

## Post Natal Parent/Guardian Informed Consent Form – **Mother & Child**

### **Randomized controlled trial of early introduction of allergenic foods to induce tolerance in infants**

#### *The Enquiring About Tolerance (EAT) Study*

Please make sure you have read the one page summary sheet available from the EAT Study website at <http://www.eatstudy.co.uk/links> (or see the contact details at the end of this form if you would like us to send you a paper copy) which explains what the study involves for you and your baby.

You and your child are being invited to take part in a research study. This information leaflet and consent form explains in detail what **you and your child's** participation in the study will involve. If you agree to participate in the study, we will ask you to sign this consent form when you attend the allergy trials unit with your baby when they are 3 months old. If you have any questions about your or your child's participation in the study please contact us.

Before you make a decision it is important for you to understand why the research is being done and what it will involve. Please take your time to read the following information carefully and discuss it with others if you wish.

#### **What is the purpose of the study?**

Food allergy now affects 6% (one in sixteen) children. Two successive studies from the Isle of Wight undertaken in 1989 and then 1994-1996 suggested that peanut allergy had doubled and peanut sensitization tripled. The purpose of this study is to test an approach for the prevention of the development of food allergy.

Food allergic reactions can range in severity from a minor reaction such as a skin rash (nettle rash or urticaria) through to the severe type of reaction called anaphylaxis, where symptoms can become life threatening. Fortunately, it is very rare for food allergy to result in death.

There is currently no available treatment for food allergies other than avoidance of the food and immediate treatment of accidental exposures with antihistamines (such as Piriton) and intramuscular adrenaline (Epi-pen). Whilst children can grow out of cow's milk and egg allergies, peanut allergy is rarely outgrown, so children and families have to be very cautious about their eating habits and always carry emergency medications for the whole of their lives.

## **The reasons for this study**

***Breast feeding is best for your baby and this study aims to encourage all participating mothers to breast feed for 6 months or more.*** This is in line with current UK Government advice that breastfeeding will help protect your baby from: “ear infections, asthma, eczema, chest infections, obesity, gastro-intestinal infections, childhood diabetes and urine infections.”

The reason for this study is that there is uncertainty as to when is the best time to introduce solid foods, and in particular when to introduce the common allergenic foods, as the best way of preventing your child developing food allergies.

The current UK Government recommendations hope to prevent food allergy by reducing or avoiding exposure to the allergenic foods in the early weaning diet.

Numerous studies spanning several decades have attempted to achieve a reduction in food allergies, including peanut allergy, by eliminating foods such as peanut, egg and milk from the diet of infants and mothers during pregnancy and whilst breastfeeding. These studies have had little success in reducing the frequency of food allergy.

One possible explanation for the failure of these studies is that the elimination of foods was not properly achieved. An alternative reason may be that avoidance is not the best strategy and that the early introduction of peanut may actually protect against the development of peanut allergy. There are countries in the world where children eat peanut foods early in life and incidence of peanut allergy in these countries is low e.g. Asia and Africa. This is also true in Israeli children where our study findings reveal that eating a high dose of peanut protein early is associated with a low prevalence of peanut allergy.

There are also now studies suggesting that delaying the introduction of solid foods that may cause allergies for too long may also be associated with a higher risk of causing a food allergy.

Given these observations and the current uncertainty regarding when is the best time to introduce allergenic foods into the weaning diet in order to minimise risks of development of food allergies, we wish to investigate whether early introduction of peanut and other allergenic foods into your child’s diet or avoidance of these foods may help to decrease their chance of developing food allergies.

## **The Learning Early About Peanut Allergy (LEAP) Study**

Our study group is already undertaking a randomized trial introducing peanut into the diet of infants aged between 4 and 10 months of age who are at high risk of developing food allergies to see whether this decreases the chances of developing peanut allergy – the LEAP study ([www.leapstudy.co.uk](http://www.leapstudy.co.uk)). 620 infants are taking part and half are successfully consuming a peanut snack.

## **Why have my baby and I been chosen?**

We have contacted mothers with a baby approaching 3 months of age who live in or around London. In order to take part in the study you must be planning on exclusively breast-feeding your baby for at least 3 months. Your baby will not be able to enter the study at 3 months of age if he or she has not been exclusively breast fed for 3 months.

We believe the opportunity to try and reduce your child’s chance of developing food allergies is best when they are young. That is why this study is seeking to test a dietary intervention during early infancy. The study will enrol 2500 infants and their mothers at 3 months of age.

### **Do my child and I have to take part?**

It is up to you whether you and your child want to participate in the study. If you decide you would like to take part you will be given this information sheet to keep and be asked to sign the consent form when you attend the allergy trials unit. If you decide you would like to take part you are still free to withdraw at any time without giving a reason. A decision not to take part or to withdraw at any time will not affect the standard of care you will receive in the future.

### **What will happen to me if I decide to take part?**

Before you attend our allergy trials unit with your 3 month old baby we would like you to behave just the same as you would have done if you were not taking part in the study.

If you take part we will ask you to complete a questionnaire about your diet during pregnancy and since you have been breastfeeding. This can be completed online (or we can post it to you if you do not have internet access).

When you attend the final 3 year assessment visit with your baby we would like to perform skin prick testing and a blood test on you (and your partner) to see if you are allergic to any common foods or airborne allergens (e.g. pollen and pets).

### **What will happen to my child if we decide to take part?**

This type of study is known as a randomized study. Sometimes because we do not know which way of treating patients is best we need to make comparisons. All children who take part in this study will be put into one of two groups at three months of age. The groups are selected randomly by a computer which has no information about the individual – i.e. by chance. Participants in each group will then have a different treatment, and the two groups will be compared. The chance of your child being in each of the two groups is 50% (the same as if a coin was tossed).

Because we do not know the best way to prevent food allergy, we will compare different prevention methods in this study. We are comparing early introduction (with the support of dieticians) of solid foods, including foods that sometimes cause food allergy, with the usual UK Government weaning advice to not introduce solids until around 6 months. At 3 months of age participants will be randomised into one of two different groups:

**Group 1** – Participants will be encouraged to continue to breast feed. Your baby will have a skin prick test to ensure they have not already developed a food allergy. At three months of age mothers will introduce baby rice mixed with breast milk or water. Your baby will then be started on a cow's milk yoghurt (2 small yoghurts eaten during a week). Subsequently your baby will have introduced in randomized order the other allergenic foods – egg (1 egg a week), wheat (2 wheat-based breakfast cereal biscuits e.g. Weetabix a week), fish (20 grams/about one tablespoon a week), peanut (3 teaspoons of peanut butter a week) and sesame (3 teaspoons of tahini – sesame paste). The aim is for all foods to be being ingested in the required quantities by five months of age. No wheat will be introduced before 4 months of age.

**Group 2** – Participants will follow the existing UK Government recommendations which recommend exclusively breast feeding for around six months and no early (before six months) introduction of allergenic foods.

## **How does the weaning method for Group 1 differ from the current UK Government recommendations?**

The UK Government currently makes several recommendations with regard to how long you should breastfeed for and when and what solids your baby should be weaned onto. How these compare with what we are doing for Group 1 in the EAT Study is summarised in Appendix 1 at the end of this document.

## **Duration of the study**

Infants will be enrolled at 3 months of age. The study will continue until the child reaches 3 years of age. Participants will be closely observed at all stages of the study, but particularly during the first year of your infant's life. All children will return to the allergy trials unit at 1 year and 3 years of age for assessments including a blood test, a non-invasive test of skin barrier function and skin prick testing to see if they have developed any allergies. If your child needs to have a food challenge to clarify whether he is allergic to a food, the challenge will take approximately 5-6 hours. You will be given specific appointments for the visits at mutually convenient times.

## **Enrolment visit (3 months of age)**

- At enrolment your child will be randomised into one of the 2 groups described above.
- If your child is in Group 1 (the intervention group). They will have skin prick tests to peanut, cow's milk, sesame, egg, wheat and fish. This will ensure that they are not already allergic to these foods.
- If these results suggest they may be allergic to a particular food, children in Group 1 will be invited to have a challenge for that particular food on our day unit. A food challenge involves feeding your child small amounts of the food under close medical supervision in the children's allergy unit at St Thomas', gradually increasing the amount to a portion that the children in the intervention half of the study will be consuming. If they show signs of a reaction they will be advised to avoid that food but will still consume the other foods.
- Children in Group 2 (the control arm), will follow the current UK Government advice of around six months exclusive breast feeding and no early introduction of allergenic foods. Children in Group 2 will not have skin prick testing done at the enrolment visit as we want their weaning to be the same as what would have happened if they were not participating in the study.

## **What happens at clinic visits?**

The following procedures will be performed during these visits:

- A blood test: at the end of the study follow-up we will process the bloods samples to look for food allergies. We will also look at additional blood characteristics which may help us to understand why some children develop food allergies and others do not. At the enrolment and one year assessment we will take not more than 10 mls of blood (approximately 2 teaspoons). At three years of age we would like to take a little bit more blood from him/her: 20 mls (4 teaspoons). These are small quantities of blood that will quickly be replenished by your child's body. A local anaesthetic ('numbing cream') can be applied to minimise discomfort.
- Skin prick testing (Group 1 at enrolment visit, both Groups at 1 and 3 year visits): to assess for allergies to foods and environmental factors. This involves a small amount of the allergen being placed onto the skin and then pricked through the first couple of layers of skin with a lancet (it does not draw blood). If your child is allergic to any of the allergens being tested a small bump (hive) will develop within 5-15 minutes. This disappears after about 30 minutes.

- A basic medical examination and measurement of height and weight and vital signs (temperature, pulse blood pressure for example).
- We will assess your child for signs of eczema, asthma and rhinitis (hay fever type symptoms). This will involve asking you some questions and examining your child. This would be performed as part of a normal allergy assessment.
- Your baby's skin provides a natural barrier against water loss. There is some evidence to suggest that children who lose more water than others across their skin have a tendency to develop dry skin and eczema. We will use a simple non-invasive probe to measure the amount of water your child loses across the skin. This does not cause any discomfort and requires the non-invasive probe to be held in place for about 2 minutes, until a stable reading is produced.
- We will ask you to let us know if your child has had any reactions to any foods.
- Filling out a questionnaire: We will also ask you to fill out a questionnaire when you attend the 3 month visit which will look at what you ate whilst you were breast feeding and what foods are being eaten by people who live in your household during the study. We will also ask you a few lifestyle related questions, such as whether you keep a pet at home, and whether you use any medicated creams or emollients on your child's skin.
- Health checks: We will contact you, once a month for the first year and three monthly until three years of age. These consultations include a short questionnaire about which foods your child is currently eating. They will also make sure that you and your child are managing with the study and you will be able to express any concerns you may have about your child's health. They can happen more frequently if you need additional help or advice.
- Five day food diaries. On three occasions (when your infant is 6 months old and just before the 1 year and 3 years assessments) we will ask you to complete a food diary for five days of all the foods your child has consumed in that time. The dietician will help explain what you should fill in.
- If your child is in Group 1 (the group that weans onto solid foods early) we will ask you to give the foods on a regular basis until your child is one year of age and encourage you to continue giving the foods until 3 years of age. After that it will be left to your own choice whether you wish to continue giving the foods to your child. If your child is in Group 2 (the group that follows UK Government advice) we will ask you to ensure your child avoids the allergenic foods during the first six months of their life.
- At the one year and three years assessments a food challenge will be performed to see whether or not your child is food allergic if they have positive skin prick tests to any of the six intervention foods. All children who have a slightly greater chance of an allergic reaction during the food challenge (e.g. children with asthma) will require an intravenous cannula to be inserted during their challenge. This is a small plastic tube that sits in a vein, just underneath the skin during the challenge and allows us to give medication directly into the blood stream in the unlikely event of a severe reaction.
- If your child is diagnosed with a food allergy you will be given the appropriate advice and we will continue to monitor your child in the appropriate clinic for as long as is necessary.
- You will be given full written information about preventing, recognising and treating allergic reactions in your child. A nurse or doctor will also discuss this information with you. If you feel that you need more information then you will be able to contact a member of the study team.

## **Additional visits**

- If your child has what you think might be a reaction to a food we will encourage you to contact us so that we can decide whether the history is suggestive of a food allergy. If so, we will invite you and your child back to the allergy unit to be investigated further with skin prick tests as described above and a food challenge if necessary to confirm or rule out a definite food allergy.

## **Parent responsibility**

The greatest responsibility is to carry out the required study intervention - either avoidance until six months of age or introduction of the allergenic foods from 3 months of age, alongside continued breastfeeding, depending on the group to which your child is randomised. Dieticians will work closely with you to help you with this.

If your child is randomised to the group that receives the allergenic foods it is very important that no other individual (friend or family member) who is currently avoiding these foods because of an allergy eats the child's food. This is to prevent any allergic reactions in these individuals.

## **What are my child's alternatives?**

There are currently no established strategies for the prevention of food allergy.

## **What are the side effects of the treatment received?**

Currently approximately 6% of children in the UK will develop food allergies (approximately 1.5% peanut, 1.5% cow's milk, 1.5% egg and 1.5% other allergenic foods). There is a small theoretical possibility that either intervention – be it complete avoidance or introduction of allergenic foods – could increase the rate of food allergy. In order to guard against this possibility your child will be monitored closely and appropriate investigations or actions taken. An independent safety committee of experts will monitor the study closely to detect any such increased rates of allergy in either group. Whether or not our hypothesis is correct, children in the allergenic food avoidance group will share the same risk of developing food allergies as other children in the UK who are not enrolled in the study.

Additional although unlikely risks include worsening of eczema, excessive weight loss or gain, and/or metabolic abnormalities. We will also record whether your child has any infectious illnesses such as diarrhoea or chest infections. The study doctors, nurses and dieticians will closely monitor your child during the study in order to prevent and detect any such changes, and will advise on ways to immediately correct any possible problems that may arise.

## **Why do you want a blood sample from me?**

The sample from you will be stored and will subsequently be used to investigate your own allergy status.

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

### Financial and time requirements

There will be no financial costs to you for participating in this study and we are able to contribute to travels costs. The assessment visits at 3 months, 1 year and 3 years of age will last approximately two hours.

We will ask you to complete a series of questionnaires about you and your baby's diet and health. The following table summarises these and gives an indication of how long we anticipate they will take to complete. You will be able to complete all the questionnaires on line but we can send you a paper copy if you require. We will use email to inform you about appointment times for the assessment visits and for general communication with you.

Assessment point	Subject	Duration
3 months	Family health and environment	20 minutes
3 months	Maternal diet in pregnancy & whilst breast feeding	20 minutes
4-12 months - monthly	Infant health and diet	20 minutes
6 months	5 day infant food diary	1 hour
One year assessment	5 day infant food diary	1 hour
15-35 months - 3 monthly	Infant health and diet	20 minutes
Three year assessment	Infant health and diet	20 minutes
Three year assessment	5 day infant food diary	1 hour

### Risk of allergic reactions

Certain study procedures are associated with a small risk of allergic reaction; the risks associated with each procedure are detailed below. Potential symptoms of an allergic reaction may include some or all of the following symptoms: nausea, vomiting, itching, urticaria (nettle rash), swelling, wheezing or difficulty in breathing, and/or a drop in blood pressure. Allergic reactions are usually mild but may occasionally be moderate or severe. The most severe type of reaction is called anaphylaxis which is where the symptoms described become life threatening. Such reactions are very rare and the study investigators will do everything possible in order to avoid causing an allergic reaction, but if a reaction were to occur, it would be promptly dealt with by experienced children's doctors and nurses.

### Skin prick testing

There is a theoretical risk that you could have an allergic reaction after skin prick testing. However no allergic reactions have ever occurred following skin prick testing in the clinical experience of the study team who have performed this test in approximately 9000 children over the last 12 years. Skin prick testing will always take place in a clinic by an experienced doctor or nurse who will be able to promptly recognise and treat the signs of any reaction.

### Introduction of allergenic foods or complete avoidance of allergenic foods

If your child is randomised to the group which will receive the allergenic foods early, there is a small (less than 1%) risk of an allergic reaction occurring. Only children who have had a negative skin prick test will have the food introduced unsupervised; otherwise the allergenic food will be introduced under strict clinical supervision so that an experienced children's nurse and doctor will be present to quickly recognise and treat any allergic reaction in the unlikely event that one was to occur.

Additionally, as mentioned above, there is a very small risk that being in the control arm or the intervention arm of the study may result in an increased risk of food allergy. However your child will be closely monitored at regular intervals throughout the study, and additionally you will have 24 hour telephone access to a member of the study team who will be able to advise or assess your child should you have concerns that he/she is developing a food allergy.

### Oral food challenges

Your child may experience an allergic reaction during a food challenge. However oral food challenges are routinely carried out for clinical reasons. Over the last 12 years, the study team has performed over 2500 food challenges in children aged 3 months to 3 years without a single case of life threatening anaphylaxis. In addition these food challenges will always be carried out by experienced children's doctors and nurses who will closely monitor your child during the procedure. They will be able to recognise the symptoms of an allergic reaction as it is beginning and administer appropriate medication to reverse the reaction.

### **Discomfort associated with study investigations**

#### Skin prick testing

Some people find skin prick testing slightly uncomfortable (to some children it feels like a prickle, others do not feel anything). After skin prick testing has been performed you develop a small hive (a bit like nettle rash) to any of the tests you are allergic too. This can be slightly itchy for about 10 minutes. Most people tolerate this very well but if necessary a small dose of antihistamine will be given after the testing to minimise the discomfort.

#### Skin examination and testing of skin barrier function (child)

An experienced doctor will examine your child for signs of eczema. The test to measure the amount of water your child loses across the skin takes only a minute and does not cause any discomfort.

#### Blood Test (child)

The blood test may cause discomfort. However this can be performed using a local anaesthetic ('numbing') cream to minimise discomfort. An experienced phlebotomist or nurse will take the blood, and a play specialist will be present if appropriate to assist with distracting your child during the procedure. Other side effects of the blood test include a small risk of bleeding, bruising, or infection at the site.

#### Cannulation (child)

Only a small number of children will require a cannula during the food challenges that take place in this study. The side effects of cannulation are similar to those of blood testing; discomfort, bleeding, bruising or infection at the site. Again the cannulation will take place after the application of a local anaesthetic cream and will be performed by an experienced doctor or nurse. The play specialist will be present to assist with distracting your child during this procedure.

#### Blood sample - parents

We will obtain blood when you attend the three year assessment.

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

We will encourage all participating mothers to achieve at least 3 months exclusive breast feeding and hope that mothers in the control arm of the study will achieve the six month target. We will ensure mothers are aware of the different sources of support that are available within the hospital and the community to assist with establishing successful breast feeding.

Ultimately we hope that all the treatments in this study will help your child. However, there is no guarantee that your child will not develop food allergy if they participate in the study. The information we get from this study may help us to prevent the development of food allergy in more children in the future.

In the same way as if they did not take part in the trial, any child who develops food allergy during the trial will be offered appropriate testing to confirm or refute the diagnosis. Usual follow up care with specialist doctors, nurses and dieticians will also be offered.

### **What if new information becomes available?**

Sometimes during the course of a research project new information becomes available about the treatment being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want your child to continue in the study. If you decide to withdraw your child, your doctor will make the appropriate arrangements for the care needed by your child to continue. If you decide your child should continue in the study you will once again be asked to sign an updated consent form. Your doctor may also decide it is in your child's best interests for them to be withdrawn from the study. If this occurs the reasons will be explained and appropriate care will be organised for your child.

### **What happens when the research is completed?**

Once the trial is completed you will be aware of your child's allergic status. If they have no allergies then they will not need any further intervention. Those participants who may have developed food allergy or who have other allergic disorders, will be given appropriate advice and follow up appointments in an appropriate clinic (in the same way as for children who have not taken part in the study).

### **What if something goes wrong?**

This trial is insured by Zurich as part of the 'no fault' clinical trials policy of Kings College London. If you are harmed due to someone's negligence then you may have grounds for legal action. Regardless of this, if you wish to complain, or have any concerns about the study, the normal NHS complaints mechanism is available to you via the Patient Advocacy and Liaison Service (PALS). They may be contacted by the following means:

Tel: 020 7188 8801 or 8803    Email: [pals@gstt.nhs.uk](mailto:pals@gstt.nhs.uk)

### **Will our participation in the study be kept confidential?**

All information which is collected about you and your child during the course of the research will be kept strictly confidential. Research folders will be labelled as confidential and kept in a locked office at all times. Access to these folders will be restricted to study investigators, study statisticians, and appointed audit authorities. Any information that is stored electronically will be kept 'locked' by password access.

With your consent, your GP will be informed that your child is taking part in the study and of any diagnoses (e.g. asthma or eczema) that may be made during the study.

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

During the study a newsletter will be posted or emailed to all participants informing them of the study progress. Once the study is completed the information will be audited and then submitted for publication to a peer reviewed scientific journal. Once again all the study findings will be made available to participants in a lay person format.

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

The study is being run by Prof Gideon Lack and his team of researchers. The Food Standards Agency, a Government Department, the Medical Research Council, and the Department of Health's National Institute of Health Research (NIHR) are funding the research.

### **Who has reviewed the study?**

St Thomas' Hospital Research Ethics Committee, the Food Standards Agency, the Medical Research Council, and the NIHR have reviewed the study.

### **Storage of Blood Samples**

You have the option to have you and your child's samples of blood stored for use in **future** research studies. These future studies may help researchers learn more about allergy, asthma and the immune system (the body's natural defence system against infectious disease and illness).

- Researchers may also study the genetics of your child's disease and other related diseases. Future genetic tests may provide information regarding the relationship between inherited characteristics and a disease condition or treatment being studied.
- Reports on future studies using these stored samples and genetic tests will not be given to you or your doctor and they will not be put in your medical record. Future studies will not be identified with you and will not affect your routine medical care.
- The stored samples will be used for research that has been approved by scientific and ethical review groups at an institution. The samples will not be sold. However, the information obtained from the samples may in the future lead to the development of commercial products. You can change your mind at any time and ask to have your samples destroyed. If your samples have not been processed they will be destroyed from the date of your request. If your sample(s) have been processed then the information will be used as part of the overall study analysis.

### **Benefits of Stored Material**

The benefit of research on stored samples is the information that can be learned about allergy, asthma and other related diseases. There are no direct benefits to you from the collection and storage of these samples. You will not receive any financial gain from studies done using your stored samples.

### **Risks of Stored Material**

We will make every attempt to insure that your personal information will be confidential, but complete confidentiality cannot be guaranteed.

### **Contact for Further Information**

If you would like to receive more information regarding the study then please contact the EAT Study Recruitment Line by telephone on 0800 358 0021.

EAT web address: [www.eatstudy.co.uk](http://www.eatstudy.co.uk)  
[www.eatstudy.com](http://www.eatstudy.com)

# CONSENT FORM

**Title of Project:**

Randomized controlled trial of early introduction of allergenic foods to induce tolerance in infant

Name of Researcher: Professor Gideon Lack

Contact Details: 0800 358 0021

Please  
initial box

1. I confirm that I have read and understand the "Post Natal Parent/Guardian Informed Consent Form – Mother & Child" dated 14th August 2009 (Version 1.00) for the above study and have had the opportunity to ask questions.

2. I understand that our participation is voluntary and that we are free to withdraw at any time, without giving any reason, without our medical care or legal rights being affected.

3. I agree that samples of our blood may be used for the research described. I understand how the samples will be collected, that giving samples for this research is voluntary and that I am free to withdraw my approval at any time, without giving any reason, without our medical care or legal rights being affected.

4. I agree to take part in the above study.

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Patient Identification Number:

\_\_\_\_\_  
Participant (mother) (print name)

\_\_\_\_\_  
Participant (mother) (signature)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of person conducting informed consent discussion (print)

\_\_\_\_\_  
Signature of person conducting informed consent discussion

\_\_\_\_\_  
Date

## Making a Decision for Stored Human Subject Material

Please read this section of the consent carefully and answer the questions listed below. It relates to the use of samples taken from you and your child in **future** research that may be undertaken. The samples will be completely de-identified and this will ensure that no findings from this future research can be traced back to the original research subjects. The choice is up to you. No matter what you decide it will not affect the care you receive as part of the study. You should answer both of the statements.

1. I agree to permit the collection and storage of our blood samples for future research studies to learn more about allergy, asthma and the immune system (the body's natural defence system against infectious disease and illness).

Yes

No

2. In addition, I agree to permit my child's stored samples to be used in future research for genetic (i.e. DNA) testing and for other diseases related to the immune system. I understand that checking yes below gives permission to use my child's stored samples for future genetic testing and future immune system studies that may or may not be related to food allergy.

Yes

No

Signature \_\_\_\_\_

Date \_\_\_\_\_

**Thank you for agreeing to take part in the study.**

**You will be given a copy of the information sheet and a signed consent form to keep.**

## **Appendix 1:**

### **UK Government weaning recommendations in relation to the EAT Study**

#### **How long to exclusively breast feed for:**

The UK Government recommends that mothers try to breast feed exclusively for about the first six months of their child's life. Exclusively means giving no other milk substitutes (e.g. infant formula) or any solid foods.

**However**, we know from the government's own UK 2005 Infant Feeding Survey that despite this recommendation currently only 13% of mothers manage to exclusively breast feed for 3 months, 7% of mothers manage for 4 months and less than 1% achieves 6 months.

#### **Protecting against infections and allergy:**

The UK Government also recommends that "six months is the best age for introducing solids. Before this, your baby's digestive system is still developing and weaning too soon may increase the risk of infections and allergy".

**Infections:** Some studies have suggested a reduced risk of diarrhoeal or chest infections in infants exclusively breast fed for 6 months or more.

**However**, the recent Millennium Cohort Study which has followed up 15,980 UK infants born between 2000 and 2002 found that the age at which infants had solids introduced into their diets had no effect on the risk of being admitted to hospital for these conditions.

**Allergy:** The UK Government states that babies who have a family history atopy (this means a history of eczema, asthma or hay fever) who are more likely to develop allergies, are particularly recommended to exclusively breast feed for six months and introduce the allergenic foods one at a time, but not before six months of age.

**However**, a World Health Organization review in 2002 found no evidence that achieving six months exclusive breast feeding as opposed to 3-4 months exclusive breast feeding leads to a significant reduction in risk of atopic eczema, asthma, or other atopic outcomes.

#### **Age to introduce solids:**

The UK Government also states that "solid foods should never be introduced before four months".

**However**, we know that the actual age that mothers introduced solids into their infants' diet in the Millennium Cohort Study was 3.8 months. This is almost identical to the government's own figure from the UK 2005 Infant Feeding Survey in which 51% of infants had started solids by four months.

#### **What solids to introduce:**

The UK Government currently recommends avoiding introducing foods that may cause allergies before six months and includes in their list: "...wheat-based foods and other foods containing gluten (e.g. bread, rusks, some breakfast cereals), eggs, fish, shellfish, nuts and seeds."

**However**, there is growing evidence that introducing foods too late may increase the chances of an allergy developing. Wheat allergy was increased in one study if it was introduced either before 4 months of age or after 6 months of age.

#### **Peanuts:**

The government issued new guidelines with regard to peanut consumption on the 25th August 2009. There is no longer any restriction on a woman consuming peanuts during pregnancy and lactation as part of a healthy balanced diet, unless she is allergic to peanuts. The new guidance states: "If your child already has a known allergy, such as a diagnosed food allergy or diagnosed eczema, or if there is a history of allergy in your child's immediate family (if the child's parents, brothers or sisters have an allergy such as asthma, eczema, hay fever, or other types of allergy), then your child has a higher risk of developing peanut allergy. In these cases you should talk to your GP, health visitor or medical allergy specialist before you give peanuts or foods containing peanuts to your child for the first time."