PARTICIPANT INFORMATION SHEET

Study Title	How do sensory shifts shape our diet? - Testing the neural mechanisms underpinning nutrient selection
Principal Investigator	Dr Mei Peng
Co-Investigators	Dr Mike Garratt, Dr Reece Roberts, Dr Jessica McCormack
Funder	Royal Society of New Zealand (Marsden Fund Standard Grant)

You are invited to take part in a study exploring the sensory, metabolic, and neural changes that occur during pregnancy and how they affect dietary choices and body weight. We are recruiting two groups of women to take part in the study – women who are planning to become pregnant in the next year and a control group of women not currently planning to get pregnant.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

The Participant Information Sheet also includes a guide on how we will use the data and tissue (blood samples) you give us.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is **9** pages long, including the Consent Form. Please make sure you have understood and read all the pages.

Do I have to take part?

Participation in this study is entirely voluntary (your choice). If you decide to take part, you are free to withdraw at any time without having to give a reason. A decision to withdraw will not affect your care or your participation in future studies.

What is the purpose of the study?

The purpose of the study is to understand how brain and sensory changes across all phases of reproduction (from pre-pregnancy, during pregnancy, to post-pregnancy) interact with metabolism and diet choices. By looking at these changes in pregnancy we hope to have a better understanding of how metabolism changes across the lifespan.

In this study we will be observing women who have never been pregnant at six timepoints over the course of two years. We will take measures on eating and diet behaviours, sensory responses, and metabolism. We will also be taking blood samples to look at hormone and macronutrient levels.

This consent form accurately describes the risks and benefits of the study. However, for the study to work, there are some things about this study that we won't tell you about until after you participate. At the end of your participation in the study, the researchers will fully explain the study, including the reasons for withholding certain information about the study.

Who can take part?

We are recruiting 230 women to take part in a longitudinal cohort study: 165 women who are planning to conceive in the next year and 65 women with no plans to conceive in the next two years.

Women can take part in the study if they:

- Are aged between 18 and 45 years old;
- Reside in the Dunedin or Auckland region;
- Have never been pregnant;
- Have no history of neurological disease or metabolic conditions;
- No known sensory dysfunction (e.g. no sense of smell);
- Able to read and understand English or Te Reo; and
- Able to give informed written consent.

Participants will be excluded if they are currently pregnant or taking oral contraception, or have had gender affirming surgery or hormone treatment procedures

How is the study designed?

This study is a longitudinal prospective cohort, meaning that it collects data on the same group of participants at multiple timepoints over a long period of time – in this case up to two years. Participants will be asked to complete assessments at six timepoints. For women planning to become pregnant (i.e., the Pregnancy Cohort), these assessments will take place at pre-pregnancy, first trimester, second trimester, third trimester, three months post-pregnancy, and one-year post-pregnancy. For women not planning to become pregnant (i.e., the Control Cohort) these assessments will take place every 3-6 months to coincide with the timing of the Pregnancy Cohort.

Each timepoint involves four consecutive days of testing, conducted in the morning after a period of fasting (2-12 hours). These sessions will last around 90 minutes (Days 1-3) or up to 2 hours (Day 4). Participants will also complete online questionnaires and a 4-day food diary. On Day 4 we will take blood samples and physiological measurements, after which participants can enjoy a buffet.

What will my participation in the study involve?

If you would like to take part in the study and meet the above criteria, you will need to complete a series of questionnaires and assessments at six timepoints over the next two years. Some of the assessments will be online, while some will be done in-person over four consecutive at the University of Otago Food Science Sensory Lab. In total, there will be 24 in-person sessions which will take 1-2 hours each. These assessments will take place approximately every 3 months. Where possible, arrangements can be made to for women affected by early pregnancy or breastfeeding if they are unable to attend lab sessions (i.e., postpone sessions or conduct assessment in-home).

We have summarised the assessments and visits at each timepoint in the table below.

Pregnancy Cohort	Pre-pregnancy	First trimester	Second trimester	Third trimester	Three months post pregnancy	One-year post-pregnancy
Control Cohort	0 weeks	3 months	6 months	9 months	12 months	21 months
Timepoint	**1**	**2**	**3**	**4**	**5**	**6**
Background information	x					x
Questionnaires (online)	x	x	x	x	x	x
Sensory tests (in-person, 3 sessions, up to 90 minutes each)	x	x	x	x	x	x
Physiological measures (in-person, 1 session, up to 2 hours)	x	x	x	x	x	x
• Blood test	x					x
Food Diary	x	x	x	x	x	x

What tests will I have to do over the study?

At each timepoint, you will be asked to attend four in-person sessions in the morning. You will also be asked to complete questionnaires or food diaries outside of these sessions.

- Questionnaires: You will be asked to complete online survey around eating behaviour, physical activity, and psychological wellbeing before each session. For women who become pregnant, the online survey will also include questions around your pregnancy and birth outcomes. These can be completed at any time in the week before you come in for your in-person session and will take around 15-30 minutes to complete.
- Sensory tests: You will be asked to attend three consecutive morning sessions where we will assess your perception of different tastes, smells, visuals, and tactile sensations. You will be asked to refrain from eating for at least 2 hours prior to each session. Each session will take around 90 minutes.
- Physiological tests: On the fourth day you will be asked to come in for physiological tests. This includes:
    - Height and weight, and skinfold thickness;
    - *Basal metabolic rate*, which is measured while resting from carbon dioxide production and oxygen consumption over a 30 minute period.

- *Blood sample* (15mL sample – equivalent to 3 teaspoons) will be taken to analyse your metabolic profile and measure levels of glucose and hormones. Blood samples will only be taken at the first and last timepoint.

You will be asked to refrain from eating for at least 12 hours (or 8 hours during pregnancy and lactating). After the tests have been completed you will be invited to have a meal from a buffet. This session will take up to 2 hours.

- Food diary: After your last visit you will be asked to complete a 4-day weighted food diary. We will give you instructions on how to complete the diary over the week following your visit.

Before the first timepoint we will also ask some question about your background and reproductive history, as well as some general health and diet questions. We will also collect contact information so that we can follow-up with you at each timepoint. A subgroup from each cohort will also be invited to take part in a sub-study which will involve an fMRI session before and after pregnancy.

What will happen to my blood samples?

Our study requires participants to provide blood samples at timepoint 1 and 6 to look at the metabolic profile, as well as glucose and hormone levels. Blood samples will be taken by a trained assistant and will be analysed locally. No blood samples will leave Aotearoa.

We acknowledge that personal and health information is taonga and we treat samples accordingly. We will not retain any samples and will ensure culturally appropriate processes regarding data management including maintain privacy and communication with whānau when appropriate.

We encourage all participants to discuss the cultural issues associated with sending and storing your tissues with whānau. Options for disposal of blood samples with karakia or returning samples can be discussed. Please let us know if there are additional things we can do to meet your needs.

What are the possible risks of this study?

We recognise that pregnancy and motherhood are potentially sensitive issues and may raise feelings of distress or embarrassment. You can decline to answer if the questions are upsetting to you and may withdraw from the study for any reason. If you would like to talk to someone about issues raised by the study, we will help you access support services.

There is a slight risk of bruising from the blood tests. In the event that testing indicates a clinical abnormality – such as high levels of glucose – we will inform you and advise you to contact your general practitioner. We will ask for contact information for your family doctor or medical centre, but will only contact them with your consent.

What are the possible benefits of this study?

There are no direct benefits to you by taking part in the study. Your participation in this research will help us to better understand how metabolism and diet change over the lifespan.

We recognise that taking part in the study will take a substantial part of your time and two years of contact with us. In recognition of your generosity you will be offered $150 in vouchers at timepoint 1 and 6 and $100 at each additional visit in order to compensate for costs you have incurred in taking part in this study (up to $700 in total). Participants that complete all six timepoints will be offered a gift hamper valued at up $100 and a certificate in recognition of their participation.

What is something goes wrong?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

What will happen to my information?

During this study the researchers will record information about you and your study participation. This includes the results of any study assessments.

Will the information about me be kept confidential (private)?

Only the researchers and study monitor will have access to your identifiable information (e.g., your name, date of birth, or address). Study monitor access will only check the accuracy of the information collected for the study, and the information will remain confidential.

To make sure that your personal information is kept confidential, information that identifies you will not be included in any report generated by the researcher. Instead, you will be identified by a code. The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed. Participants will be known to the research team, but no material that could identify you will be used in any reports on this study.

The following groups may have access to your coded information:

- The researchers and suitably trained study staff, to conduct the study
- Southern Community laboratory, for sample processing, analysis, and reporting purposes
- Study sponsor for the purposes of the study

De-identified data may be included in published study results including, but not limited to, peer-reviewed publications, scientific meetings, and regulatory / marketing submissions. The results of the project will be available in the University of Otago Library (Dunedin, New Zealand).

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it

harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

How will study information be stored?

Your information will be stored securely in hard-copy at the University of Otago or in databases hosted by the University of Otago. All computer records are password protected and paper records stored in a secure storage area. At the end of the study all hard-copy records will be transferred to a secure archiving site and stored for 10 years. Any personal information held on participants, such as contact information, may be destroyed at the completion of the research, although the data derived from the research may be kept for much longer. All future use of the information collected will be controlled in accordance with the Privacy Act 2020.

Can I request to see my data?

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access the results of your screening and safety tests during the study.

If you have any questions about the collection and use of information about you, you should ask the Principal Investigator, Mei Peng.

Will my information be used in future studies?

De-identified data may be made available on request to other researchers in Aotearoa for future research related to diet and metabolism in pregnancy. You will not be told when future research is undertaken using your information. Your information may also be added to information from other studies, to form much larger sets of data.

You will not get reports or other information about research that is done using your information. Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.

The study team may remove the code from your de-identified information – this is called 'anonymisation'. This makes it very difficult (but not impossible) to identify the information that belongs to you. In addition to the uses described above, anonymised data may be included in online repositories (such as Otago University Research Archive) for the purpose of ensuring reproducibility, transparency, integrity and fidelity of our study design and analysis methods. To protect participant privacy and minimise the risk of re-identification, we will limit the publicly available demographic information (i.e., remove ethnicity information and report ranges rather than values). Your anonymised information may be accessed from overseas where there may be no New Zealand representation on governance committees for how the data is used. There is a risk that overseas researchers may work with information in a way that is not culturally appropriate for New Zealanders.

What if I change my mind?

You may withdraw your consent for the collection and use of your information at any time, by informing the research team.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you. Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

What happens after the study?

The data will be analysed and a report written. These data will be presented in scientific journals and conferences. Our findings may be shared with policy makers in health and nutrition.

We will keep your information for 10 years after the study is completed.

If you would like to receive a summary of the study findings, please include a contact email or address. We hope to be able to share the results in early 2026.

If you have any questions or concerns about this research, please contact **xxx@otago.ac.nz**

Principal Investigator:
Dr Mei Peng
Email: mei.peng@otago.ac.nz
Phone: (03) 479 4052

Head of Department – Food Science:
Professor Indrawati Oey
Email: indrawati.oey@otago.ac.nz
Phone: (03) 479 8735

If you want to talk to someone who isn't 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@advocacy.org.nz
Website: https://www.advocacy.org.nz/

To ensure ongoing cultural safety, the Southern District Health Board encourage those who identify as Māori, and who are participating in health research or clinical trials, to seek cultural support and advice from their own Kaumātua or Kuia in the first instance, or please contact:

Wendi Raumati & Eleanor Russell
Kaiāwhina
Te Ara Hauora - Māori Health Unit,
Dunedin Hospital
Phone: (03) 474 0999 ext 58649

Andrea Jerry
Kaiāwhina
Te Huinga Tahi Māori Health Cultural Support,
Southland Hospital
Phone: (03) 218 1949 ext 48509

This study has been approved by the University of Otago Human Ethics Committee (Health). If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (phone +64 3 479 8256 or email gary.witte@otago.c.nz). Any issues you raise will be treated in confidence and investigated, and you will be informed of the outcome.