

# Participant Information Sheet

Study title: **[MINI - Mother and Infant Nutrition Investigation]**

Locality: **Palmerston North** Ethics committee ref: **15/NTA/172**

Lead investigator: **Ying Jin** Contact email: **[mini@massey.ac.nz](mailto:mini@massey.ac.nz)**  
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## Would you like to help us?

We invite you to take part in a research study: Mother and Infant Nutrition Investigation (MINI). This sheet gives detailed information about the study. Please read it carefully before deciding whether you wish to join our study.

We need mothers and their infants to take part. It is important that you understand why we are doing this research, and what it may involve for you. Please take time to read the sheet carefully. Feel free to discuss it with other people, such as your family, whānau, friends, or your health care providers. Please ask us questions if anything seems unclear, or if you wish to know more details.

## Introducing the researchers

This research is led by PhD scholar Ms Ying Jin. Ying's supervisors are Dr Louise Brough and Professor Jane Coad. They are human nutritionists in the School of Food and Nutrition, Massey University, Palmerston North. Anne Broomfield, research officer, will also assist in the study.

## What is the purpose of this study?

After the birth of their baby, most women continue to see their health care professionals. However, the focus is often on the infant's health. Only limited attention is given to the mother's health. This study will monitor the mothers' health by assessing her nutrient status, thyroid function and mental health. The thyroid is a small butterfly-shaped gland at the base of the neck which produces hormones. How a mother's health status might affect her baby's development during early life is important. The three nutrients we are studying are iodine, selenium, and iron. Understanding these nutrients will help to provide better health care to future mothers. This leads to greater knowledge about the health and wellbeing of both the mothers and their infants.

## Do I have to take part?

No. It is entirely up to you to decide whether you wish to take part. If you do agree, you will be asked to sign a Consent Form. You will be given a copy of both the Participant

Information Sheet and the Consent Form to keep.

Should you change your mind about being in the study, you are free to withdraw from the study at any time without giving any reason.

### **What would your participation involve?**

If you are interested in taking part in the study, please phone or email us. You can also enter your details on this study's "Express of Interest" webpage. We will reply immediately and arrange a brief telephone conversation. We will ask you some questions to ensure that you are eligible. You must feel totally comfortable about taking part in the study.

Soon after, we shall make an appointment for you and your baby to come into the Human Nutrition Research Unit at Massey University. If this is not possible, we may visit you either at home, at a local community Centre, or at a health professionals' clinic.

During the first visit, we shall

- ask you some questions about your nutrient supplement use, and your nutrition knowledge. We will also ask you about your health, diet and some personal information;
- measure your weight, height, and body composition;
- ask you to provide small samples of urine and breast milk which we will use to assess your nutrient status;
- measure your baby's weight, length and head circumference.
- collect a small urine sample from your baby to assess his/her nutrient status.

Your first visit should take no more than two hours.

After the first visit, you will be given

- two small paper bags for you to collect nail clippings from yourself and from your baby to assess selenium status.
- a 4-day food record diary to measure your nutrient intake.

Within a month after your first visit, at a convenient time, we will collect the samples and food diary from you at home.

The second visit will be when your baby is 6 months old. The last visit will be when your baby is 12 months old. We will ask you to complete a questionnaire to assess your child's development at 4, 8 and 12 months.

A detailed Flow Chart is on pg. 6 of this Information Sheet.

### **How would the required samples be collected?**

A clear detailed instruction of how to collect infant or adult nail clippings would be given at the first visit. Infant urine samples will be collected by placing a pad inside the nappy, checking every 10 minutes until wet, and then urine aspirated (extracted) with a syringe. Blood samples will be drawn by experienced phlebotomist. The collected biological samples will be frozen, labelled with a unique code (no personal information will be displayed on the samples), and then stored for 10 years to allow a number of analyses to take place. After 10 years, the samples will be properly disposed in biohazard bags to be incinerated (burned) by a professional company who specialise in destroying biological samples. We acknowledge that the use and storage of tissue is a cultural concern for some Māori people. We are unable to return body fluids such as blood, urine and breastmilk due to safety (microbiological) issues. However, if you wish, the nail clippings, after analysis, will be returned to you if you request this in advance.

### **What are the possible risks to you?**

There are small risks when taking blood samples such as discomfort, bruising, infection or fainting. To minimise any risk, your blood will only be taken by experienced and fully trained research staff.

Any risks involved in this study are very minor. All of the checks are routinely made. If you have any concerns during the study you may discuss these with any of the study team.

Any complaints you may make will be fully investigated. If you have any concerns about any aspect of this study, you should speak immediately to a member of the study team. They will do their best to answer all of your questions fully.

### **What are the advantages of taking part in the study?**

- Both your thyroid function and iron status will be monitored during the study. These are not normally covered by primary health care services;
- Repeated monitoring of your wellbeing during the first year after delivering a baby;
- Based on your food diary, you will receive feedback on your intake of nutrients within a month after we receive the dietary diary. This will be compared to New Zealand standard dietary guidelines.
- You will also receive information about your child's development assessments at 4, 8 and 12 months.

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

Yes. All information collected about you and your baby during the study will be kept strictly confidential. Each mother will be given a unique code which will be used on all data collected. No identifying details will be recorded on the interview sheets or other records. When the study results are presented, you will not be named or recognised from any of the

information given. All information will be entered into a protected database at Massey University. Information collected about you and your baby will be kept strictly confidential and secure in a locked filing cabinet. All electronic files on computers will have passwords and restricted access. Only the named members of research team will have access to detailed personal information.

Massey University maintains a central record of all research projects undertaken. This does not include personal information about those who take part. The data (without containing personal information) will be held for 10 years after the youngest person in the study has reached the age of consent or 16 years old.

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

Should you wish, you will receive all the results about you and your baby. Should your results be, in any way, unusual, you will be encouraged to contact your general practitioner and seek appropriate medical advice. Once the whole study has ended, we can send you a summary of the study results, should you wish to have it. The results will also be presented at scientific meetings or published in peer reviewed journals. This ensures that a wider community, including health professionals, can know and read about the findings. You and your baby will not be identified by any of these publications or presentations.

### **What would happen if you were injured in the study?**

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC. This would be the same as if you were injured in an accident at work or at home.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not in any way affect your cover.

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

This project has been reviewed and approved by the Northern A Health and Disability Ethics Committee through the full review pathway.

Contact for further information:

If you have any further questions or if you have any concerns whilst taking part in the study then please contact:

*Ms Ying Jin, Lead Investigator/PhD Scholar*

*Email: [mini@massey.ac.nz](mailto:mini@massey.ac.nz)*

*Cell phone: 027 399 4138*

*Telephone: +64 (06) 9517556*

*Dr. Louise Brough, Principle Supervisor/Senior Lecturer*

*Telephone: +64 (06) 356 9099 ext. 84575*

*Email: [L.Brough@massey.ac.nz](mailto:L.Brough@massey.ac.nz)*

**Where can you go for more information about the study, or to raise concerns or complaints?**

If you have any questions, concerns or complaints about the study at any stage, you can contact:

*Ms Anne Broomfield, Research Technical Officer  
Human Nutrition Research Unit  
Massey Institute of Food Science and Technology  
Telephone: +64 (06) 356 9099 ext. 84566  
Email: [A.M.Broomfield@massey.ac.nz](mailto:A.M.Broomfield@massey.ac.nz)*

If you want to talk to someone who is not involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050  
Fax: 0800 2 SUPPORT (0800 2787 7678)  
Email: [advocacy@hdc.org.nz](mailto:advocacy@hdc.org.nz)

If you feel you would like to talk to a Māori health support person, please contact:

*Dr Maureen Holdaway  
Associate Director, Research Centre for Maori Health & Development  
Telephone: +64 (06) 356 9099 ext. 85092  
Email: [M.A.Holdaway@massey.ac.nz](mailto:M.A.Holdaway@massey.ac.nz)*

You can also contact the health and disability ethics committee (HDEC) that approval this study on:

Phone: 0800 4 ETHICS  
Email: [hdec@moh.govt.nz](mailto:hdec@moh.govt.nz)

# MINI STUDY FLOW CHART

