Participant Information Sheet

Study title:	**GlucoTRIG: measuring the impact of high carbohydrate and high fat composite meals on postprandial insulin and triglyceride responses – a randomised controlled crossover trial**		
Locality:	**Massey University Albany Campus, Auckland**	Ethics committee ref.:	SOA 22/34
Lead investigator:	**Wen Xin Janice Lim**	Contact email:	**w.x.j.lim@massey.ac.nz**

Researcher Introduction

My name is Dr Janice Lim at the Riddet Institute, Massey University, Auckland campus.

Invitation to Participate in this Research Study

Thank you for your interest in our research on developing a new indicator (GlucoTRIG) for the measurement of the healthiness of foods. 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. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

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.

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

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

WHAT IS THE PURPOSE OF THE STUDY?

Elevated insulin and triglyceride levels from poor food choices are known to increase the risk for cardiovascular disease (CVD) and type 2 diabetes (T2D). The present study seeks to investigate whether the GlucoTRIG indicator is able to accurately

measure the impact of a meal on blood insulin and triglycerides and therefore help inform the nutritional quality of a meal. This may aid in better food choices.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

To take part in this study you must be:

- ✓ Male or females aged between 18 and 40 years old with BMI between 18 and 30 kg/m^2 (BMI is calculated using formula body weight (kg)/ height (m) x height (m))

You are NOT eligible to participate if you:

- ✓ Are currently taking any glucose- or lipid-lowering drugs, or supplements (e.g. statins, fish oil) or anti-hypertensive drugs;
- ✓ Are dieting or have any dietary restrictions or eating disorders;
- ✓ Have allergy or intolerance to any of the food products or ingredients used (during the screening, you will discuss with one of the investigators any food allergies you may have);
- ✓ Have history of congestive heart failure, stroke, myocardial infarction, coronary artery bypass graft, or atherosclerotic CVD;
- ✓ Have history of diabetes, hypertension, triglycerides higher than 3 mmol/L; total cholesterol higher than 5 mmol/L;
- ✓ Have history of gastrointestinal disorder or liver disease;
- ✓ Smoke;
- ✓ Are pregnant or breastfeeding

HOW IS THE STUDY DESIGNED?

The study will involve 15 people from the Auckland region. The study consists of **ONE** screening visit, followed by **THREE** test visits over a period of four weeks.

Screening visit

The study will involve you coming to the Massey University Nutrition Research Facility, located at Albany campus, Auckland for the screening. The screening will be completed within an hour. You will be required to fast (i.e. no food or drink except water) for at least 12 h prior to your screening visit. During the screening visit, you will be asked to complete a consent form, brief medical questionnaire, health screening questionnaire, eating attitudes test, and a physical activity questionnaire. A finger prick blood sample will be taken from one of your fingers for fasting glucose, haemoglobin A1c (HbA1c), and lipid profile measurements. Your weight and height, waist and hip circumference, Body Mass Index (BMI), body fat and muscle mass, blood pressure and heart rate will also be taken. You will be provided a copy of the measurements at the end of your screening visit.

Study visits

If you are eligible after the screening visit, you will need to be available for three mornings taking approximately 3.5 h each. Each study visit will be at least a week apart.

You will be required to fast overnight (i.e. no food or drink except water) for at least 12 h before each study visit. The day before each visit you will be asked to refrain from physical activity and alcohol consumption for 24 h. In addition, you will need to consume a standardised normal meal (not high in carbohydrates or fats, or total energy) the evening prior to the visit the following day and to fast for at least 12 hours. You will be provided a form to complete a 24 h food recall to record what you have eaten for the day before each of your study visit.

During your study visit, you will be provided one of the three meals in a randomised manner. This means that you will not know which meal will be allocated to you on the study visit. The three meals are a 1) reference meal of normal proportions of carbohydrates, fats and proteins, 2) a high-carbohydrate low-fat meal, and 3) a low-carbohydrate high-fat meal to be consumed on each separate study visit. Each meal will provide a total energy of 2000 kJ (478 calories). You will be provided a cup of water (250 mL) along with your meal.

A trained phlebotomist will be on site to obtain a baseline fasting blood sample from you on your forearm five minutes before being provided the test meal. Following blood collection, you will be served a meal for you to consume within 20 minutes. After you are finished with your meal, a 3 h after-meal blood sample will be obtained from you at 180 min. Refer to **Figure 1** below for an overview of the study visit. Blood samples taken will be used to measure blood triglycerides, insulin, glucose, and inflammatory markers. At each visit, 18 mL of blood will be obtained at each blood sampling, and a total of 36 mL (approx. 2.5 tablespoons) of blood will be collected for each visit. The whole study will therefore involve collecting a total of 108 mL (approx. 7.5 tablespoons) of blood. You will need to remain in the research facility for 3.5 hours and not undertake any physical activity. Study and quiet activities are allowed, as are trips to the bathroom.

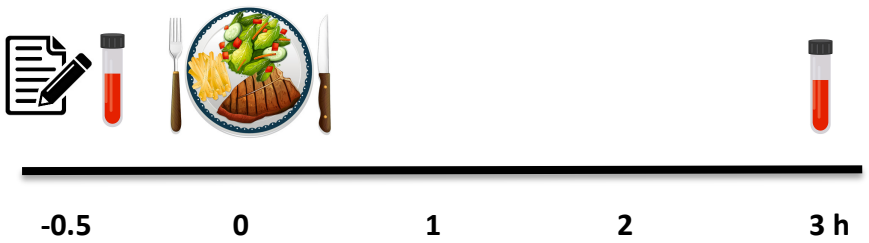

Figure 1. An overview of each study visit.

WHAT WILL HAPPEN TO MY BLOOD SAMPLES?

Your blood samples will be identified using a code unique to you. The samples will be sent to Waitemata DHB North Shore Hospital Laboratory and Massey University Nutrition Lab for the analysis of glucose, insulin, triglycerides and inflammatory markers (c-reactive protein (CRP), interleukin-6 (IL-6)).

Please note that subject to you giving consent to be part of this study, any stored blood samples may be used for additional testing related to this study including further markers of inflammation.

Blood samples will be stored at Massey University, Albany for a maximum of two years.

If you withdraw during the study your blood samples will be disposed of or returned to you upon request. If you have completed the study, you cannot withdraw the samples.

The cultural issues associated with storing your blood samples and analysis on them should be discussed with your family/whānau as appropriate. We are happy to meet with you and your family/whānau to discuss the study further. We also suggest that your family/whānau is involved with you at all stages of the study. You may hold beliefs about a sacred and shared value of all or any blood samples removed. There is a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Research is a big part of medicine and healthcare and being involved can be very rewarding. You can learn a lot about the processes that are involved in research by actively participating and it can be satisfying to know that you are contributing to knowledge. Furthermore, by participating in the study you also obtain information about your general health status, HbA1c value, body composition and blood pressure measurement entirely at no cost to you.

It is highly unlikely that you will be injured during this study. Obtaining blood samples via the vein of your arm is safe and routinely used. Foreseeable risks, adverse-effects and discomforts that you may encounter by taking part in this study are minimal, but could include possible infection from the site in which blood is drawn and there may be some minor bruising at this site as well. A registered personnel will be available during each study session and researchers will be present to assess for adverse events (i.e. feeling nauseous, dehydrated or faint) during each blood sampling, and any event will be documented in alignment with Massey Code of Ethical Conduct.

WILL ANY COSTS BE REIMBURSED?

There is no cost to you, the participant, for taking part in this study.

In recognition of your participation in this study, you will receive a koha of $20 for screening and $50 for completion of each session. You will be given a total koha of $170 for completing the whole study (1 screening visit and 3 study visits) in the form of a gift voucher. If for any reason you are unable to complete the study, you will be reimbursed for the visits you completed.

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, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. The study is covered by Massey University Insurance Policy.

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 ARE MY RIGHTS?

Participating in this study is completely voluntary and you are free to decline to participate, decline to answer any particular question, or to withdraw from the research at any practicable time, without experiencing any disadvantage.

You, the participant has a right to access information about you, collected as part of this study. You will be told of any new information about adverse or beneficial effects related to this study which may impact upon your health.

It is important to us that we maintain your privacy throughout this study. Your name and contact information will be held electronically and stored on the Principal Investigators computer only for data recording purposes. Each participant in the study will be allocated a unique code. Staff involved in blood sampling and analysis will have access to participant codes only. All data from study sessions will be recorded against your participant unique code and your name will never be used in any report, correspondence or publication. Your involvement in this study is confidential.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

You are able to pull out of the study at any time, and will be compensated accordingly for your time. Further you are welcome to discuss any concerns you have with the research team at any time, and you have free access to your data. If you pull out of the study all of the data that was related to you will be shredded/destroyed.

The study data will be stored at a secure location at Massey University Albany Campus. Electronic data and records will be the responsibility of the Principal investigator. All data will be kept for five years, at which point it will be destroyed using University Security methods for removal of confidential material.

CAN I FIND OUT THE RESULTS OF THE STUDY?

Participants are welcome to discuss the findings of this study with the researchers when data collection and analysis have been completed. It is very likely that the results of this study will be written up for publication in a peer-reviewed journal and/or presentation at a Nutrition conference within 12 months of completing the study. You will also be provided with a copy of the publication, if requested. If this happens no participant identification information will be included.

WHO IS FUNDING THE STUDY?

The funding is internally funded by the Riddet Institute, Palmerston North, New Zealand.

WHO HAS APPROVED THE STUDY?

The study has been independently reviewed and approved by the Massey University Human Ethics Committee (MUHEC) to ensure the study meets the established ethical standards.

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

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

Dr Wen Xin Janice Lim: Postdoctoral research fellow, Riddet Institute, Massey University, Albany Campus, Auckland
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You may also contact the Massey University Human Ethics Committee (MUHEC) involving any concerns that you may have:

This project has been reviewed and approved by the Massey University Human Ethics Committee: Southern A, Application 22/34. If you have any concerns about the conduct of this research, please contact Dr Negar Partow, Chair, Massey University Human Ethics Committee: Southern A, telephone 04 801 5799 x 63363, email humanethicsoutha@massey.ac.nz