

## Patient Information sheet

Title of Project: **PAFA-Stage 2: Patterns and prevalence of adult food allergy in a UK population (Stage 2)**

<Trust/Site address 1>

<postcode>

<Trust/Site address 2>

<postcode>

Tel: <telephone number>

Name of Researcher:

**Professor Angela Simpson [Study site 1 - Manchester] or Professor Graham Roberts [Study site 2 - Southampton and Isle of Wight].**

**Please read the following information which will help you to decide whether or not to take part in the study**

### Why are we doing the research?

Many people in the UK suffer from food allergies and intolerances, which cause problems for them and their families when choosing what to eat. Although this is well recognised in children, it affects many adults too. We would like to find out how many adults in the UK aged 18-70 years have food allergies and intolerances, so we can help them to avoid their problem food(s) and live a better life.

### Why am I being asked to take part in this research?

You have previously completed a questionnaire for Stage 1 of the PAFA study and agreed to be contacted for Stage 2. We would like to arrange a visit, so that we can ask more questions about food and health and do some allergy tests.

### Do I have to take part?

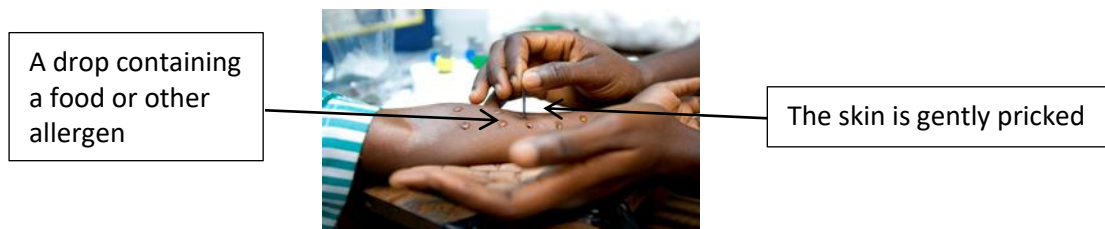
No. It is entirely up to you to decide - joining the study is entirely voluntary. If you don't want to take part, that's OK. Your decision will not affect the quality of care you receive. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please feel free to talk to others about the study. If you decide that you would like to withdraw from the study at any point, just let the study team know.

### What happens if I agree to take part?

If you agree to take part, we will book you an appointment to come for a PAFA visit [local address here] at a time convenient to you. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We will then ask you to complete a questionnaire about food and allergies using a touch-screen computer or tablet, followed by allergy tests. The visit will take about 1 hour.

## Allergy tests

**Skin prick test** - we will check if you have a possible allergy to peanut, hazelnut, Brazil nut, cashew nut, walnut, almond, egg, milk, sesame, cod, shellfish, house dust mite, grass pollen and birch tree pollen with a skin prick test. Each allergen will be tested by putting a drop of reagent onto your forearm and gently pricking through it into the surface of the skin. If you develop a small itchy bump on your skin where it was pricked with the individual food or pollen, you might have an allergy to that food or pollen. The itching goes away quickly but, if needed, we will put some anti-histamine or steroid cream on the skin.



We will take a photograph of your forearm to record the test result.

**Sample of blood** - some people have signs of possible food allergies in their blood. We will collect a small sample of blood (about a tablespoon) which will be used to measure allergy levels (antibodies) to peanut, Brazil nut, hazelnut, walnut, cashew nut, almond, shrimp, blue mussel, cod, peach, cow's milk, hen's egg, birch tree pollen, grass pollen and house dust mite. The blood sample will be sent to the Amsterdam University Medical Centre (AMC) in the Netherlands where the measurements will be done. If the food that you have reacted to is not on this list and an allergy test is available to that food, we will arrange that test as well. We will also store some blood at either Manchester University NHS Foundation Trust or the Isle of Wight NHS Trust for future analysis, including DNA. Your blood contains DNA, which makes up the genes that serve as the "instruction book" for the cells in our bodies. Analysing your DNA (also called genetic testing) will help us study how genes play a role in allergy and intolerance. This genetic testing is optional.

## What happens after that?

On the day, the researchers will not be able to confirm whether or not you have a food allergy. Once we have got all the test results together, we will be in touch with your GP.

1. If your food skin prick test(s) is positive, we will invite you to take part in the next stage of PAFA (PAFA-Stage 3), which will involve a more detailed clinical assessment with a medical doctor, and we will inform your GP.
2. If your food skin prick tests are negative, we will wait for the results of the blood test.
  - If these are positive, we will invite you to take part in the next stage of PAFA (PAFA-Stage 3), which will involve a more detailed clinical assessment with a medical doctor, and we will inform your GP.



- If your blood tests are negative, we will send this information to your GP together with any advice about what to do next and we will send a copy of this letter to you.
- 3. If the results are not clear, your case will be discussed with the study doctor and clinical advice will be sent to your GP and we will also send a copy of this letter to you.
- 4. If you decline to take part in the stage 3 (PAFA-Stage 3), we will send a letter summarising all available results to your GP.

### **Will I need to change my medications?**

If you take anti-histamine (e.g. Loratadine, Cetirizine) regularly, we will request that you stop this for 3 days before your allergy test (skin prick test), but only if you are able to. If you wish to discuss this, please contact the study team on the number below.

### **Will I receive payment for taking part?**

We will pay for any expenses during your visit such as petrol, taxi or bus fares and parking costs. Anyone who attends the appointment will receive £10 of vouchers (e.g. Amazon, or love-to-shop).

### **Are there any benefits from taking part?**

- If you have reported an adverse reaction to food in PAFA-Stage 1, you will find out more about whether this could be a food allergy.
- You will find out whether you are eligible to take part in PAFA-Stage 3 which will involve a more detailed clinical assessment with a medical doctor.
- You will find out if you have allergies to pollen and/or dust.
- You will contribute to helping us understand more about food allergy in adults. This new knowledge will allow public health policies regarding prevention and treatment of food allergies to be updated.

### **Are there any risks in taking part?**

The possible risks and side effects of allergy tests include itchiness, redness and swelling at the skin test site. If you develop this, we will offer you anti-histamine or steroid cream. Rarely, having blood taken can cause minor discomfort including possible bruising, which will diminish in a few days. Some people can feel faint whilst blood is being withdrawn.

### **How do I take part and contact the study team?**

If you are interested in taking part in Stage 2 of PAFA, please contact the study team on:

email: [pafastudy@manchester.ac.uk](mailto:pafastudy@manchester.ac.uk)

phone: 07918576785

They can answer any questions you may have and arrange the appointment at the PAFA study centre. If you have a mobile phone registered with your GP, you will receive a text message with information about booking in the next few days – so

please look out for this. If we don't hear from you within 1-2 weeks of sending this invitation, we will contact you by telephone.

### How will we use information about you?

We will need to use information from your GP for this research project. This information will include the following: Initials, Name, Contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

Your GP will use this information to invite you to take part in the research study. 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.

We will keep all information about you safe and secure. Some of your non-identifiable information will be sent to the AMC in the Netherlands, a study partner. They must follow our rules about keeping your information safe. The AMC researchers will not be able to identify or contact you.

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. You will be able to access a summary of the study results once they are available at <https://sites.manchester.ac.uk/pafa/>.

### 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.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the personal data we hold about you.
- If you agree to take part in the second stage of this study, you will have the option to take part in future research using your data and samples saved from this study within the Manchester Allergy, Respiratory & Thoracic Surgery Biobank. Please see the "how do I take part" section above for more details on how to take part.

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

You can find out more about how we use your information

- at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- at <https://research.cmft.nhs.uk/getting-involved/gdpr-and-research>
- by asking one of the study team; our leaflet is also available from <https://sites.manchester.ac.uk/pafa/>



- by sending an email to [local team e-mail] or by ringing us on [local team phone number].

### What happens if something goes wrong?

We do not expect that anything will go wrong, but if you have a concern about any aspect of this study you should ask to speak with the lead researchers who will do their best to answer your questions [Insert PI/ Study team contact Details]. If you remain unhappy and wish to complain formally, you can do this by contacting local NHS Patient and Liaison Service (PALS) or equivalent [Insert Local PALS].

The hospital is insured to carry out clinical research through the NHS Indemnity scheme, and the GPs through the NHS Clinical Negligence Scheme for General Practice. The Universities of Manchester, Southampton and Amsterdam University Medical Centre are insured for the design, management and laboratory work. However the normal National Health Service complaints procedures should be available to you. In the unlikely event that something does go wrong and you suffer harmed during the research and this is due to someone's negligence then you may have grounds for legal action or compensation against Manchester University NHS Foundation Trust but you may have to pay your legal costs.

### Who is funding the research project?

This study is being sponsored by Manchester University NHS Foundation Trust and the project is funded by the Food Standards Agency.



### Who has reviewed the research project?

The project has been reviewed by Yorkshire & The Humber – South Yorkshire Research Ethics Committee (IRAS project ID 295890)

### Who is doing the research?

Researchers at the University of Manchester, Manchester University NHS Foundation Trust, the University of Southampton, the Isle of Wight NHS Trust, and Amsterdam University Medical Centre.

**You are invited to take part in the second stage of the PAFA study (Patterns of Adult Food Allergy) to find out how many people in the UK have food allergies or intolerances.**