

<b>HREC Project Number:</b>	35133		
<b>Research Project Title:</b>	Taking care of children with suspected food allergy: the Allergy in the Community Trial (ACT)		
<b>Study Group:</b>	Intervention cohort		
<b>Principal Researcher:</b>	Associate Professor Harriet Hiscock, Paediatrician and co-group leader, Community Health Services		
<b>Version Number:</b>	6	<b>Version Date:</b>	03/01/2017

Thank you for taking the time to read this **Parent/Guardian Information Statement and Consent Form**. We would like to invite you and your child to participate in a research project that is explained below.

This document is 6 pages long. Please make sure you have all the pages.

### What is an Information Statement?

These pages tell you about the research project. It explains to you clearly and openly all the steps and procedures of the project. The information is to help you decide whether or not you would like to take part in the research. Please read this Information Statement carefully.

Before you decide if you want to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

### Important things you need to know

- It is your choice whether or not you and your child take part in the research. You do not have to agree if you do not want to
- If you decide you do not want to take part, it will not affect the treatment and care your child gets at The Royal Children's Hospital

If you and your child would like to take part in the research project, please sign the consent form at the end of this information statement. By signing the consent form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to you and your child taking part in the project

We will give you a copy of this information and consent form to keep.

## 1. What is the research project about?

Food allergies are becoming more and more common in children and babies. This means that a lot of children end up on hospital waiting lists for specialist allergy advice. As hospital waiting list times are around 18 months, we want to try a new approach to caring for babies and children with possible food allergies.

This research project aims to improve the management of food allergies in babies and children and is designed to see if community paediatricians (children's doctors) can look after children with possible food allergies.

In this study, we will compare two groups of children with possible food allergy:

- Group 1 – RCH Allergy Clinic: children currently on The Royal Children's Hospital (RCH) Allergy Clinic wait list, who will stay on the wait list
- Group 2 – Community: children currently on the RCH wait list will be offered an appointment with a community paediatrician, who has been trained by RCH allergy specialists to care for children with food allergy.

## 2. Who is funding this research project?

This research is funded by The Royal Children's Hospital Foundation.

## 3. Why is my child being asked to take part?

We are asking you and your child to take part in this project because your child is under 12 years old, and is on the RCH Allergy Clinic waiting list for possible food allergy.

## 4. What does my child need to do in this research project?

We would like you and your child to participate in the Community Group. This means that you and your child will have an appointment with a community paediatrician for allergy advice, and your child will be taken off the waiting list for the RCH Allergy Clinic. The community paediatrician may be located near to your home and you will not need to travel to the RCH. For children aged 12 months and over, seeing the community paediatrician may mean not such a long wait for an appointment (children under 12 months may not be seen more quickly). The community paediatrician will decide which foods to test for, based on what your child has reacted to and their clinical opinion. As part of this research we would like you to:

### **A) Complete three surveys:**

The first needs to be done now and will take about 10-15 minutes. The questions ask about your child's possible food allergy, quality of life and about your family.

We will contact you again in 6 and 12 months' time to ask you to complete the same survey. The survey will ask additional questions about your appointment with the community paediatrician and how satisfied you are with the care your child received. Each survey will take about 10-15 minutes to complete.

### **B) Attend an appointment with a community paediatrician:**

Your child will have an appointment with a community paediatrician who has been trained by the allergy specialists from the RCH in how best to diagnose and manage food allergies. The paediatrician's consulting room will be near where you live. We will contact the GP who made your referral for the RCH Allergy Clinic to let them know about your involvement in this study. We will ask your GP for a new referral to be made to the community paediatrician. We will give you information on how to book your appointment to see the community paediatrician.

During the appointment, the paediatrician will assess your child's health and test for possible food allergy. Food allergy testing involves collection of blood sample which up to four foods can be tested for allergy. The paediatrician will give you a referral for a local pathology service to get this blood test done. This test will be bulk billed i.e. you will not pay any out of pocket costs.

If your child has a food allergy, the paediatrician will give you and your child advice on how to manage the allergy.

If your child has a complex food allergy (e.g. more than three foods), the paediatrician will refer your family back to the RCH Allergy Clinic, and you will move up the waiting list so your child will be seen sooner.

Children who are diagnosed with a food allergy need a follow-up review appointment once a year. If your child is diagnosed with a food allergy, you can choose for your child to be seen by the same community paediatrician, or by your own GP, or by another GP who has been given information by our research team about how to manage children with food allergies. If you prefer to see your own GP for the review appointment, we will contact your GP about this to offer information on how to manage child food allergy.

***C) Use of information collected during the Community Paediatrician appointment:***

As part of this research project, we would like to access and use medical information collected by the community paediatrician during your child's appointment: this information includes the tests ordered, test results, any diagnosis made, information and handouts given to you, and advice given on how to manage any allergy.

***D) Optional Consent:***

We would like you to consider giving permission for us to contact you and your child about possible future research projects that may be suitable for your child. By giving consent, you are agreeing to us sending you information – you are not obliged to take part in any future research. Please complete the tick box on the consent form if you agree to this or not.

**5. Can my child withdraw from the project?**

If you give your consent and change your mind, you and your child can withdraw from the project. You do not need to tell us the reason why you or your child want to stop being in the project. If your child leaves the project we will use any information already collected unless you tell us not to.

**6. What are the possible benefits for my child and other people in the future?**

By taking part in the project, you and your child will help us find out if a new program can help children with food allergy to be seen more efficiently and safely in the community. If the program works, it could be offered to more Victorian and Australian families. Many more children and families might then benefit from getting the help they need sooner.

**7. What are the possible risks, side-effects, discomforts and/or inconveniences?**

We do not expect there to be any major risk to you or your child if you take part in this project.

It is unlikely the survey questions will cause any distress. However, if you find any of the questions upsetting and you want to talk to someone about them, we can arrange for you to speak to a counsellor.

There are some inconveniences associated with this project:

### *Out-of-pocket costs*

By choosing to see a community paediatrician, you may expect to pay out-of-pocket costs which usually range between \$0 (if bulk billed) to \$150 for first consultations; and \$0-\$100 for any follow-up review consultations. This charge is to cover the gap fee between Medicare and private paediatrician billing. Although we are not able to reimburse you and your family for the out-of-pocket costs, as a token of appreciation, your family will be given a \$20 EFTPOS voucher for taking part in this research project.

### **8. What will be done to make sure my child's information is confidential?**

- All the information you give us will stay private.
- We can disclose the information only with your permission, except as required by law.
- We will use the information only for this research project. We will remove your names from the information and we will use an identification number instead.
- We will keep the information in the Centre for Community Child Health at the RCH. The only people who can access your information are the research team and the RCH Human Research Ethics Committee.
- Research records will be kept for 7 years after the youngest participant's 18th birthday or 15 years after the completion of the study, whichever date is later. After this time, all records will be destroyed.
- In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access and correct the information we collect and store about you and your child. Please contact us if you would like to access this information.
- The results of the project may be presented at conferences and published in professional journals. These results will not identify you or your child in any way.

### **9. Will we be informed of the results when the research project is finished?**

At the end of the project, we will send you a summary of the overall project results. This will be for the whole group of participants, not your child's individual results.

### **10. Who should I contact for more information?**

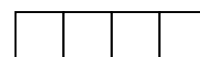
If you would like more information about the project or if you need to speak to a member of the research team in an emergency please contact:

**Name:** A/Prof Harriet Hiscock

**Contact telephone:** (03) 9936 6158

**Email:** allergy.aprn@mcri.edu.au

If you have any concerns and/or complaints about the project, the way it is being conducted or you and your child's rights as research participants, and would like to speak to someone independent of the project, please contact: Director, Research Ethics & Governance, The Royal Children's Hospital Melbourne on telephone: (03) 9345 5044.



# Your copy to keep



## CONSENT FORM

**HREC Project Number:** 35133

**Research Project Title:** Taking care of children with suspected food allergy: the Allergy in the Community Trial (ACT)

**Version Number:** 6

**Version Date:** 03/01/2017

- I have read, or someone has read to me in a language that I understand, the information statement version listed above and I understand its contents.
- I believe I understand the purpose, extent and possible risks of our involvement in this project.
- I voluntarily consent for me and my child to take part in this research project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that this project has been approved by The Royal Children's Hospital Melbourne Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007) – including all updates.
- I understand I will receive a copy of this Information Statement and Consent Form.

### OPTIONAL CONSENT

<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent to be contacted about future research projects on allergy in children
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\_\_\_\_\_  
Child's Name

\_\_\_\_\_  
Parent/Guardian Name

\_\_\_\_\_  
Parent/Guardian Signature

\_\_\_\_\_  
Date

Declaration by researcher: I have supplied an Information Statement and Consent Form to the parent/guardian who has signed above, and believe that they understand the purpose, extent and possible risks of their involvement in this project.

\_\_\_\_\_  
Research Team Member Name

\_\_\_\_\_  
Research Team Member Signature

\_\_\_\_\_  
Date

Note: All parties signing the Consent Form must date their own signature.

**To send back to us**



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\_\_\_\_\_  
Child’s Name

\_\_\_\_\_  
Parent/Guardian Name

\_\_\_\_\_  
Parent/Guardian Signature

\_\_\_\_\_  
Date

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\_\_\_\_\_  
Research Team Member Name

\_\_\_\_\_  
Research Team Member Signature

\_\_\_\_\_  
Date

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