

# THE BEEP STUDY ALLERGY TEST



## Your child is invited to have an allergy test as part of the BEEP study

- It is important you understand why this part of the study is being done, and what it would involve for you if you decide to take part.
- Please take time to read this information. Talk to others if you wish, and ask if you would like more information.

*Thank you for reading this information.*

## Important things that you might like to know


- Allergy problems such as asthma, eczema, hayfever and food allergy are troublesome and increasingly common.
- Recent studies have shown that having dry skin as a baby may increase the risk of developing other allergies, especially food allergies such as milk, egg or peanut allergy.
- Children may have milk, egg or peanut allergy even if they have never eaten the relevant food, or if they have eaten small amounts of the food without having a reaction.
- You are being offered the allergy test for your child at the BEEP study visit which has been arranged close to your child's 2<sup>nd</sup> birthday. We will do an allergy test for foods that commonly cause allergy, and for allergens in the air including pollen and dust mite.

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## How to contact us

If you have any questions about this study, at any time, please contact the study team at:-

 XXXX

 XXXXX

## 1. Why we are doing allergy tests?

By the time they go to school, a third of children have allergy symptoms such as asthma, eczema or hayfever and one in 12 will have a food allergy.

There are treatments for allergy, but we don't know how to prevent it. Advice to apply moisturiser from birth might prevent food allergy, and possibly other allergies, as well as preventing eczema. The best way to find this out is to do an allergy test for children in the BEEP study.

Sometimes food allergy is not known about, because the relevant food has not been eaten very much. An allergy test helps us to find out for certain whether or not your child has a food allergy.

## 2. Why are you offering this for my child?

We are offering your child an allergy test because you and your child are already taking part in the BEEP study.

## 3. What will happen if my child has an allergy test?

The allergy test will happen during the BEEP study visit close to their 2nd birthday. For the allergy test the BEEP nurse will place tiny droplets containing allergens such as peanut, pollen and dust mite on your child's forearm, and make a tiny pin prick through each drop into the surface of the skin. For allergic children, this will cause a tiny red lump to appear within 15 minutes. The nurse will measure the size of any reaction to the allergens which should disappear within 20 minutes. We will let you and your GP know the results after they have been reviewed by a team of allergy experts.

## 4. Possible risks?

There is very little risk involved in these allergy tests, which have been done on children in their own homes for research studies before. The test will add approximately 10-15 minutes to your BEEP visit, and may cause slight itching on your child's forearm. Children with a severe allergy can occasionally have other allergy symptoms after a skin prick test, such as a rash or coughing. This is very rare, and if it happens to your child the nurse will be able to give a treatment.

## 5. Possible benefits?

The test will indicate whether or not your child may have an allergy. Knowing your child does not have an allergy is reassuring, and if an allergy is identified this can then be managed appropriately by you and your GP. The allergy test will also help us know whether moisturisers prevent allergy, so may benefit other children in the future.

## 6. Do I have to take part?

Your child's participation in the allergy test is optional and if you decide not to have the allergy testing done, this will not affect your continued participation in the BEEP study; we will still ask you to complete yearly questionnaires until your child is 5 years old. If you don't want to have all of the allergy test, but would like to have an allergy test to peanut, to check that your child can safely eat as much peanut as they want, then your BEEP nurse will be happy to just do an allergy test for peanut.

If you do decide to give consent to the allergy testing, you are free to withdraw this consent at any time, without giving any reason, and without your legal rights being affected. If you withdraw consent from the allergy testing, then the information collected for the allergy test up to that point cannot be erased and may still be used in the project analysis.

## 7. Will this be confidential?

We will follow ethical and legal practice and all information about you and your child will be handled in confidence.

If you join the study, some parts of your child's medical records and the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you and your child as a research participant and we will do our best to meet this duty.

All information which is collected about you and your child during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database.

Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

<https://www.nottingham.ac.uk/utilities/privacy.aspx>.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

You and your child's personal data (address, telephone number) will be kept for 3 years after the end of the study so that we are able to contact you about the findings of the study *and possible follow-up studies* (unless you advise us that you do not wish to be contacted). All other research data will be kept securely for 7 years. After this time you and your child's data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team, given permission by the data custodian, will have access to you and your child's personal data.

## 8. Results of the study

We will publish the results of the BEEP study in scientific journals and send you a copy unless you ask us not to.

## 9. What if there is a problem?

If you have concerns about the study you should speak to the BEEP team. If you remain unhappy you can formally complain via the Patient Advisory and Liaison Service at your local hospital. If something goes wrong and you are harmed during the study, there are no special compensation arrangements. If you are harmed due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you. **[Insert the contact details of local PALS or the hospital Complaints]**

## 10. Who reviewed the study?

This study has been reviewed and given favourable opinion by the West Midlands Solihull Research Ethics Committee, who look after the rights, wellbeing and dignity of people invited to take part in research. The Trial Steering Committee and study funder (NIHR HTA) have also approved including the allergy testing. The allergy tests are funded by grants from Sheffield Children's Hospital Charity and Imperial Healthcare Charity.