Participant Information Sheet

Study title: **The GLARE Study (Glucose Lowering Antioxidant Rich Plant Extracts)**

Ethics committee ref.: 17/STH/82

Locality: **Massey University Campus, Auckland**

Lead investigator: **Associate Professor Rachel Page**

Contact phone number: **0800 627739 ext. 63462**

You have been invited to take part in the GLARE (**G**lucose **L**owering **A**ntioxidant **R**ich Plant **E**xtracts) study which is looking at the effects of antioxidant-rich plant extracts on blood sugar levels in men and women. 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 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 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 read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of the study is to look at certain antioxidant-rich plant extracts (which include grapeseed, rooibos tea and olive leaf extract) and the impact they have on blood sugar levels in people diagnosed with prediabetes. Prediabetes is a warning sign for development of type 2 diabetes. It is a term given for when you have blood sugar levels higher than normal but not high enough yet to be considered type 2 diabetes. Antioxidants are substances that are able to fight against unstable molecules formed in the body. The plant extracts chosen for this study contain plenty of antioxidants.

This study aims to build on information from a recent study (Chepulis et al, 2016) which showed that 4 antioxidant-rich plant extracts (amla berry, grapeseed, rooibos tea and green tea extracts) had a positive impact on blood sugar response in subjects with normal blood sugar levels. Little is known about whether these plant extracts can be used to improve blood sugar control in people with prediabetes, or whether they can slow the development to type 2 diabetes (a more serious condition than prediabetes).This study aims to examine the short term effects of these antioxidant-rich plant extracts (rooibos tea, grapeseed and olive leaf) on blood sugar control in people with prediabetes.

The sources of funding for this study have been provided by the Massey University Research Fund, COMVITA NZ Ltd., Rooibos Council of South Africa and Toiohomai Institute Technology. Should you have any questions about this study during your participation in the study you can contact the following people:

Dr Lynne Chepulis: *Senior Research Fellow, Medical Research Unit, University of Waikato, Hamilton*

Phone +64 7 837 9553 *(work) or 022 675 3353*
Email: lynne.chepulis@waikato.ac.nz

A/Prof Rachel Page: *Head of School of Health Sciences, Massey University*
Phone 0800 627739 ext. 63462
Email: R.A.Page@massey.ac.nz

Dr. Pam Von Hurst *: Associate Professor, School of Sport, Exercise and Nutrition, Massey University, Albany Campus*
Phone: +64 (09) 2136657
Email: P.R.vonHurst@massey.ac.nz

The ethical considerations of this study have been approval by the Southern Heath & Disabilities Ethics Committee (HDEC). You can contact HDEC via email on hdecs@moh.govt.nz

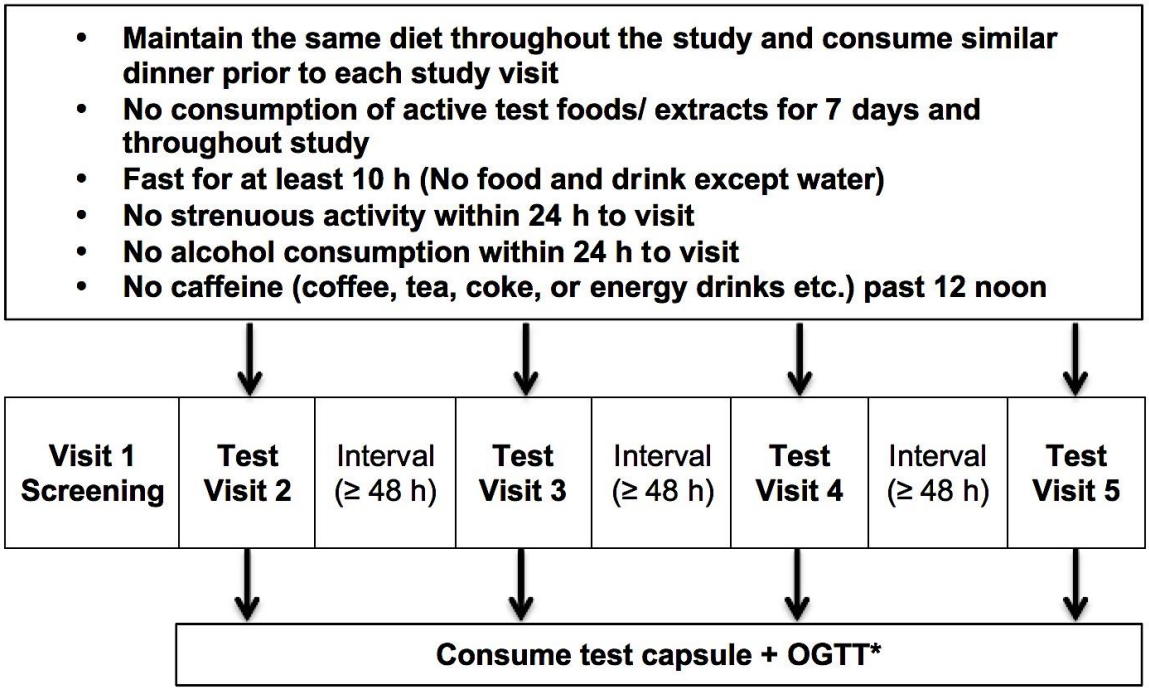
WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been chosen to participate in the study because you have met the criteria to be included in the study. The criteria includes:

- *A high blood sugar level (known as prediabetes), (HbA1c between 41-49 mmol/mol)*
- *Not being on medication that influences blood sugar levels*
- *Not a smoker*
- *Able to speak and read English*

*The study will involve you coming to the Massey University Food & Nutrition Laboratory, located at the Albany Campus, North Shore. You will need to be available for **FIVE** visits over an 8-10 week period. Each visit will be for approximately 2.5 hours from 7 -7.30 am – 9.30 -10 am in the morning. You will be required to fast overnight (i.e. no food or drink except water) for at least 10 hours prior to coming into the Lab for each visit (with the exception of your first screening visit). The research team will provide you with breakfast and tea or coffee after each of your visits.*

The whole study at a glance



**OGTT stands for Oral Glucose Tolerance Test, which comprises a 300 ml sugary drink (containing 75 g carbohydrates).*

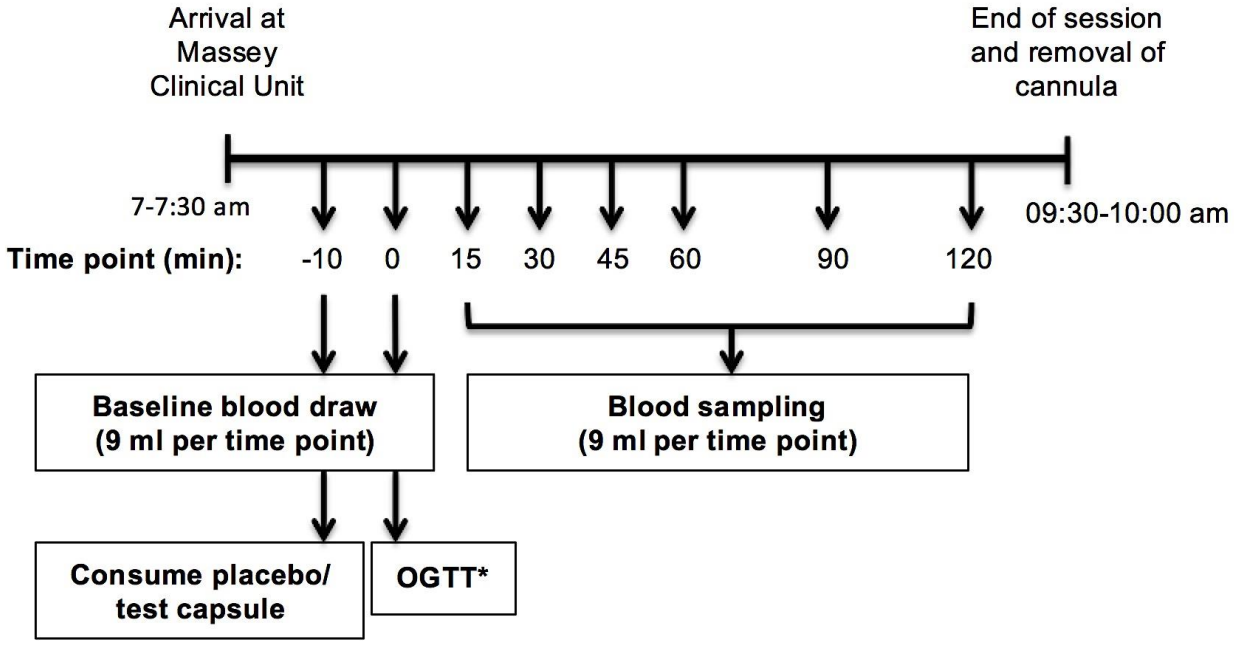
*Your **first** visit will be the screening visit, which will include collecting the following data:*

- *Collection of some personal health information such as weight, height, hip and waist circumference, body fat percentage (as measured by a bioelectrical impedance (BIA) scale), blood pressure, medical history, and any medication use.*
- *Additional information will be collected around your diagnosis of prediabetes, particularly around duration of prediabetes and the dietary and lifestyle advice given to you at the time of diagnosis.*

*Your **subsequent** visits (visits 2-5) will involve consuming either a placebo or antioxidant-rich plant extract capsule and drinking a 300 mL sugary drink (contains 75g of glucose). This study is a randomised placebo-controlled blinded study. This means that you will not know what test sample i.e. antioxidant-rich plant extract in a capsule or control (placebo capsule) you will be consuming with a sugary drink. The placebo capsule contains no antioxidant or active substance and acts as a control as it will have no effect on your blood sugar levels. When you turn up for your visits 2-5, the capsule you receive is randomised by the researcher administering the capsule and you will receive the placebo and antioxidant capsules in no particular order.*

*The **last visit** will also involve collecting personal health information again (including; weight, waist and hip circumference, body fat percentage and blood pressure).Blood pressure will be recorded at every visit.*

What happens at Visits 2-5



**OGTT stands for Oral Glucose Tolerance Test, which comprises a 300 ml sugary drink (containing 75 g carbohydrates).*
All blood samples collected will be used to quantify blood glucose levels, insulin levels, and antioxidant capacity.

When you arrive at 7-7.30 am on your visit, a small plastic chute will be inserted into one of your veins in your arm to allow a blood sample to be taken to measure your baseline blood sugar level. Ten minutes before drinking a 300 mL sugary drink you will be given a capsule that will either contain an antioxidant-rich plant extract (rooibos, olive leaf or grapeseed extract) or a placebo capsule. Once you have consumed your sugary drink, you will then need to remain in the Massey University Food and Nutrition lab for the next two and half hours and not undertake any physical activity. Study and quiet activities are allowed, as are trips to the bathroom. Further blood samples will be taken from the same chute at 15, 30, 45, 60, 90 and 120 minutes after consuming the antioxidant-rich extract or placebo, and the blood sugar levels, insulin levels and antioxidant activity will be determined at a later date. We will have qualified phlebotomists (people trained to draw blood) on site to collect these blood samples.

At the completion of your 2.5 hour visit you are welcome to eat and drink as normal (this will be provided). We will have DVDs available for viewing also to help pass the time.

What happens between Visits 2-5

You will be asked to keep your diet and lifestyle as constant as possible throughout the study and to refrain from engaging in any strenuous physical activity (walking is fine) or consumption of alcohol in the 24-hour period prior to each test session. You will also be asked to avoid the active test foods/extracts for at least seven days prior to the first test session and throughout the duration of the test period, including avoiding other teas and formulations where the extracts may be present.

The research team understands that some of the information that we are collecting is very sensitive and it will be treated as such. Only the research team and you, the participant, will have knowledge of your personal information.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Direct benefits of participating in this study include; an increased awareness and knowledge of the processes involved in research by actively participating in it, and a satisfaction in knowing that you are contributing to nutrition knowledge in the community. Additionally, there is also a monetary payment for involvement in this study.

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. You may also feel some nausea or gastrointestinal discomfort from ingestion of the glucose (in the sugary drink) for the oral glucose tolerance test. These discomforts will be managed by the presence of a qualified health professional who will be available to assist you should you require it. A record of all adverse events will be monitored and maintained throughout the course of the study.

WHO PAYS FOR THE STUDY?

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

In recognition for your time and participation in this study, you will be reimbursed a total of $210. This total amount is based on your attendance to all FIVE visits to the Massey University Food and Nutrition Laboratory on Albany campus. If for any reason you are unable to complete the study, you will be reimbursed for your total time contributed to the study. You will receive $10 for completing the screening visit and then for each study visit that you complete, you will be reimbursed with $50.

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.

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, 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 number. Staff involved in blood sampling and analysis will have access to participant numbers only. All data from test sessions will be recorded against your participant ID number 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.

The treatment intervention (antioxidant capsules being tested in the GLARE study) will not be available to any participant after the study. The outcomes of this study will enable selection of antioxidant-rich plant extracts that can be investigated further in a long term intervention study.

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 10 years, at which point it will be destroyed using University Security methods for removal of confidential material. At the completion of the study all biological samples collected will be disposed of using established methods for discarding biological waste. Any participant can request to have their remaining blood sample returned to them.

You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Maori 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.

We anticipate that the results of this study will be published in a peer-reviewed journal within 12 months of completing the study. Participants are welcome to discuss the findings of this study with the researchers at any time

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:

Researchers in the Study:

You can contact the following researchers: A/Prof Rachel Page, Dr Lynne Chepulis or Dr Pam von Hurst. Contact details are at the beginning of this information sheet.

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

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

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Consent Form

Please tick to indicate you consent to the following *(Add or delete as appropriate)*

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.	Yes ☐	No ☐
I have been given sufficient time to consider whether or not to participate in this study.	Yes ☐	No ☐
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.	Yes ☐	No ☐
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes ☐	No ☐
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.	Yes ☐	No ☐
I consent to the research staff collecting and processing my information, including information about my health.	Yes ☐	No ☐
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes ☐	No ☐
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	No ☐
I am aware that my blood samples will be disposed of using established guidelines for discarding biological waste.	Yes ☐	No ☐
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	Yes ☐	No ☐
I understand the compensation provisions in case of injury during the study.	Yes ☐	No ☐
I know who to contact if I have any questions about the study in general.	Yes ☐	No ☐
I understand my responsibilities as a study participant.	Yes ☐	No ☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

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

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

Researcher's name: _____

Signature: _____ Date: _____