Participant Information Sheet

Study Title	**A flourishing biome for gut health – Promoting a diverse microbiome through bread (BREAD Study)**
Short Title	**B**read **R**elated **E**ffect on Microbi**A**l **D**istribution (BREAD Study)
Principal Investigator	Professor Richard Gearry Professor Nicole Roy
Locality	University of Otago, Christchurch
Ethics com. ref	H22/061

You are invited to take part in a study on the effect of dietary fibre in bread on gut function, digestive health, and overall health and wellbeing. 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 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 15 pages long, including the consent form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

We are performing this study to understand more about effect of different types of dietary fibre on the gut microflora (bacteria/microorganism residing in gut) and its functions. The fibre in our diet is known to reduce the risk of constipation by increasing the bulk of stools. In addition to this, it is also essential in maintaining a healthy gut microflora. The gut bacteria break down fibre and produce a vast range of products (metabolites) which influence body functions like bowel movement, fight infections, modulate appetite and hunger, mood and wellbeing.

The average NZ diet lacks fibre, adult women consume 17g of DF on average instead of recommended 25 g per day and adult men consume 22 g instead of 30 g per day. The low intake of fibre can alter the gut microflora and result in dysfunction, and may contribute to the development of chronic diseases such as intestinal bowel disease, colorectal cancer, allergies, obesity, heart diseases, and type 2 diabetes. These diseases can, at least in part, be prevented by optimal fibre intake. An optimal fibre intake (25-30g) is associated with improvement of digestive function, general wellbeing, and decreased risk of chronic diseases.

Bread is the main food source of fibre in the NZ population. It is an ideal product to add ingredients to increase fibre content. In this study, we aim to find differences in the gut microbiota in individuals with inadequate fibre intake. As the recommended intake of fibre differs between genders, males will be consuming four slices, females will be consuming three slices of Bread A and Bread B, each for four weeks. The findings may allow us to better understand how different quantity and quality of fibre affects the microflora and to improve knowledge of the effects of fibre on gut health and general wellbeing.

For a deeper and more holistic understanding of the effects of fibre on the gut and body function, we would like to collect information from you by questionnaire, blue food dye to measure the time of digestion from beginning to end, as well as biological samples in the form of blood and stool. You may also be selected to swallow a diagnostic device, a pill-sized Atmo gas-sensing capsule. We will then analyse the samples and compare the results between Bread A and Bread B.

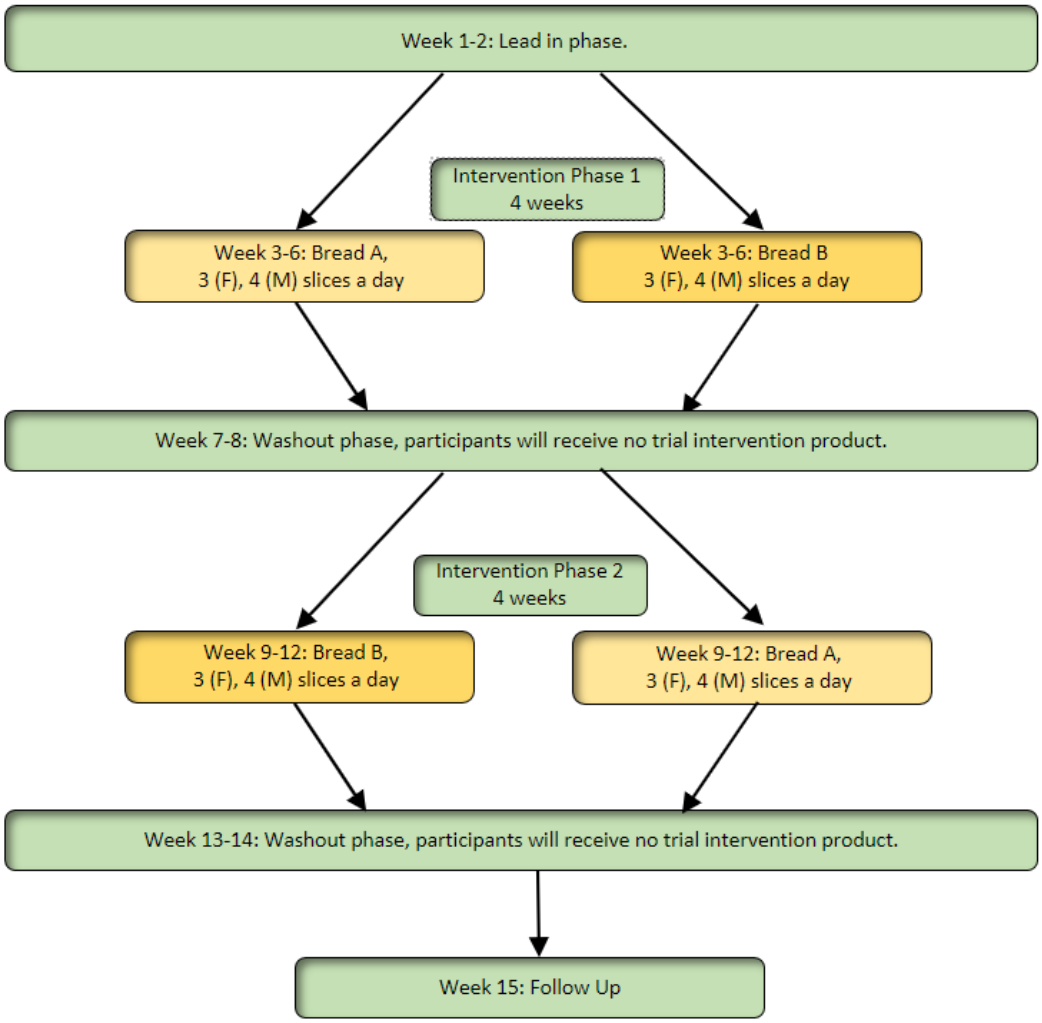
The study is being performed by researchers from the University of Otago, Department of Medicine, Gastrointestinal Unit for Translational Studies in Christchurch. The study is funded by the High-Value Nutrition National Science Challenge and Goodman Fielder Ltd. Goodman Fielder Ltd is providing both Bread A and Bread B. Laboratory studies will be performed by the Canterbury District Health Laboratories, AgResearch, Riddet Institute, Plant & Food Research, Teagasc, Agriculture and Food Development Authority, Ireland.

The study protocol has been reviewed by the University of Otago Human Ethics Committee (Health), reference number H22/061.

WHAT DOES THE STUDY INVOLVE?

The study is a double-blinded, placebo-controlled, cross-over study. This means that if you choose to take part, you will be randomly allocated to an intervention order by a researcher and you will consume Bread A and Bread B in random order. Each participant will receive both breads. You and the researchers will not know which intervention you are having. This is to ensure that there is no influence from the participants and researchers as to the effect of the interventions.

The trial will be a maximum of up to 15 weeks in total. A diagram of the study is shown below:



Participants: Study participants will be recruited through the general population with inadequate dietary fibre intake.

The age range of all participants is 18 to 65 years, and the BMI range is 18 to 35 kg/m^2 (BMI is the abbreviated term of body mass index, used to estimate a healthy weight range for individuals based on weight and height. BMI is determined by your weight in kilograms divided by your height in metres squared).

All participants will need to be:

- Able to give informed consent and understand what is required of them during the course of this study.
- Free of any known significant gut disorder and diseases. This includes chronic constipation, diarrhoea, irritable bowel syndrome (IBS), inflammatory bowel disease (IBD) (Ulcerative colitis and Crohn's disease), diverticulitis, coeliac disease or previous bowel resection.
- Free of alarm features associated with bowel habit, such as recent changes in bowel habits (onset less than three months), rectal bleeding, sudden weight loss, occult (hidden) blood in stool, anaemia, anal fissures, bleeding haemorrhoids, and family history of gut cancer at a young age
- Free of systemic disease that could influence the gut directly or through medication use (e.g. diabetes, opiates or regular NSAID use (painkillers)
- Free of severe chronic disease or neurological conditions.
- Female participants who are **NOT** pregnant, breastfeeding or planning a pregnancy in the three months post-selection (study time frame).
- Free of known intolerance or allergy to wheat or rice.
- Free of antibiotic use within the last month
- Free of prebiotics, probiotics and fibre supplement use during month prior to screening
- Non-smokers
- Willing to stop laxative, pre- and probiotics or fibre supplement throughout the study.
- Able to comply with the study procedures.

The research in this project will be undertaken in a culturally sensitive manner, with all aspects of the trial explained in full to you in a manner most suitable to you. The research team will be available to answer questions throughout the study and will seek advice from appropriate advisory groups should it be necessary. You will be given access to interpreters at any time in the study should you require them. The opportunity for Whānau support is available at all times.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You are invited to this study because you have indicated that you are interested in supporting our research.

If you choose to take part in the study, you will be expected to do the following:

Screening

You will be asked to complete a screening questionnaire to assess if this study is right for you. The questionnaire will include questions on your general health, bowel health and dietary history. You can use this link to assess your eligibility https://redcap.otago.ac.nz/surveys/?s=8WR7WCNRCETYTAC7

If you are eligible we will make an initial appointment for you to come either into 40 Stewart Street in central Christchurch, or to the Nicholls' Centre of Christchurch Public Hospital during the week at a mutually convenient time. At this appointment, you will have the time to ask questions, and we will give further explanation of the study. If you provide written informed consent, we will measure your height, weight, blood pressure and waist circumference.

You will also be asked to give a fasting blood sample. This means that you must have nothing to eat or drink except water from 10 pm the night before until you attend the clinic (9 hours fast) and have your blood taken. The blood sample will be done first thing in the morning, so we will not be asking you to go without food for long. We will also provide you with a light snack after your blood sample has been collected.

A researcher will take a blood sample (total amount of 10-15 mL, approximately one tablespoon) from a vein in your arm. Due to the nature of the analysis, we will not be able to return this blood sample to you once it has been collected. The following tests will be performed on your blood sample, which will give us information about your health. Canterbury Health Laboratories will perform the analysis. You will be given access to the results of these blood tests if you wish.

It is common that a test result falls just outside the normal range and is usually not concerning. Should any of your blood test results be clinically significant, we will inform you and recommend that you make an appointment with your medical practitioner. We will provide a copy of the test results for your GP.

If you fit all the eligibility criteria, you will be offered a place in the study.

TEST	**REASON**
Albumin	Liver function
Alkaline Phosphatase	Liver function
Alanine aminotransferase (ALT)	Liver function
Aspartate aminotransferase (AST)	Liver function
Blood Urea Nitrogen (BUN)	Kidney function
Calcium	Heart, Nerve, Kidney function
Chloride	Acid/base balance
Carbon dioxide	Acid/base balance
Creatinine	Kidney function
Glucose	Glucose metabolism
Potassium	Acid/base balance
Sodium	Acid/base balance
Total bilirubin	Liver function
Total protein	Liver function
C-reactive protein	Immune response
Blood count	Immune response, overall health
Lipid profile	Cardiovascular function

During the study

The study will require you to make five visits to the clinic, either at 40 Stewart Street or to the Nicholls' Centre of Christchurch Public Hospital. It is estimated that the visits will take a maximum of 30 minutes each time.

Due to the nature of the study and the outputs we are measuring, we would prefer that you stop taking any fibre supplements, prebiotics and probiotics you are currently taking for the duration of the study and not take any laxative in the week before your appointments.

Intervention: We will provide you with Bread A and Bread B during the study. The research staff will organise pick up with you, and instruct you on how the interventions are to be taken. Please let the research staff know when you run out, so we can provide more, if necessary.

Stool sample collection: At the baseline visit, you will be asked to provide us with stool samples. We ask you to collect the stool sample the day before you come and to bring the sample in with you. We will provide you with the appropriate gear to collect the samples hygienically. These samples will be frozen at -80^{o}C and shipped to our New Zealand collaborators for analysis. Stool DNA (genetic code of the gut microflora) or RNA (DNA copy for protein production) extracted will also be shipped to a commercial service provider lab in Ireland for sequencing before these data is analysed by our research team. We will only analyse genetic code of the gut bacteria and microbes.

The stool will be used for several analyses. We will measure the concentration of a range of bacteria and other microbes that live in the gut and what they make with the fibre you are eating.

During the course of the study, you will be asked to provide further four stool samples at each of the following time points: end of treatment 1 (week 6), end of washout period 1 (week 8), end of treatment 2 (week 12), and end of washout period 2 (week 14). This is a total of five stool samples (including baseline visit).

Blood sample collection: At the baseline visit, you will be asked to provide us with a fasting blood sample. We will collect a total of 12 mL (approximately one tablespoon). The blood will be split into different components and stored. Experiments will include metabolites of normal body processes (what your body makes from food), and lipid profile. The baseline measurement tells us the level before you start the trial, so we have a comparison.

During the course of the study, you will be asked to provide further fasting blood samples at the following time points: end of treatment 1 (week 6), end of washout period 1 (week 8), end of treatment 2 (week 12), and end of washout period 2 (week 14). This is a total of five blood samples (including baseline visit).

You may hold beliefs about a sacred and shared value of all or any samples removed. The cultural issues associated with sending your samples overseas and/or storing your samples should be discussed with your family/ whānau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with the 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.

If you wish, we can arrange for the remainder of your blood and faecal samples to be returned to you on completion of the analysis or to dispose of them with appropriate karakia.

Gut Transit Measures: Over the course of the study, we will use various methods to measure gut function and motility.

- **Blue food dye:** at each visit (week 2, 6, 8 and 12) you will be asked to ingest Royal Blue Liqua-gel® food colouring in 200 mL water to measure how long it takes for food to travel through your body. You will be asked to record the passing of the dye in stool via the daily bowel movement app.
- **ATMO gas-sensing capsule:** Selected participants will be required to ingest an Atmo gas-sensing capsule at baseline visit (week 2), end of treatment 1 (week 6), end of washout period 1 (week 8), and end of treatment 2 (week 12) to measure transit time, temperature and various gases in the gut. We will also give you a standardised food bar before swallowing the capsules. This also means that you are asked to carry recorders on your body until the capsules have passed, to fill in additional details such as food, drink, and bowel movements into the recorders, and to drop the recorders off at our clinic at 40 Stewart Street once all capsules have passed.

Questionnaires: Over the course of the study, we will provide you with the following online questionnaires to complete. These questionnaires relate to your bread intake, bowel habits, health, socio-economic status, and how you are feeling, both mentally and physically. While many of the questions of these questionnaires are very similar, they do cover different aspects and details.

- **Gastrointestinal Symptoms Rating Score:** The primary interest of the study is your level of gut comfort. This questionnaire asks you to mark on a scale of seven points how you are feeling. The questionnaire contains 15 questions and will take you about five minutes. There will be a total of five of these questionnaires over the duration of the study.
- **Daily Bowel Habit Diary (accessible via smartphone app):** We like to know how and if your bowel habits change in relation to the bread you eat. In order for us to assess this, we need you to fill out a record for each bowel movement you have in a day and its consistency (using the Bristol Stool Scale). This is done using a short questionnaire. The diary must be completed **EVERY DAY AFTER ENROLMENT OF THE STUDY**. There are 11 questions in total which require you to tick an answer, so it will not take very long. If the daily bowel habit diary is not completed regularly, you may have to be withdrawn from the study. If you have problems with the online version or cannot go online for a while, we can provide you with paper versions to cover that time if you wish.

- **Daily Bread Diary (accessible via smartphone app):** We like to know how you eat your bread (toasted/non-toasted) and if you eat extra slices of bread. In order for us to assess this, we need you to fill out a record for the bread you have in a day. This is done using a short questionnaire. The diary must be completed **EVERY DAY AFTER ENROLMENT OF THE STUDY**. There are 5 questions in total which require you to tick an answer, so it will not take very long. If the daily bread diary is not completed regularly, you may have to be withdrawn from the study. If you have problems with the online version or cannot go online for a while, we can provide you with paper versions to cover that time if you wish.

- **Patient-Reported Outcomes Measurement Information System:** We also want to know how your bowel habits affect your mental health and vice versa. This questionnaire contains 16 questions but should not take longer than 5 minutes to fill out. There will be a total of five questionnaires over the duration of the study.

- **World Health Organisation - Five Question Well-Being Index (WHO-5):** This questionnaire only contains five questions assessing how you have felt in the past week. You only have to fill it out five times over the duration of the study, and will not take you more than five minutes to complete.

- **Warwick-Edinburgh Mental Wellbeing Scale:** Alongside with other questionnaires that assess mental wellbeing, this questionnaire contains 14 questions that are all worded positively and cover both your feelings and functioning aspects of mental wellbeing. Similar to other questionnaires, you will only require to complete these five times over the duration of the study, which will take you no more than five minutes to complete.

- **Multidimensional Fatigue Inventory:** This questionnaire contains 20 questions designed to measure fatigue. It contains a seven point-scale to indicate to what extent the particular statement applies to you. You will be asked to fill up this questionnaire three times over the duration of the study.

- **Subjective Vitality Scale:** This questionnaire contains 6 questions assessing your state of subjective vitality. You only have to fill it out five times over the duration of the study, and will not take you more than two minutes to complete.

- **Diet Records:** During the course of the study, we would like to get an idea of your usual dietary intake. There will be five food diaries to fill out. We ask you to record the type and amount of all the food and beverages you have consumed over a three-day period. The time points for these will be one week before the baseline of the study (week 1), end of treatment 1 (week 5), end of washout period 1 (week 7), end of treatment 2 (week 11) and end of washout

period 2 (week 13). We ask you not to change your diet radically over the course of the study.

- **Modified Hunter New England Health Survey:** At the beginning of the study, you will be asked to fill out this questionnaire, which covers specific health, lifestyle and mental health questions, as well as some personal data. We want to get an overall view of you and to raise any issues that may affect the data. This questionnaire contains 11 questions, and you only have to fill it out once.
- **Economic Living Standard Index short form**: This questionnaire, which you only have to fill out once, allows us to understand your standard of living and your socioeconomic situation. It allows us to find out if symptoms or results are tied to specific issues in your life that have no obvious link to your bowels. It contains 25 questions and asks you to rate each by ticking a box. It should take you no more than 10 minutes to complete.

If you cannot complete the questionnaires during the study, you will have to be withdrawn from the study.

If you would like to switch from online to paper or from paper to fill out the questionnaires online at any time of the study, just tell us. We are happy to provide you with the necessary paperwork or send you the links via email.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

You may or may not benefit from taking part in this study. There is no guarantee that you will experience any changes in stool frequency or satisfaction from taking any of the study products. You will, however, gain knowledge regarding bowel health and be issued with bread for yourself during the study and your immediate family/whānau/fellow living companions after the study.

Additionally, if we are successful in understanding the impact of increasing quantity and quality of dietary fibre on gut microflora and on general health, we may be able to make further recommendation on fibre consumption.

Bread is a staple food for the majority of the population; however, a small percentage of the population has gluten allergy and is intolerant to various ingredients in bread. We recommend that those suffering from allergy or intolerance do not participate in this study. You may experience abdominal discomfort, distension and wind by consuming bread with high fibre content due to increased production of gas by your gut bacteria. These symptoms should settle by themselves in few days. We recommend participants to replace their regular bread with the study bread to avoid excessive consumption.

As with all blood tests, there may be some slight discomfort when the needle is inserted. You may also receive a bruise from the blood sampling. Should any serious adverse event related to the blood sampling procedure occur during the study period, you will be immediately withdrawn if you wish and asked to seek medical treatment.

There are minimal but possible risks associated with the use of Atmo gas-sensing capsules. There is a risk of the capsule becoming stuck on the way through the gut, but this has not yet been reported in healthy adults. For most people, the capsule is passed within five days of ingestion. Bowel obstruction is another possible serious risk but has not been reported with Atmo gas-sensing capsules.

Brilliant Blue food colouring is primarily used as a food colouring; it is not digested and can be found in the stool. It is non-toxic and commonly used in medical settings. However, it can induce allergic reactions. Should any adverse event related to the procedure occur, you will be immediately withdrawn and asked to access medical treatment.

There is a slightly increased risk of being exposed to COVID-19 during the study visits. We will screen participants prior to every visit and reschedule or postpone visits if either participant or researcher are positive for COVID-19 or develop COVID-19-like symptoms.

If you require it, we will return leftovers of your stool and blood samples to you after analysis. Otherwise, it will be disposed of hygienically (in accordance with NZS 4304:2002 “Healthcare Waste Management”) or with the appropriate karakia, if you wish.

Although necessary efforts (password protected files, secure database) will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with de-identified information, there is no guarantee that you cannot be identified. Your de-identified information is being sent overseas. Other countries may have lower levels of data protection than New Zealand. There may be no New Zealand representation on overseas organisations which make decisions about the use of your information. There is a risk that overseas researchers may work with information in a way that is not culturally appropriate for New Zealanders.

WHAT IF SOMETHING GOES WRONG?

Both breads are safe for consumption. If you are injured in this study, which is unlikely, you will be eligible for compensation from ACC just as you would be if you were injured in an accident at work or 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 will not affect your cover.

WHAT ELSE DO I NEED TO TELL YOU?

It is really important that you keep us informed on any health issues that may come up suddenly during the study, especially if they are related to your digestion. This includes a stomach bug or food poisoning, but also if you get ill and need to take antibiotics.

We need to know this to make sure the health issue is not related to the intervention we gave you, and to make sure it does not change the data we collect. Depending on the severity, we may need to withdraw you from the study in those cases.

YOUR PARTICIPATION AND COMPENSATION

Your participation in this study is completely voluntary. We are happy for you to bring along support persons to each of the clinic appointments if you like.

We will give you a $20 MTA voucher for the initial screening visit to compensate you for your travel and time. If you are accepted into the study, you will receive a further $60 in New World Vouchers each time you come in for your appointments. This will make a total of $320, which we will give you at the completion of the trial. If you are selected for the additional gas fermentation investigation with the ATMO capsule, you will be given an additional $100 compensation for your time and inconvenience.

If you decide to take part but later change your mind, you are free to withdraw at any time without having to give a reason. Your participation in the study will be withdrawn if it appears harmful to you in any way.

WHAT ARE MY RIGHTS?

Your participation in this study is voluntary, and you are free to decline participation or withdraw from the study at any time without compromising your medical care.

You have the right to access information about yourself that is collected as part of the study. If new information becomes available during the study that may have an impact on your health, you will be informed immediately.

At all times, your privacy will be maintained. No material that could personally identify you will be used in any reports on this study or closely related projects in the future. If the results of the trial are published, anonymity will be maintained. A code that identifies you to the research team will be used on all study documentation. The code will also be used for the faecal DNA or RNA that has to be sent to a commercial service provider lab in Ireland. The code is held on a database that is separate from the database being used to store your information. Both databases are securely housed on a University of Otago server and are password protected. This means only the Christchurch research team can link important results from the research to your identity so we can communicate these results to you, but other researchers analysing data cannot.

During the study, your physical file will be held in a locked filing cabinet when not in use. At the end of the study, your files will be kept for 10 years in secure document storage and then destroyed by shredding. The biological samples will be stored until publication of results has occurred, but not longer than 10 years, after which they will be destroyed hygienically (in accordance with NZS 4304:2002 “Healthcare Waste Management”) or with the appropriate karakia, if you wish.

If you have any queries or concerns about your rights as a participant in this research study, you can contact an independent health and disability advocate. This is a free service provided under the Health and Disability Commissioner Act.

Telephone (NZ wide): 0800 555 050

Free Fax (NZ wide): 0800 2787 7678 (0800 2 SUPPORT)

Email (NZ wide): advocacy@hdc.org.nz

If you have any questions about the study at any time, please do not hesitate to call.

This study has been preliminary approved by the University of Otago Human Ethics Committee (Health).

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

Once the information and samples are collected, there are no further requirements with regard to participation in the study, you would be released from the study but advised to keen the copy of this participant information sheet. All information and biological samples will be stored in the University of Otago on password-protected servers and in secure research freezers. No identifying data is kept in the same place that could link results to you as an individual. Secure storage is the responsibility of the University of Otago and the other institutions where the research will be undertaken. The information and samples will be stored securely and be used for ongoing research into role of dietary fibre and gut microbiome.

The hard copy data will be destroyed 10 years after the commencement of the study. The biological samples will be stored until publication of results has occurred, but not longer than 5 years. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

Your coded information or tissue sample may be used for future research related to intervention or research question or outcomes. This future research may be conducted overseas. You will not be told when future research is undertaken using your coded information. Your coded information may be shared with other researchers or companies. Your coded 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 any / some 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.

If you withdraw from the study after the samples and data have been collected, we will remove any data relevant to you or the samples that you have given from the study database. However, if the samples have already been processed and the data has been used for research purposes, then the data cannot be removed from scientific reports. If you were to die, your family will not be able to withdraw the data and samples from the study. Findings from this study will be communicated to participants who wish this by a newsletter.

WHO IS FUNDING THE STUDY?

Funding for this study has come from High Value Nutrition Science Challenge (The Ministry of Business Innovation and Enterprise) and Goodman Fielder Ltd. Goodman Fielder is also providing in-kind contribution

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

If you have questions, concerns or complaints about the study at any stage, please contact:

Research team:

Dr Simone Bayer, Jasjot Maggo, and Hwei Min Ng

HVN.GIstudies@gmail.com ☎ 021 279 1519

If you want to talk to someone who is not 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

For **Māori health support** please contact:

Nga Ratonga Hauora Christchurch Hospital

Tel 3640 640 (Ext 86160)

You can also contact the University of Otago Human Ethics Committee (Health) that approved this study on:

Phone: +64 3 479 8256 Email: gary.witte@otago.ac.nz

Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.

Consent Form

If you need an interpreter, please tell us

I have read (or have had read to me) and understand the Participant Information Sheet.
I have been given sufficient time to consider whether or not to participate in this study.
I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.
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.
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.
I consent to the research staff collecting and processing my information, including information about my health.
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.
I understand that this study involves five 30-minute visits with the research team at different locations.
I agree to my stool and blood samples being sent to New Zealand collaborators and I am aware that these samples will be disposed of using established guidelines for discarding biohazard waste.
I consent to use of de-identified data from this study to be used in future studies.
I consent to my de-identified data and faecal samples being sent overseas.
I understand that during the week before sample collection I must refrain from taking any laxative medication other than the rescue treatment offered by the research staff
I consent to my GP or current provider being informed about my participation in the study in case of any significant abnormal results obtained during the study.

I agree to an approved auditor appointed by the University of Otago Human Ethics Committee (Health), or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

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

I understand the compensation provisions in case of injury during the study.

I know who to contact if I have any questions about the study in general.

I understand my responsibilities as a study participant.

I consent to be contacted by the researchers if there are other studies that I may be eligible to participate in.

I would like any remaining samples to be disposed of at the end of the study (please tick one):

Using standard disposal methods ☐ Disposed with appropriate karakia ☐

Be handed back to me ☐

I wish to receive a summary of the results from the study ☐

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: