THE UNIVERSITY OF AUCKLAND
Te Whare Wānanga o Tāmaki Makaurau
NEW ZEALAND

MEDICAL AND HEALTH SCIENCES

PARTICIPANT INFORMATION SHEET

Project title: **Acute Evidence of Digestive, Metabolic and Nutritional Differences in Beef, Lamb and Meat-Alternative Meals**

Principal Investigator: Dr Andrea Braakhuis (The University of Auckland)
Research Team: Dr Matt Barnett (The Liggins Institute), Dr Toan Pham (The University of Auckland), Ms Julie Brown (The University of Auckland)

Research introduction and aim
There has been much discussion about the nutritional value of eating red meat, however very few scientific studies have been conducted on red meat arising from different feeding systems (grain versus grass) and on meat-alternatives. The aim of this study is to investigate what nutrients end up in the bloodstream after consuming a grass-, grain-fed beef, or grass-fed lamb, or plant-based meat alternative containing meal.

Project description and invitation
You have been invited to participate because you are a male between the age of 20 and 34 years who eat red meat. This study will involve you visiting the Research Facility at The University of Auckland on four separate occasions in the morning. Each visit you will be required to consume a red meat or meat alternative containing meal and bloods will be taken for 4 hours after the meal. Before any meal, your saliva sample will be also taken only in the first visit.

Project Procedures
There will be four study visits in total with at least one week between meals. Any questions or concerns about the study will be discussed via email or phone prior to commencing. You will be asked to complete pre-screening documentation prior to be invited to participate. If you are satisfied with everything and agree to take part, we will ask you to sign the consent form (below) prior to testing. The study includes four test clinical visits. The four test occasions will occur on mutually agreed upon days, with at least one week, but no more than one month apart. Each test day you will be joined with other participants.

All interested participants will be asked to complete a screening questionnaire which will ask for weight, height, physical activity, ethnicity, education, and eating habits. Participants will be excluded if they are smokers, have previously tested with high cholesterol or blood lipids or demonstrated disordered eating habits.

Procedures for Test Days

The procedures for all four visits will be the same. Before each clinical visit, you will be asked to avoid eating foods high in fat and fibre as well as alcohol and caffeine. You are not to eat after 10 pm as this will affect your digestion in the morning. Except for water, you will be required to fast overnight and then come to the Clinical Research Centre as scheduled in the morning. You will be asked to provide informed consent and will have your height and weight measured. During each visit, we will ask you to rest quietly for 20 minutes before we measure your blood pressure. You will be asked to provide your saliva sample into a test-kit tube before having a test meal and this sample will be used to measure your specific nutrition-related genetic markers (only in the first visit). A small needle will be also placed into your arm vein.

This can be slightly painful and can cause discomfort. The needle has a plastic cannula (thin tube) that will be left in your arm vein. This too is a little uncomfortable and you will not be able to fully bend your arm. The researcher will then take 30 mL of blood and this will be used to measure your resting amino acids and lipids.

After the first blood sample, you will be given a meat-containing meal to consume within 15 minutes. You will also be asked to complete a visual analogue scale (VAS) questionnaire to score your appetite and digestive symptoms, before consuming the meal, and at regular intervals during the trial. We will also ask you to record digestive symptoms as they happen with a separate questionnaire. Blood samples will be repeated every hour for 4 hours after your meal (in total 150 mL per visit). These blood samples will assess your digestion, metabolism and inflammatory responses.

After the 4 hours, the cannula will be removed which may cause mild discomfort. You will be offered lunch and you are free to go. Before departing we will invite you to make an appointment for the next clinical visits. We appreciate that this takes four visits to our research centre and approximately 20 hours of your time and would like to offer you a $400 gift voucher in total to reimburse for your time and efforts.

Blood and Saliva

Your blood will be used in the analysis of proteins, lipids, and sugars and markers of inflammation. These will provide vital insights into whether there are differences in the digestive responses to the four meals. We will be measuring metabolites (digested products of the meat and markers of your body's metabolic process) including amino acids (the digested products of proteins), lipids (the digested products of fats), sugars such as glucose (digestion products of carbohydrates), and hormones involved in digestion and absorption such as insulin.

Some analysis techniques will take place in the laboratories of the Liggins Institute (University of Auckland). Your samples will also be sent to AgResearch Limited (Palmerston North, New Zealand) for analysis of things that we are unable to do in Auckland. After these analyses have been performed, it will not be possible to return any unused samples to you. You can request the return of your saliva or blood prior to any analysis; this would mean we would not use your information in the study.

Different versions of a gene can make us response differently to certain components in food such as the gluten in bread, the lactose in milk, the caffeine in coffee along with various proteins, fats, minerals and vitamins found in various foods. The differences between individuals can be explained by gene variations within the population. Some individuals may benefit from limiting their consumption of nutrient component (e.g. caffeine, gluten…) or increasing their intake of other nutrient components (e.g. omega-3 fat, zinc…). Understanding our genetic profile and its complications on our unique response to the foods, supplements and beverages we consume will provide us with the tools needed to make the best dietary choices. We will take gene samples from your saliva. Your saliva sample will be used in analysis of various genetic markers related to nutrition and physical activity. The sample will be sent to the Nutrigenomix laboratory (Nutrgenomix Australia, Level 10 & 11, 20 Martin Place, Sydney, Australia, 2000)for the genetic test. Nutrigenomix testing is a safe and non-invasive saliva collection kit or buccal swab developed for use by healthcare professionals. The Nutrigenomix test kit involves saliva or buccal swab collection, testing of the client's DNA for specific nutrition-related markers, and generation of a personalized nutrition and fitness report. The test analyses variations in 70 genes that impact nutrient metabolism, eating habits, weight management and body composition, food intolerances and physical activity. The accuracy of the genetic test results is between 99.7 – 100%.

The information collected in this study will be kept for a total of 10 years. Your samples will be kept until the end of the analysis. At the end of this time a medical waste contractor will dispose of your tissue. If you would like a karakia said at this time, please indicate so in the consent portion of this form. Cremation and karakia ceremonies take place through the Auckland District Health Board, and occur every 2 months during the year.

Many iwi, hapu, and whānau disagree with transport of blood samples due to issues with the loss of rights to your whakapapa. However, it is acknowledged that individuals have the right to choose. These concerns may also apply to non-Māori. We encourage you to consult with your family or whānau before agreeing to participate, if you think this might apply to you. As the saliva samples are sent overseas they will be destroyed upon the completion of the testing for this trial.

Detection of Abnormalities
Some blood markers analysed in this research can be early indicators of diseases such as diabetes and heart disease. Any blood results outside of the normal healthy range will be provided to you. We will also inform your usual doctor of any results that might be significant for your health, so follow-up can be arranged if appropriate. The genetic test (Nutrigenomix) does not assess genetic predisposition to certain diseases. The test only includes genes related to nutrition and physical activity. Nevertheless, if an individual has a Nutrigenomix test, he/she is required to answer 'yes' on any legal forms or questionnaires that ask whether they have had a genetic test.

What if Something Goes Wrong?
This clinical trial is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Section 32 of the Accident Compensation Act 2001 provides that participants injured as a result of treatment received as part of this trial will not be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC). However, compensation may be available from the study's sponsor, Auckland UniServices Ltd., in line with industry guidelines. We can give you a copy of these guidelines if you wish. You would be able to take action through the courts if you disagreed with the amount of compensation provided.

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.

You may have your friend, family, or whānau support help you understand the risks and/or benefits of this study or any other explanation you require. You are also welcome to have a friend, family, or whānau support with you during every session.

Right to Withdraw from Participation
You have the right to withdraw from this study at any time. Your contribution is entirely voluntary and if you chose to withdraw any remaining samples and data will be destroyed at that point, but data or samples that have already been collected and processed will continue to be used.

AnonymityConfidentiality and Risks
All samples and the measurements will be coded and recorded against this code to keep your identity confidential. Coding will be numerical and you will not be identifiable by this code. Each saliva sample is anonymized using a barcode and this is entered into a password protected online system. Nutrigenomix uses a Secure Socket Layer (SSL) protocol to encrypt information that is transmitted over the Internet. This technology uses 256-bit encryption, which ensures that confidential information and transactions cannot be viewed, intercepted or altered.

Nutrigenomix will never reveal client information or genetic data to a third party except as required to provide the services requested, or as required by law. The only person able to link the code with your name is Dr Andrea Braakhuis who will keep the coding list in a locked filing cabinet. When the analysis is completed the researchers will analyse the whole group's data and report on averages. This data will be used for scientific publication and presentations. No person will be identifiable from the analysis. 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 is currently very small but may increase in the future as people find new ways of tracing information.

Contact Details
For more information please contact either:

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APPROVED BY THE HEALTH AND DISABILITY ETHICS COMMITTEE ON Approved Amendment – 18th November 2020. Reference Number 19/STH/226 AM02

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CONSENT FORM
THIS FORM WILL BE HELD FOR A PERIOD OF 10 YEARS

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- I have read the Participant Information Sheet, have understood the nature of the research and why I have been selected. I have had the opportunity to ask questions and have them answered to my satisfaction.
- I agree to take part in this research.
- I have had the opportunity to use support from a family (whānau) member or a fried to help me ask questions and understand the research.
- I understand that I am free to withdraw participation at any time
- I understand that blood and saliva samples will be collected and used for research.
- I understand that samples will be sent around New Zealand and Australia for analysis and disposed of at the end of the study
  - I wish for a karakia said at the time of my tissue disposal (*please circle*). *Yes* *No*
- I understand that any blood results found to be outside the normal healthy range will be conveyed to me and that if I do not wish to be informed, I cannot participate in this study.
- I wish to receive the summary of findings. I understand that there may be a delay between data collection and the publication and availability of the research results (*please circle as appropriate*). *Yes* *No*
- I wish to receive a copy of my genetic test results *Yes* *No*
- I understand that the results from this study will be used for scientific publication and presentations.
- I agree not to restrict the use of any data or results that arise from this research provided such a use is only for scientific purposes.

Name _____

Signature _____ Date _____

Researcher's Signature_____ Date _____

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