PARTICIPANT INFORMATION SHEET
Biobank

Study title:	**NiPPeR Study:** Nutritional intervention preconception and during pregnancy to maintain healthy glucose metabolism and offspring health		
Locality:	**Grafton**	**Ethics committee ref.**	**15/NTA/21**
Lead investigator:	**Professor Wayne Cutfield**	**Phone 09 923 4476**	

This information is additional to the Participant Information Sheet (main study). The biobank is an important and necessary part of the study. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you start in the study, but change your mind later, you can pull out of the study at any time, and it won't affect the care you receive.

We will go through this information sheet with you and answer any questions you have. You do not have to decide today. Before you decide, feel free to talk about the study with other people, such as family, whānau, friends, or healthcare providers.

If you agree to take part in this study, we will ask you to sign the study Consent Form. We will give you a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 7 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

Healthy nutrition for a mother before and during pregnancy is important for both mother and baby. Many questions will be answered by analyzing your information and blood and other samples soon after they are collected.

We want to store some of your blood and other samples for future research. In 5 years, or 10 years, and so on, people will invent new tests. They will learn new facts. They will have new questions. Instead of having to organize this whole study over again, important new questions will be answered quickly by doing a new analysis on one of your stored samples.

Tests done later on your samples will all be similar to the tests done during the main study. They will all be about healthy pregnancy and healthy nutrition, growth and development of your baby.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

During the study we will ask you for a number of samples. These will include blood, urine, hair, mouth swabs, skin swabs (and perhaps stool). We will ask for samples from your baby. These will include umbilical cord, cord blood, placenta, mouth swabs, hair and stool.

To take samples from the placenta, we need to take the whole placenta from hospital or birth unit to the laboratory at the University of Auckland. We will only take small samples from the placenta. The remaining placenta will be returned to you or disposed according to standard laboratory process for biohazard waste.

HOW DOES THIS STUDY RESPECT MĀORI CULTURE VALUES?

We understand that many Māori consider their blood and genetic material to be tapu and that participation in this type of study requires careful consideration. Some of your genetic information will be the same as your whānau, and when donating a tissue sample it may be appropriate to discuss participation with them. You may also wish to obtain the blessing of your iwi for participation in this research. They may have a position on participation in genetic studies and issues such as sending tissue samples overseas and access to results of the study. Should you have any concerns regarding appropriate practice/ tikanga to address cultural issues arising from your participation in the study it is recommended that you consult with a kaumatua. We respect the importance of these values and beliefs so please inform us if you wish to have whānau support present or perform a karakia when donating blood or other samples.

WHAT HAPPENS TO MY SAMPLES AFTER THEY HAVE BEEN COLLECTED?

Samples will be stored with a code (not your name or your baby' name) on them. A single sample will be divided into many smaller samples which will be frozen. Each of the small samples can later be unfrozen and tested separately. Most will be stored and analysed in New Zealand. A few will be sent to the University of Southampton in England, the National University Hospital and National University in Singapore, and Nestec Ltd Research Centre in Switzerland or other places for specialised tests. Some samples may be stored by our research partners in England or Singapore but not elsewhere. Unused samples may be returned to New Zealand. Any test result may be linked to anonymous data from questionaires or other tests.

After 20 years any unused samples will be disposed of using standard laboratory processes for biohazard waste. It is possible that an ethics committee will later be asked to extend the length of storage.

The people and organisations that collect and store the samples now remain responsible for the samples and any analysis in the future, and pass on these same responsibilities to those

who follow them. Auckland Uniservices Ltd (part of the University of Auckland) will remain responsible for looking after samples in New Zealand.

Future studies on your samples in New Zealand will need ethical approval in New Zealand. Analyses overseas may be part of a study approved in New Zealand. Analyses overseas that are not part of a New Zealand study will need ethical approval in their own country, and that review in unlikely to have a New Zealand representative.

Samples are stored and analysed without your name. Your name is kept securely on a separate list. If you withdraw from the study, it will be possible to re-link you name to your samples and withdraw your samples. These can be disposed of, using established guidelines for biohazard waste, or returned to you or your family / whanau. Your child also has the right to withdraw when he/she is old enough.

You will not own any intellectual property rights that may arise out of future research.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

BENEFITS OF TAKING PART

There is no direct benefit to you. We expect that analysis of your anonymous samples in the future will lead to new knowledge which we hope will contribute to future health benefits for others.

RISKS TO TAKING PART

We do not expect any risks to you.

WHO PAYS FOR THE STUDY?

This project is mainly funded by governmental and other academic research funding awards to Gravida: National Centre for Growth and Development (New Zealand), MRC Lifecourse Epidemiology Unit (UK) and the Singapore Institute for Clinical Sciences, together with a research collaboration with Nestec Ltd, Switzerland (who provided funds and manufactured the nutritional drink). The study in NZ is sponsored by Auckland UniServices Limited (part of the University of Auckland).

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC. 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.

VOLUNTARY PARTICIPATION

We decide if you fit our study. **YOU** decide whether or not you want to join the study. Even if you do join the study you are still free to withdraw from the whole study or parts of the study at any time and you do not have to give a reason. However, the data you've already given will

kept anonymously and analysed. Withdrawing from the study at any time will not affect your health care.

If we learn anything new that may be relevant to your willingness to continue in the study, we will inform you promptly.

CONFIDENTIALITY

All information collected about you will be anonymised and kept strictly confidential. Your GP will be informed that you are taking part in the study and we suggest you tell any doctor looking after you that you are taking part. When you become pregnant we will send a letter to your lead maternity carer (LMC) informing them of your participation.

WHAT HAPPENS AFTER THE STUDY?

The results of this study will be published in medical journals and possibly local and national press. You will not be identified in any of these. You will be able to read the overall results on the study website once the study has finished.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

Please feel free to ask the Lead Researchers any further questions before deciding to take part or at any time during the study.

Prof. Wayne Cutfield, Principal Investigator
Phone: 09 923 4476
Email: w.cutfield@auckland.ac.nz

A.Prof. Timothy Kenealy, Co-Investigator
Phone: 0274 905 914
Email: t.kenealy@auckland.ac.nz

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@hdc.org.nz

If you require Māori cultural support, talk to your whānau in the first instance. If you have any questions or complaints about the study you may contact the Māori cultural support by telephoning below details

If you live within Auckland and Waitemata District Health Boards' Catchment area please call phone: 486 8920 ext. 3204.

If you live within Counties Manukau District Health Board's catchment area please call

Phone: 021 221 5225

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

Statement of approval

This study has received ethical approval from the Northern A Health and Disability Ethics Committee 15/NTA/21

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BIOBANKING CONSENT FORM

If you need an INTERPRETER, please tell us.

Please initial to indicate whether you consent to the following

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.	Yes ☐	No ☐
I am satisfied with the answers I have been given about the biobank and I have a copy of this consent form and information sheet.	Yes ☐	No ☐
I agree for my anonymous tissue samples and information (and those of my baby) to be stored and used in properly approved future research studies of mothers' health and babies' and children's growth, development and disease.	Yes ☐	No ☐
I understand that it is my choice to be included in the study and that being included in the biobank is a necessary part of participating in this study.	Yes ☐	No ☐
If I decide to withdraw myself and my baby from the study, I agree that the data already collected may continue to be used. I am aware that my child may withdraw when he/she is old enough.	Yes ☐	No ☐
I am aware that if I withdraw myself and by baby from the study I can request that unused samples be disposed of, using established guidelines for biohazard waste, or returned to me. I am aware that this right extends to my child when he/she is old enough.	Yes ☐	No ☐
I understand that my inclusion in the biobank is confidential and that no material, which could identify me or my baby personally, will be used in any documents from the biobank.	Yes ☐	No ☐
I agree that some of my samples, or my baby's samples, may be sent to the University of Southampton in England, the National University Hospital and National University in Singapore, and Nestec Ltd Research Centre in Switzerland, or other places for specialised tests.	Yes ☐	No ☐

I agree to my tissue samples and those of my baby being disposed of, if unused after 20 years, using established guidelines for biohazard waste.	Yes ☐	No ☐
I know who to contact if I have any questions about the biobank.	Yes ☐	No ☐

OPTIONAL CONSENT I would like the placenta to be returned to me after sample collection rather than disposal according to established practices	Yes ☐	No ☐

Declaration by participant:
I hereby consent to be included in the biobank

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the biobank to the participant, and have answered the participant's questions about it.

I believe that the participant understands the biobank and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____