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**iFAAM: EuroPrevall birth cohort follow-up study**

**PARTICIPANT INFORMATION SHEET (Parents/Guardians) – FACE-TO-FACE VISIT**

Many thanks for taking the time to complete our study questionnaire. You and your child are now being invited to attend a face-to-face visit at a hospital or community centre near where you live.

In our previous information sheet, we explained the purpose of the iFAAM study and why you have been chosen to take part. This information sheet tells you what will happen at the face-to-face visit.

Please read the following information carefully and discuss it with others if you wish. Please do not hesitate to contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

**What will happen at the face-to-face visit?**

Your child will be assessed for signs and symptoms of food allergy and asthma by:

1. Examining your child’s skin.
2. Allergy skin prick testing - drops of allergens (such as foods and pollens) are placed on your child’s arm. The skin is then gently pricked to see if a reaction occurs. This is a safe, routine test used in allergy clinics.
3. Lung function testing and measurement of exhaled nitric oxide (eNO) levels - this involves breathing into two different machinces. We will ask your permission to give your child an asthma medication to see if their lung function improves. eNO is a marker for airway inflammation and is often raised in children with asthma. Both tests are safe and are performed routinely in asthma clinics.
4. A blood test- to look for antibodies against allergens and genes that predispose to/protect against allergy and asthma. **This is completely optional.** If your child agrees to having a blood test, their skin will be numbed with anaesthetic cream first. We will collect approximately 10ml (less than one tablespoon) of blood.

If your child has asthma, we would ask them to try not to use their blue reliever inhaler (eg salbutamol, ventolin, bricanyl, terbutaline) during the 4 hours before the visit. We would also ask you not to use any antihistamines (eg loratidine, clarityn, cetirizine, zirtec, piriton) in the 3 days before the visit.

**This study does not involve any study medication.**

**How long does the visit take?**

The visit will take around 1 hour.

**What if my child has symptoms or signs suggestive of food allergy?**

We expect that a small number of children will have symptoms/tests results suggestive of food allergy. These children will be offered a double-blind, placebo-controlled food challenge under the supervision of a paediatrician at Southampton General Hospital. A food challenge is the best way to accurately diagnose food allergy. For this aspect of the study you will be provided with an additional information sheet and consent form.

**What are the possible disadvantages and risks of taking part?**

There may be a little discomfort associated with skin prick testing. When blood is drawn, your child may also feel a little discomfort and a small bruise may form at the area. Rarely, someone may faint. Prior to attending the visit your child will need to stop taking their blue asthma reliever inhaler and/or antihistamine for a specified period (see above). This could present a risk, but if you feel the use of the inhaler or antihistamine is necessary the appointment can be re-arranged.

**What are the possible benefits of taking part?**

Your child will be evaluated for symptoms or signs of allergies and asthma. These can be difficult to diagnose by non-specialists. Allergy testing may help to reveal any allergies that your child has and help to guide their diet. Taking part in this study will have no negative influence on the regular care of your child. **Your travel expenses will be reimbursed** and your GP will be informed about the allergy and asthma tests results. Your participation in this study will help scientists and doctors develop tools to help the diagnosis of food allergy and asthma and identify preventive strategies.

**Do we have to take part?**

No, you and your child do not have to take part. It is completely voluntary and you can choose which aspects of the study you want to take part in. If you decide to participate, you will asked to sign a consent form and will be be given a copy of this. .You are free to withdraw at any time and without giving a reason. This will not affect your child’s medical care.

**What if there is a problem?**

If you have a concern about any aspect of this study, please ask to speak with the research team (see contact information below). If you still have questions or concerns, you can contact Research and Development, University Hospitals Southampton NHS Foundation Trust (023 8120 5078). In the very unlikely event that something does go wrong and you are harmed during the research study, there are no special compensation arrangements. If you are harmed and this is due to someone’s negligence then you may have grounds for legal action for compensation against University Hospital Southampton NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

**Will our taking part in this study be kept confidential?**

All personal information collected in this study will be kept confidential. Data collected will not be labelled with your or your child’s personal details and will be stored securely. Data may be shared with our research collaborators; however they will not know who the information belongs to. Only the study personnel will have access to your child’s personal details. The sponsor of the study (University Hospital Southampton NHS Foundation Trust) may also wish to access the records as part of their monitoring of ongoing research. You will not be individually identified in any reports or publications resulting from the study. We will keep your data on file for use in future studies approved by the Research Ethics Committee.

**What will happen to the blood samples.**

The blood to be analysed for antibodies (against allergy-causing proteins such as foods or pollen) will be sent to and stored frozen at *Amsterdam Academic Medical Center, Department of Experimental Immunology (led by Dr. Ronald van Ree), Meibergdreef 9, Amsterdam 1105 AZ, The Netherlands*.

Blood used for genetic testing will be shipped to and stored frozen at *Charité – Universitätsmedizin Berlin, Department of Paediatric Pulmonology and Immunology (Prof.Kirsten Beyer), Augustenburger Platz 1, 13353 Berlin, Germany*.

All samples will be identified by your child’s study number only and not with their name or **any** other personal information.

Who will have access to my health records?

Senior Investigators on this project will need to look at your health records to ensure safe conduct of the study procedures.

Involvement of the General Practitioner

We will ask your permission to notify your General Practitioner (GP) of your participation in this study and of your child’s allergy/asthma test results, as they may be useful for their future medical care..

**What will happen to the results of the research study?**

We aim to publish the results of the study in medical journals so that other doctors and researchers can make use of them. This is likely to be accompanied by an article in the press. It will not be possible to identify any individuals involved in this study from these published results.

**Who is organising and funding the research?**

Researchers at the University of Southampton are organising and carrying out this study. The study is being funded by the European Union within the project *Integrated Approaches to Food Allergen and Allergy Risk Management* (iFAAM, grant agreement no. 312147).

**Who has reviewed the study?**

This study was given a favourable ethical opinion by the NRES Committee South Central - Hampshire B.

**How long do we have to decide whether we should take part?**

You and your childs decision to participate in this study is entirely voluntary. You should take as much time as you need.

**What happens at the end of the study?**

If we find that your child has any allergies or asthma, we will write to your GP with suggestions for how to manage the condition. Where necessary we will suggest referral to a paediatric clinic.

The EuroPrevall Birth Cohort is an important group of Hampshire children who have already provided us with very valuable information about how and why some children develop food allergy. We aim to re-assess the cohort again in the next 5-10 years as part of a separate follow on study. Where children have moved, we would ask permission to use the NHS tracing system to obtain an up to date address. If you are unable to be involved in a future follow up, we would ask permission to contact your GP to find out if your child has food allergy, asthma or any other allergies or breathing problems.

**Contact for further information, questions or concerns**

Professor Graham Roberts on 023 8120 6160, email iFAAM@southampton.ac.uk or visit [www.southampton.ac.uk/iFAAM](http://www.southampton.ac.uk/iFAAM).

*Thank you for taking time to read this information sheet.*