Participant Information Sheet/Consent Form

Women's & Children's Hospital, North Adelaide, South Australia

Lay Title	In Pregnancy eating Eggs and Nuts to reduce food allergies – **The PrEggNut Study**
Scientific Title	**Maternal diet rich in eggs and peanuts to reduce food allergies: a randomised controlled trial**.
Principal Investigator	Dr Debra Palmer
Coordinating Chief Investigator	Professor Maria Makrides
Investigator(s)	Professor Michael Gold, Doctor Thomas Sullivan Professor Susan Prescott, Professor Dianne Campbell Professor Ralph Nanan, Doctor Jennifer Koplin

Part 1 What does my and my baby's participation involve?

1. Introduction

This research project is testing whether the amount of eggs and peanuts a mother eats during pregnancy and breastfeeding has an influence on her baby's food allergy development. We think that the ideal time to prevent food allergy may be during pregnancy and breastfeeding, before you introduce solid foods to your baby. However we do not know how many eggs and peanuts eaten by a mother will help to reduce the risk of her baby developing food allergies.

We plan to compare two different amounts of eggs and peanuts eaten by mothers: 'a standard egg and peanut diet', which is typical for most women, and 'a high egg and peanut diet'. We will compare the outcomes of egg and peanut allergies in the babies at one year of age.
This Participant Information Sheet/Consent Form tells you about the research project. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. You and your baby will receive the best possible care whether you take part or not.

2. What is the purpose of this research?

By 1 year of age, 10% (1 in every 10) of babies will develop a food allergy. To date, little is known about the effect of what mothers eat during pregnancy and breastfeeding on the risk of food allergies in their babies. We have designed this study to help us develop recommendations about how much egg and peanut to eat during pregnancy and breastfeeding to reduce egg and peanut allergies in babies.

3. What does participation in this research involve?

Study participants will be randomly (like tossing a coin) put into one of two groups: 'a standard egg and peanut diet' or 'a high egg and peanut diet'. Neither you, nor the research team, will be able to choose which group you are in. At the end of the study the results are compared to see if one diet is better at reducing food allergies than the other.

We would ask you to follow the diet advice from 22 weeks of pregnancy until your baby is 4 months of age. We will ask that you try to exclusively breastfeed your baby until at least 4 months of age. If you have any breastfeeding problems, the assistance of a lactation consultant will be provided to you free of charge as part of this study.

3.1 Eating eggs and peanuts

- Group 1: High egg and peanut diet – eating at least 6 eggs and 60 peanuts per week.
- Group 2: Standard egg and peanut diet – eating no more than 3 eggs and 30 peanuts per week.

You will be able to include egg and peanut containing foods, towards your weekly target of egg and peanut ingestion. You will be provided with a conversion table showing the amount of egg and peanut present in common foods, for example peanut butter, or egg in quiche, or in baked goods like cake or muffins.

3.2 Study Visits (both groups)

Enrolment Study Visit

At the start of the study, we will ask you some questions about your family history of allergic diseases, your education history, ethnicity, number of previous pregnancies, any smoking in the household and whether you have any pets. We will also ask about how many egg and peanut containing foods that all members of your household usually eat. We will measure your current weight and height, and ask about your pre-pregnancy weight.

Monthly Survey

Each month we will send a text to your mobile phone with a link to complete a quick (less than 5 minute), four question survey about how much egg and peanut you have recently eaten. After birth, one additional question on breastfeeding will also be asked via the same mobile phone link each month along with the egg and peanut intake questions. These quick surveys will stop when your baby is 4 months old or prior if you stop breastfeeding.

Phone call when your baby is 2 weeks old

We will telephone you 2 weeks after your baby's estimated date of delivery. We will ask a few questions about your baby's date of birth, sex, birth weight, gestational age and type of delivery. Any breastfeeding and any episodes of mastitis will also be recorded. You will be asked whether there is any aspect of breastfeeding that you would like more support or advice on, and if you would like to be referred to a Lactation Consultant for advice and support. At this phone call, you will also be asked not to divulge which dietary group you are in to the researchers undertaking the assessments when your baby is 4, 8 and 12 months of age (see below).

Study Visit when your baby is 4 months old

We will ask you to attend an appointment when your baby is 4 months old.

- We will ask a few questions about breastfeeding, infant formula use, introduction of solid foods, allergic disease symptoms in your baby, episodes of mastitis and hospitalisations.
- A research nurse trained in assessing eczema will examine your baby's skin and you will be asked about the use of any eczema treatments for your baby.
- You and your baby will be weighed and your baby's length and head circumference will be measured.
- You will also be provided with the current Australasian Society of Clinical Immunology and Allergy (ASCIA) infant feeding and allergy prevention guidelines, which provide advice on the introduction of solid foods into your baby's diet at around 6 months of age. This includes the recommendation to introduce allergenic foods including peanut butter, cooked egg, dairy and wheat in the first year of life.
- You will be provided with education on recognising the signs and symptoms of an allergic reaction and advice of what to do in such circumstances, consistent with the information provided in the ASCIA Action Plan for Allergic Reactions.

Phone call when your baby is 8 months old

We will telephone you when your baby is 8 months old. We will ask a few questions about breastfeeding, infant formula use, introduction of solid foods, allergic disease symptoms in your baby and hospitalisations.

Study Visit when your baby is 12 months old

- We will ask you to attend an appointment when your baby is 12 months old. We will ask a few questions about breastfeeding, infant formula use, introduction of solid foods, allergic disease symptoms in your baby and hospitalisations.
- Your baby will be weighed, and your baby's length and head circumference will be measured.

- A research nurse trained in assessing eczema will examine your baby's skin and you will be asked about the use of any eczema treatments for your baby.
- Your baby will have skin prick testing (allergy testing) to determine whether s/he has a sensitisation to egg or peanut food allergens. In this test, a liquid containing tiny amounts of these allergens is placed on your child's forearm and a small prick is made on the skin. If your baby has an allergic sensitisation response a small bump (or wheal) will develop. This may cause some temporary discomfort such as itching. The wheal should subside within 2 hours. The skin prick test will be performed by an experienced research nurse in a clinical area and it takes 20 minutes to complete the test. Your child will not be skin prick tested if your child has a previous history of anaphylaxis or is unable to cease antihistamine use. If your child has active or unstable asthma or widespread eczema/atopic dermatitis the skin prick test will be deferred to another day when the asthma or eczema/atopic dermatitis has improved.
- If your baby has a positive skin prick test to egg and/or peanut there is a chance they may have an egg and/or peanut allergy, so you will be given the opportunity for your baby to have a medically supervised egg and/or peanut challenge to determine if s/he can eat egg and/or peanut safely at home. During the egg and/or peanut challenge your baby will be given increasing amounts of egg and/or peanut and watched for any signs of an allergic reaction. After finishing all of the egg and/or peanut your baby will be observed for 2 hours as most serious reactions (i.e. anaphylaxis) occur within this time. Very rarely, a baby might have a mild reaction after leaving your challenge appointment and we ask parents to report these delayed reactions (rashes, diarrhoea etc) to study staff as soon as possible. Please note that if your baby has ever had a confirmed severe reaction (called "anaphylaxis") after eating egg and/or peanut s/he will not undergo this challenge. If your baby needs both an egg and peanut challenge, you will have the egg challenge on one day and will then need to return on a separate day for the peanut challenge.

These study visits will be at no cost to you, nor will you be paid. All the tests and medical care required as part of the study will be provided to you free of charge. You will be reimbursed $40.00 for each of the three study visits to cover your travel and parking expenses.

The study finishes when your baby is 12 months old. We may contact you at a later stage to see if you are interested participating in a follow-up of this study. If we are unable to contact you directly during the study, we may attempt to contact one of the additional contacts that you have provided to us.

4. Other relevant information about the research project

More than 2100 pregnant women will be enrolled in this study around Australia; approximately 1050 in the standard egg and peanut diet group and 1050 in the high egg and peanut diet group. This study is being conducted at the Women's & Children's Hospital and Flinders Medical Centre in Adelaide; at the Nepean Hospital and Children's Hospital at Westmead in Sydney; at the Mercy Hospital for Women and Royal Children's Hospital in Melbourne; and at the St John of God Health Care Hospitals (Subiaco, Murdoch, Midland and Mt Lawley), Joondalup Health Campus, Telethon Kids Institute and Perth Children's Hospital in Perth.

5. Do I and my baby have to take part in this research project?

Participation in any research project is voluntary. If you decide that you and your baby can take part and later change your mind, you are free to withdraw from the project at any stage.
Your decision that you and your baby can or cannot take part, or that you can take part and then be withdrawn, will not affect your routine treatment, relationship with those treating you, your hospital or relationship with SAHMRI.

6. What are the possible benefits of taking part?

We cannot guarantee or promise that you or your baby will receive any benefits from this research. This study will help us develop recommendations about how much egg and peanut to eat during pregnancy and breastfeeding to reduce egg and peanut allergies in babies, which you and your family may benefit from in the future.

If there is any aspect of breastfeeding that you would like more support or advice on, we will arrange for you to be referred to a Lactation Consultant for advice and support, the cost of which will be covered by the research study.

You will be provided with the updated Australasian Society of Clinical Immunology and Allergy (ASCIA) infant feeding and allergy prevention guidelines, which provide advice on the introduction of solid foods into the infant's diet at around 6 months of age.

You will also be provided with education on recognising the signs and symptoms of an allergic reaction and advice of what to do in such circumstances, consistent with the information provided in the ASCIA Action Plan for Allergic Reactions.

7. What are the possible risks and disadvantages of taking part?

Skin prick testing and egg/peanut challenges are safe procedures with minimal discomfort. Rarely, generalised allergic reactions such as hives, generalised skin rash or severe reactions like anaphylaxis (breathing difficulties and/or a floppy unresponsive child) can occur. If an allergic reaction occurs a medical doctor will be immediately available to treat your child with antihistamine, ventolin or adrenaline medication if needed and your child will remain under an extended period of observation to ensure resolution of symptoms prior to discharge from the hospital. The risk of anaphylaxis to the skin prick test for this study would be extremely rare as we are not using any fresh food extracts or latex allergens, only commercially available allergen extracts designed for skin prick testing use. The risk of anaphylaxis to the egg/peanut challenge for this study would also be extremely rare as we are using a graded dose approach where by the amount of egg given to your child is slowly increased over time and if allergic symptoms occur the challenge will cease and no more egg/peanut will be given to your child.

8. What will happen to the study data?

Any stored data will be identified by a unique study number only, so that you and your baby cannot be identified. This data may be used in future research projects, which may or may not be related to the original research project, unless you have not consented for this to happen. Use of any stored data for research purposes would only occur if the research has been approved by the trial steering committee and the Human Research Ethics Committee.

Your information will remain confidential except in the case of a legal requirement to pass on personal information to authorised third parties. This requirement is standard and applies to information collected both in research and non-research situations. Such requests to access information are rare; however we have an obligation to inform you of this possibility.

9. What if I withdraw myself and my baby from this research project?

If you decide to withdraw yourself and your baby from the project, please notify a member of the research team If you and your baby withdraw during the research project, the study staff will not collect additional personal information, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

10. What happens when the research project ends?

Following completion of this study, all records identifying you and your baby will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. When this study is completed we will send you a summary of the study findings. The results of this study may be published in medical journals or presented at professional meetings, but you or your baby will not be identified in any way.

Part 2 How is the research project being conducted?

11. What will happen to information about yourself and your baby?

Information about any admission to hospital for longer than 24 hours that you or your baby may have had during this research project or any allergic reactions your baby has had to either egg or peanut foods may be obtained from health records held at this hospital and other health services, for the purpose of this research project. Research nurses will access your or your baby's medical records only if you have been admitted to a hospital for longer than 24 hours to record the primary

diagnosis and length of stay, or if you have visited a health service due to an allergic reaction to record any allergy related symptoms experienced by your baby and any egg or peanut food allergy diagnosis. By signing the consent form, you agree to the study team accessing health records if they are relevant to your and your baby's participation in this research project.

Your and your baby's health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the institution relevant to this Participant Information Sheet, SAHMRI, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above. Information about your and your baby's participation in this research project may be recorded in their health records. Any information obtained for the purpose of this research project that can identify the participant will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

12. Who is organising and funding the research?

This research project is being conducted by SAHMRI Healthy Mothers, Babies and Children theme together with the Women's and Children's Hospital and funded by a project grant from the National Health and Medical Research Council (NHMRC ID: 1147576).

13. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the Women's & Children's Health Network. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

14. Further information and who to contact

We will collect your contact details so that we can communicate with you throughout the study. We recognise that people often change their telephone number and address, and therefore cannot be contacted by researchers. To help keep in contact with you we are asking you to provide us with the names and contact details of persons who would be able to let us know your new contact details; these people are usually friends or relatives and are called *alternate contacts*. If we needed to use one of the alternate contacts we would call them, explain who we are and that you were involved in a study and have given us their contact details so that they can put us in touch with you.

If you would like to contact us, the person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact a member of the study team on 8128 4436 or any of the following people:

Clinical contact person

Name	Dr Michael Gold
Position	Head of Department of Allergy and Clinical Immunology, Women's & Children's Hospital
Telephone:	8161 8638
Email:	michael.gold@adelaide.edu.au

Study related matters

Name	Prof Maria Makrides
Position	Theme Leader, Healthy Mothers Babies and Children, SAHMRI
Telephone	8128 4416
Email	maria.makrides@sahmri.com

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Women's & Children's Health Network
HREC Executive Officer	Dr Tamara Zutlevics
Telephone	8161 6149
Email	tamara.zutlevics@sa.gov.au

Local HREC Office contact (Research Governance Officer)

Name	Camilla Liddy
Position	Research Governance Officer
Telephone	8161 6688
Email	camilla.liddy@sa.gov.au

PrEggNut Study CONSENT FORM

LAY TITLE: In Pregnancy eating Eggs and Nuts to reduce food allergies – The PrEggNut Study

SCIENTIFIC TITLE: Maternal diet rich in eggs and peanuts to reduce food allergies: a randomised controlled trial.

I _____

hereby consent to my and my child's involvement in the research project described above:

1. The nature and purpose of the research project described on the attached Information Sheet has been explained to me. I understand it and agree to myself and my child taking part.

2. I understand that I and my child may not directly benefit by taking part in this study.

3. I acknowledge that the possible risks and/or side effects, discomforts, and inconveniences, as outlined in the Information Sheet, have been explained to me.

4. I understand that I can withdraw myself/my child from the study at any stage and that this will not affect medical care or any other aspects of my/my child's relationship with this healthcare service.

5. I understand that there will be no payment to me or my child for taking part in this study, but that I will be reimbursed for travel costs for my study visits.

6. I have had the opportunity to discuss taking part in this research project with a family member or friend, and/or have had the opportunity to have a family member or friend present whilst the researcher was explaining the research project.

7. I am aware that I should retain a copy of the Consent Form, when completed, and the Information Sheet.

8. I consent to the following:

   a) To follow the dietary advice given to me about the amounts of eggs and peanuts to eat per week from study entry until my child is 4 months of age, or until I stop breastfeeding my child, whichever comes first.

   b) To be contacted to ask a few questions about my egg and peanut intakes on my mobile number each month from study entry until my child is 4 months of age, or until I stop breastfeeding my child, whichever comes first.

   c) To be telephoned 2 weeks after my child's expected date of delivery, and when my child is 8 months old, to be asked a few questions as detailed in the information sheet.

   d) To attend appointments when my child is 4 and 12 months of age as detailed in the information sheet.

9. I agree to the accessing of my and my child's medical records for the purpose of this study.

10. I understand that my and my child's information will be kept confidential as explained in the information sheet except where there is a requirement by law for it to be divulged.

PrEggNut Study CONSENT FORM

11. I do/do not consent to my and my baby's data being used in other research projects, provided the project has the approval of a Human Research Ethics Committee.

12. I understand that the alternate contacts I have provided may be used to contact me as explained in the information sheet for study related purposes.

13. I understand that I may be contacted following the completion of this study to see if I am interested in participating in a follow-up of this study.

Participant Signature: .....

Full name of participant:…….....

Dated: .....

I certify that I have explained the study to the participant and consider that she understands what is involved.

Researcher Signature: …….....

Title: .....

Dated: .....