of the skin test but if this develops, we will offer you some antihistamine cream to treat the symptoms.

BREATHING TESTS

Spirometry

You will be asked to breathe in as deeply as possible and then blow into the machine as hard and long as you can so that we can measure your lung capacity and measure how much flow they generate when blowing hard, so that we can determine whether there is any airflow obstruction.

Exhaled Nitric Oxide

Measuring the amount of nitric oxide in the airways tells us whether there are any signs of inflammation in the lungs. You will be asked to do a long blow into our machine for about 10 seconds and keep a picture of a cloud in the middle of a square.

Impulse Oscillometry

This test uses sound waves at different frequencies to measure the resistance in your airways. You will be asked to breathe normally into a handheld machine and may feel a slight vibration as the sound waves are sent. Each measurement only takes about 2 minutes, and we will do 3 measurements so the whole procedure will take a maximum of 10 minutes in total.

Airway Resistance and lung volumes

This test is designed to see whether there are any signs of tightness in your chest, and to measure your total lung capacity. You will be asked to sit in a large Perspex cabinet and will need to use a mouthpiece and a nose clip during the test. You will be asked to breathe normally for a few breaths, then asked to pant against a shutter for about two seconds so we can measure the pressure generated while breathing. You will then be asked to breathe in as much as you can, then out as much as you can, so we can measure the lung volume. This will be done three times.

Reversibility

At the end of these tests, we will give you four puffs of an asthma inhaler (salbutamol), wait for 15 minutes, and then repeat your spirometry and body box tests once again to determine whether it improves your lung function.

QUESTIONNAIRES

General health and respiratory symptoms

As you have done previously, we will ask you to complete a questionnaire to assess your general health and development which are important in identifying risk factors for asthma and allergy. Wherever possible the questionnaire will be answered directly on to the computer. We will also ask questions about respiratory symptoms, such as coughing and wheezing. We would also like to collect information about current and previous prescriptions relevant to asthma, allergies and respiratory diseases, and hospital admissions. The easiest way to do this may be through your NHS App, and we would ask that, if possible, you have this available during the study visit, so that you can check the answers to the questions.
We have developed a short questionnaire about where you lived and where you went to school during childhood, so that we can do further work on exposure to pollutants and the effects on lung function and asthma. If you are not sure, it would be helpful if you could check with family members before you attend the visit. We will also ask you to complete a short questionnaire about symptoms of attention deficit hyperactivity disorder (ADHD), as this has been linked to asthma and allergies in other studies.
We will also ask you to complete an Equality, Diversity and Inclusion (EDI) survey, which is anonymous and optional and will not be linked in any way to other research data collected in this study. We are collecting this data to help us comply with our policy of ensuring equality, diversity, and inclusivity in our work. By answering this questionnaire, you will help us to ensure that the work we do is as inclusive as possible.
We also ask permission to collect information about medical history and prescribing data from your GP record.

BlOOD TESTS

We will ask to take up to 20mls (4 teaspoons) of **blood**. This will be collected by a nurse or a fully trained research practitioner. Occasionally a slight discomfort is felt, and bruising can occur where the blood is taken. We will do a full blood count and the results of this will be sent to your GP (with your permission). We will measure allergy antibodies, molecules in the blood that may predict asthma and allergies, and markers of exposure and inflammation.
Samples will be coded, processed and securely stored in the North West Lung Research Centre but may be batched and sent to other laboratories for analysis, together with coded data, with no personal identifiable information attached (lung function results, allergy test results and clinical outcome results such as whether or not you have asthma). We are collaborating with several other academic institutions (including the University of Arizona, USA) to find new markers which may help with the diagnosis of asthma and allergies. No identifiable data about you will accompany these samples and there will be no way that any unauthorised person will know the identity of individuals taking part.
As this study is at the forefront of research, we would like to store a portion of your samples for use in the future as new areas of interest in asthma and allergy research are identified. To allow us to do this we are asking you to “gift” your samples to us for research purposes. At the end of the study, it will be adopted by a research tissue bank:- Manchester Allergy, Respiratory and Thoracic Surgery (ManARTS) Biobank REC: 20/NW/0302, IRAS: 285126 North West - Haydock Research Ethics Committee). This will facilitate further sample analysis and data analysis within a research ethics and governance framework.

Occasionally having blood taken can cause minor discomfort and sometimes slight bruising which should resolve in a few days. Some people may feel faint, in which case our research staff will treat you appropriately until you feel better.

With your consent, a summary of your lung function and skin tests results will be sent to your GP and you will also receive a copy

Home Visits

If you are unable to attend for a clinic visit and we are able to offer a home visit instead, we will ask that you complete the questionnaires. Wherever possible the questionnaires will be answered directly on to the computer, but paper versions will be available as an alternative. We will complete vital signs and offer skin prick tests to airborne allergens (foods will be omitted). For breathing tests, we will offer spirometry and FeNO and the reversibility test for spirometry. We will ask that you have the blood test.

Online (or postal) visit
If it is not possible to arrange a clinic visit or a home visit, we can arrange for you to do an Online visit. We will send a link to complete an electronic consent form and to complete the questionnaires (or send a pack of questionnaires to you with a stamped addressed envelope for you to return them). In addition, we may ask that we can post a spirometry machine to you so that you can do this lung function test at home. We will arrange live video training for this. We will supply packaging so that you can return the spirometer to us when you have competed the test.

About the research

Who will conduct the research?

This study is being carried out by a team of trained doctors, nurses and researchers under the supervision of Professor Clare Murray (the principal Investigator and Professor of Respiratory paediatrics) and Professor Angela Simpson (co-investigator and Professor of Respiratory Medicine) at the University of Manchester and Manchester University NHS Foundation Trust (MFT).

The study is funded by the North West Lung Centre Charity, the National Institute for Health and Care Research (NIHR) Manchester Biomedical Research Centre (UK) and the National Institute for Health (USA). The project has been reviewed by NHS Research Ethics Committee [to be completed after approval]

What is the purpose of the research and who can take part?

The Manchester Asthma and Allergy Study (MAAS) is a research project investigating the development of asthma and allergies. You are one of approximately 1,100 people who have been involved in this project since 1995. Having so many young people continuing to take part in this study is providing invaluable information about how asthma and allergies develop and change, during childhood into adulthood. We are extremely grateful for your help and support so far. We would now like to invite you to come for another review at the North West Lung Research Centre, Wythenshawe Hospital (MFT).

How will we use information about you?

We will need to use information from you and from your medical records from your GP for this research project.

This information will include your:

- your name
- address
- contact details
- date of birth
- ethnicity
- record of consent
- name of your GP practice
- medical history information from your GP records (with consent for our access)
- responses to questionnaires as described above

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University of Manchester is the sponsor of this research.

The University of Manchester is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Individuals from The University of Manchester, NHS Trust or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

<u>We will keep all information about you safe and secure by:</u>

The study team will store your identifying information (name and contact details) securely and separately from your study data. Your data will be marked with an ID number and not your name. The key for linking your ID number to your identity will be accessible only to the research team and will not be stored with the data which has your ID number present. As this study is linked to previous studies and information you have provided to us we are unable to destroy the link between your name and study ID, this is to enable us to link the data that you have provided previously, presently in this study, and in future follow up studies should you wish to take part in these.

If you complete the questionnaires online and not at the hospital with a member of the study team then we will need you to complete these with your name so that we can link these to your data. Once we receive the questionnaires we will remove your name and replace them with your ID number This will be done as soon as possible and within 7 days.

The only document to have your name on that will be kept for the purposes of this study will be your consent form.

Your consent form will be retained for 2 years after the end of the study in a locked cabinet on UoM premises. At the end of the study, it will be adopted by a research tissue bank:- Manchester Allergy, Respiratory and Thoracic Surgery (ManARTS) Biobank REC: 20/NW/0302, IRAS: 285126 North West - Haydock Research Ethics Committee) and the signed consent form will be passed to them for secure storage at MFT for 20 years

We are collaborating with several other academic institutions and will be providing data to them for the analysis for this study. The information we provide to them will not identify you and will not be combined with other information in a way that could identify you. This data will be linked to your name however none of these researchers will have access to the key that links your name to the data so it will not be identifiable by them, to you. This data will be transferred to other researchers using University approved secure file transfer protocols. The information will be used for the purpose of studying risk factors for asthma and allergies and cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you.

We may share data about you outside the UK for research purposes related to:

- study risk factors for asthma and allergies

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. If your data is shared outside the UK, it will be with the following sorts of organisations:

- academic institutions (including the University of Arizona, USA)

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

At the end of the study data will be stored for up to 10 years for analysis. We will deposit a fully anonymised dataset in an open data repository where it will be permanently stored.

What are your choices about how your information is used?

- you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- you have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. We will use Figshare. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results. The data will also be adopted by a research tissue bank (along with your samples, as described in the tissue section) to facilitate ongoing future analysis under a research ethics and governance framework.
- With your consent, we would also like to retain your contact details for 15 years in order to inform you about future studies that you may be interested in. You can opt out of this when signing the consent form. If you provide consent for this, your details will be safely stored on UoM servers in a digital folder only accessible to the study team and used only for the purposes described above.

Where can you find out more about how your information is used?

You can find out more about how we use your information by consulting our Privacy Notice for Research. http://documents.manchester.ac.uk/display.aspx?DocID=37095

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- our leaflet [**www.hra.nhs.uk/patientdataandresearch**]
- by asking one of the research team
- by sending an email to [**maas@manchester.ac.uk**], or

- by ringing us on [**01612915036**].

Will the outcomes of the research be published?

The findings from the study will be published in medical journals and presented at local, national and international academic meetings. Published results will not contain any names or addresses of study participants and all your information will be anonymised. **Results of the study will be available at https://www.maas.org.uk**

What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form/provide online consent if not taking part in the face to face activities.

If you decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself. If you wish to withdraw from the study at any time, please contact the study team via email at the address in the **Contact Details section** on the following page. However, please note that if you do withdraw then data and tissue already collected in this study would be retained for the purposes of the research.
If you decide not to take part, you do not need to do anything further.

What if I want to make a complaint?

If you have a complaint that you wish to direct to members of the research team, please contact: PROFESSOR CLARE MURRAY clare.murray@manchester.ac.uk or telephone 01612915871

If you are not satisfied with the response you receive or your wish to make a formal complaint to someone independent of the research team, please contact: The Research Ethics Manager by emailing research.complaints@manchester.ac.uk or by telephoning 0161-306-8089

Harm

In the unlikely event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s) **maas@manchester.ac.uk, or telephone 01612915036**