School of Biological Sciences

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# Effects of a dairy protein (whey) hydrolysate on blood sugar, metabolic rate, gut and immune function after eating

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**Formal Study Title**

## Acute effects of a dairy protein (whey) hydrolysate on postprandial metabolism in healthy adults:

glycaemia, thermogenesis, gut barrier function, immune/inflammation

**Participant Information Sheet/Informed Consent Form**

# Participant Information Sheet

You are invited to take part in a research study which will investigate the effect of a specially-processed dairy protein (called a "whey hydrolysate") on metabolism in the hours after eating. Specifically, this study will be looking at how drinking a beverage containing this protein changes your blood sugar levels, metabolic rate, appetite, and your gut and immune function.

This Participant Information Sheet (PIS) will help you decide if you would 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 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, cultural leaders, friends, or healthcare providers. Please feel free to do this. 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.

If you agree to take part in this study, you will be asked to sign the Informed Consent Form on the last page. You will be given a copy of this Participant Information Sheet/Informed Consent Form to keep.

This document is 22 pages long, including the Informed Consent Form.

**Please make sure you have read and understood all the pages.**

## 1. Voluntary participation and withdrawal from this study

Your participation in this study is entirely voluntary. You are completely free to decline to participate, or withdraw from the present study at any time. In the event of doing so, you will not experience any disadvantage.

## 2. What is the purpose of the study?

It is well known that what we eat affects our health. It is now also well recognised that some products contain additional properties, that can provide health benefits above a food's nutritional value.

Firstly, it has been suggested that such 'functional' foods and beverages may help to regulate our blood sugar response. Secondly, 'functional' foods could increase the amount of energy (calories) burned in the hours after eating. Thirdly, these products may be able to promote the breakdown of fat after a meal has been eaten. Finally, consuming certain food and beverage products could help us to feel fuller for longer, and maintain a healthy gut and immune function.

Several of the components found in dairy products are thought to have these sorts of beneficial effects, but they seem to depend on the way that the components are processed and produced.

Whey and casein are the two main types of protein found in milk, and whey protein has been found to have a number of positive effects on the body that might help protect against metabolic diseases, like obesity and type 2 diabetes. It is also thought that if the whey protein is "hydrolysed" (broken down into smaller pieces) before you drink it, it might have an even greater effect. However, most research investigating this has been conducted in lab and animal studies, so there are a lot of questions about if, and how, these effects occur in humans. This is what we will look at in this study.

This study will be composed of three experimental test days, with a beverage provided on each day, in a random order. These beverages will be: (1) a drink containing the whey hydrolysate; (2) a drink containing whey protein that is "intact" (has not been hydrolysed); (3) a control drink that contains no whey protein. The drinks will be a similar type of flavour, and you will not be told the order of the beverages.

The results from this study will increase our knowledge of how whey protein and whey hydrolysates affect our blood glucose control, the energy that we

burn and how we process foods after eating. Learning how these effects work could inform future dietary guidelines which may help people to avoid weight gain and poor metabolic health outcomes (e.g. type 2 diabetes), and also help in the design of food products which may have health benefits.

## 3. Who designed the study?

This study is designed by research staff at the School of Biological Sciences (SBS) and the Human Nutrition Unit (HNU), University of Auckland, as part of the New Zealand National Science Challenge – High Value Nutrition (NSC-HVN) Programme, funded by the New Zealand Ministry of Business, Innovation and Enterprise (MBIE).

## 4. Who can take part in this study?

If you fit the following criteria, you may be eligible to take part in this study:

- Between 18-60 years of age
- Body mass index (BMI, calculated by dividing weight by height-squared) of 18-25 kg/$m^2$
- Healthy by self-report and based on a fasting blood sugar test

We would like to enrol 20 healthy adults into this trial.

## 5. What will my participation in the study involve?

You are invited to take part in this study because you meet the initial inclusion and exclusion criteria for this study (summarised above). If you decide you wish to take part in this study, you will first need to attend a "screening visit" to confirm that you are eligible. After the "screening visit", if you meet the inclusion criteria, you will be invited to attend three further "study visits".

## Screening Visit

If you are interested in being a participant in this current study, a member of the research team from the Human Nutrition Unit will contact you via telephone or email to confirm your age, height, body weight and medical history. These questions are important for us to understand whether you might be eligible for the study.

After assessing your responses, if you appear to be eligible for the study, the researchers will invite you to come to the Human Nutrition Unit in Mount Eden for a screening visit in the morning. This screening visit will take approximately 1-2 hours.

During the screening visit, we will explain the study in more detail, and you will have the opportunity to ask any questions that you might have up to this point. Once you are well informed about the study, we will give you enough time to decide if you want to participate or not. If you decide to take part in the study, we will ask you to sign a form stating that you agree to participate in the study. This is called an 'informed consent form (ICF)' - by signing it, you consent to take part in the study. Please note that you remain free to withdraw from the study at any time without any consequence even after signing the consent form.

If you decide you would like to take part in the study, we will proceed with a clinical assessment of your health which will be very similar to a visit to your family doctor/healthcare provider/general practitioner (GP). We will ask you some personal questions (e.g. about where you live, your medical/medication history etc.). For this part, we ask that you bring any prescriptions/medication/supplements that you may have or any other information that you think may be important for us to know so that we can record your health information accurately. You do not have to answer all of the questions and that you may stop the visit at any time. Do not worry if you are unsure of any of your personal details, we can also contact your GP for further information if given your written consent.

We will also do some body measurements (height, body weight, body mass index/BMI, waist & hip circumference, blood pressure) at the screening visit.

Finally, we will take a blood sample to check your blood glucose (sugar) levels to confirm that you do not currently have diabetes. As your blood glucose levels will need to be examined in an overnight fasted state, we will require that you do not eat or drink anything (other than water) on the morning of your screening (or study) visit. We will also check your blood iron to ensure you are fit for repeated blood collections.

If you meet all of the inclusion criteria at the Screening Visit, you will be enrolled into the study.

**DXA Body Composition Scan Visit**

Following your screening visit, one of the researchers from the Human Nutrition Unit will be in contact to confirm whether you are eligible for the study. If your eligibility is confirmed, we will invite you to attend a "Body Composition Assessment" at the University of Auckland's Grafton campus (Clinical Research Centre) between your screening visit and your first study visit. Specifically, this body composition visit involves a DXA (Dual-energy X-ray Absorptiometry) scan. This is a whole-body scanning machine which will assess how your muscle and fat is distributed across your body (See more in *Section 7*).

**Study Visits**

After the body composition scan visit, we will invite you to the Human Nutrition Unit on three further occasions for the (three) study visits.

Each of the study visits takes the full morning and will follow the same procedure. At each study visit you will receive one of the two test beverages (i.e. the "hydrolysed" whey protein drink or the "intact" whey protein drink) and the matched control drink, in a randomised order. By the end of the study you will have consumed all 3 beverages. There must be a minimum of a 2 day break between each study day.

*Day before study visit*

We will provide you with a standardised meal which we ask you to consume in full as your evening dinner meal between 7:00 – 8:00 pm. You cannot eat or drink any other foods and beverages (except water) since 7:00 pm. We also ask that you abstain from intense exercise, alcohol and excessive caffeine for 24 hours before each visit.

*Study visit day*

For all study visits, we will ask you to arrive at the Human Nutrition Unit (HNU) in Mount Eden at 7:45 am after an overnight fast (no food or drink since your evening meal at 7:00 pm). Please travel to the HNU by car, bus or train as we don't want you to do more than minimal physical activity on the morning of your study visits (please don't jog, run, or cycle to HNU). You will then remain at our research facility for 5-6 hours whilst we first conduct baseline measurements and subsequently assess your metabolism after you've consumed the test beverage.

When you arrive, you will be given a glass of water and we will record your body weight. After this, our Research Nurse will insert a cannula (small plastic tube, using a needle) into your arm. This will allow us to collect blood samples throughout the study visit without having to repeatedly prick with a needle. We will collect 12 small blood samples in total throughout the whole study day. This technique is commonly used in hospitals, and once the cannula is in place it does not usually cause any discomfort. Nonetheless, you will be monitored by Research Staff over the 5-6 hour study period.

Once the cannula is inserted, we will collect a blood sample and measure your heart rate, blood pressure and body temperature. For the measurement of heart rate and body temperature, we will require you to wear a chest strap (which sits underneath your top) and a small battery-sized sensor (which sits on the tip of your finger), respectively. You will then wear both of these monitors whilst we continue to non-invasively assess your heart rate and body temperature for the duration of the morning visit.

We will also ask you to complete a short questionnaire about your appetite repeatedly throughout the morning using a visual analogue scale (VAS). An example of this type of measurement is shown below in the image (see *Figure 1*). You are required to mark a point along a continuous scale between two extreme limits to indicate how you feel.

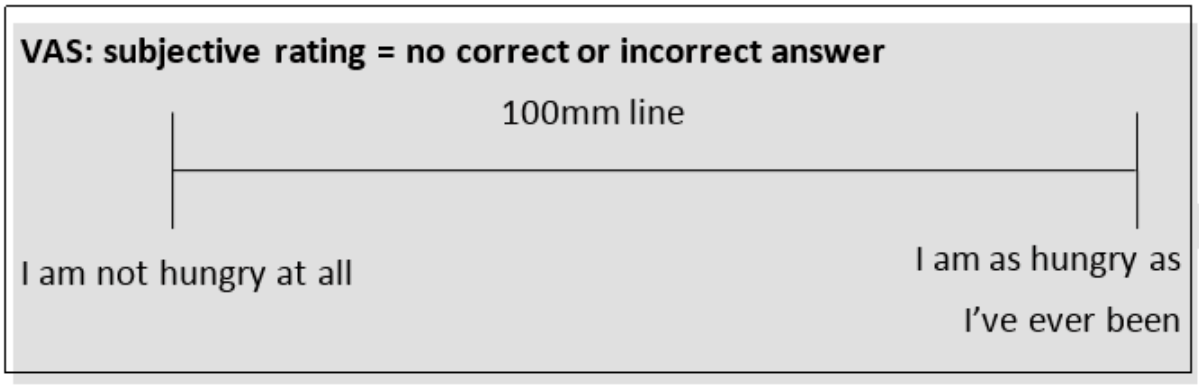


**Figure 1**. An example of a single visual analogue scale (VAS) appetite question.

Another key feature of the study visits will be an assessment of energy expenditure (the amount of calories your body is burning) using the method of indirect calorimetry. A picture to help you understand what this procedure entails and what you expect is shown in *Figure 2*. For these measurements, we will ask you to sit in a comfortable chair whilst we place a canopy (a transparent head covering) over your head.

**Figure 2**. Indirect calorimetry.

This system allows us to measure the air that you are breathing in and out which we can subsequently use to calculate your metabolic rate (rate at which you are burning energy at rest). You will remain seated in this chair (apart from a short toilet break at 11am) with the canopy hood over your head from around 8.00 am until 12:30 pm. There is an opening at the top of the canopy for fresh air to enter and circulate the system.

During your time under the hood, you will be able to watch a calm movie, documentary or TV show on our clinic room TVs. However, it is important that you do not fall to sleep or fidget excessively (e.g. use a laptop/mobile phone) during these measurements.

The first indirect calorimetry measurement will be completed whilst you are still in a fasted state and will last approximately 30-45 mins. After this initial baseline measurement, we will remove the hood and provide you with the test beverage to drink.

After giving you 5-10 minutes to consume the test beverage, we will place the canopy hood back over your head and continue taking measurements for 30 minutes. Then we will remove the canopy hood again and give you a small breakfast meal (for example, bread, butter, jam, and a small glass of water). We will then replace the hood and measure for a further 3-3.5 hr. You cannot eat or drink anything (including water) until the lunch meal that we will be providing to you at around 12:15pm.

During the indirect calorimetry session, we will also be conducting frequent blood samples from the inserted cannula (no additional needles), collecting

subjective assessments of appetite using questionnaires, and taking multiple measurements of blood pressure.

It is important that you are relaxed throughout the indirect calorimetry procedure so please tell the researcher if you are uncomfortable or if there is something you need. During all of the measurements it is important that you avoid large movements, but if you need to readjust your position, use the bathroom, or itch in order to be more comfortable, of course you may do so. There is a scheduled toilet break at 11am.

At 12:15-12:30 pm we will have finished the above measurements and the canopy hood will be removed, and you can get up from the chair. We will then serve you a lunch meal (beef and tomato pasta with water) in the dining room and you will be asked to eat as much as you like until you are comfortably full within 30 minutes. We ask that you be seated in the dining room until the end of the lunch break. After lunch we will do 2 more appetite questionnaire measurements and 2 final blood samples. You will be finished with the study visit at around 2:00 pm and will be able to leave the HNU after we have removed the cannula. A scheduled timeline of the tests which will be conducted throughout the course of a study visit morning is given on the next page.

Study visit schedule

| | |
|---|---|
| 0745h | Approximate arrival at HNU (fasted) |
| 0800h | Venous cannulation by registered nurse |
| 0815h | Commencement of cardiometabolic monitoring (indirect calorimetry, heart rate, body temperature), appetite questionnaires, and baseline blood sample (t=-45) |
| 0845h-0854h | Indirect calorimetry measurement paused (canopy removed), appetite questionnaires, blood pressure and baseline blood sample (t=-15 – t=-5) |
| 0855h | Drink a test beverage (t=-5) |
| 0900h | Canopy replaced, and indirect calorimetry measurement restarted (t=0) |
| 0915h | Appetite questionnaires, and blood sample (t=15) |
| 0930h | Appetite questionnaires, blood sample (t=30), and blood pressure; eat a breakfast meal |
| 0945h | Appetite questionnaires, and blood sample (t=45) |
| 1000h | Appetite questionnaires, and blood sample (t=60) |
| 1015h | Appetite questionnaires (t=75) |
| 1030h | Appetite questionnaires, blood sample (t=90), and blood pressure |
| 1100h | Appetite questionnaires, blood sample (t=120), and toilet break |
| 1130h | Appetite questionnaires (t=150) |
| 1200h | Appetite questionnaires, blood sample (t=180), blood pressure |
| 1230h | Appetite questionnaires, blood sample (t=210), blood pressure, cardiometabolic monitoring stopped and standardised lunch meal provided |
| 1310h | End of lunch, Appetite questionnaires, blood sample (t=250), and blood pressure |
| 1340h | Appetite questionnaires, blood sample (t=280), and blood pressure. Cannula removed, participant discharged |

In total, approximately 288 ml of blood will be collected for a total of 3 study visits (96 ml/visit). In addition, 4 ml will be collected at the screening visit, bringing the total amount of blood collection for each trial to 292 ml (see *Table 1* for a breakdown of the amount of blood that will be sampled at each timepoint during the screening visit and each study visit).

**Table 1.** Blood sample amount (ml) at each timepoint (t, min) during the screening visit and each study visit.

| Fasting (Baseline) samples (ml) | | | Postprandial (after eating) samples (ml) | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Screening | t= -45 | t= -5 | t= 15 | t= 30 | t= 45 | t= 60 | t= 90 | t= 120 | t= 180 | t= 210 | t= 250 | t= 280 | |
| **4.0** | 13.5 | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | **96.0** |

For reference, it should be noted that the overall amount of blood taken during each study visit is only just over a fifth of the amount of blood typically collected during a standard blood donation (~470 ml). These blood samples will be used to measure what effect the test beverages have on blood glucose (sugar) and fat levels, and markers of inflammation and the immune system.

The use of indirect calorimetry with the ventilated hood will allow the researchers to measure the rate at which oxygen is used and carbon dioxide is produced by the body. These values will then be used to determine roughly how much energy (calories) you are expending (i.e. metabolic rate) and the source of this energy (i.e. fats or carbohydrates). Heart rate and blood pressure are also measured throughout the trial to help understand your cardiovascular response to each meal. Finally, we use the appetite questionnaires and lunch meal to compare how hungry/full you feel following the different beverages.

## 6. How will my samples and data be stored?

All of your data will be securely stored at the Human Nutrition Unit. Data will be both written and also on computer files which can be accessed only by the study staff, using security codes. No one else at the University or outside the University will have access to your information. If you drop out of the study at any time (perhaps you become too busy), we ask that all of the data that we have collected can remain in the database in Auckland – we respect your right to withdraw from the study. All data collected from you to that point will remain in our database and be analysed as part of the study however, we will collect no other samples and data from you from that point onwards. The research team will need data from all study

participants in order to report to regulatory authorities and also to publish the findings from the study.

With regards to the fate of your blood samples, these will be securely stored in freezers dedicated for human blood samples only for up to four years. These samples will only be stored in New Zealand and used only for the purpose of this research. Once your blood has been collected, it will be sent for storage at a secure facility at the School of Biological Sciences, University of Auckland, and then analysed as a group at the University laboratory, with all other participants' blood samples. A small aliquot of your blood may also be sent for analysis to the Malaghan Institute of Medical Research in Wellington. Any leftover samples will be destroyed by incineration according to University policy at the end of the study, or returned to you, if you have requested.

If you would like to request a specific tikanga (Māori custom) or other process, please feel free to talk with the research team. You may hold beliefs about a sacred and shared value of blood samples removed. The cultural issues associated with storing your blood 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 storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.

## 7. What are the possible risks of this study?

There is very low risk associated with taking part in this research study.

Nonetheless, you may experience discomfort during cannulation, however this is uncommon. Research staff will be present to monitor you during all assessments. The research will be stopped should any harmful effects appear or if research staff feel that it is not in your best interest to continue. You should promptly inform the research staff if you feel uncomfortable or unwell at any stage.

DXA is a scanning method, to measure body composition (bone, fat, muscle). The scanning process takes about 15 minutes and is not unpleasant. We will ask you to wear gym-style clothing and to remove any metal from your person for the scan. You will need to lie quietly, without moving, on an open bed whilst a scanning arm passes quickly over the top of you. As the scanning arm passes over you it emits two types of very low dose X-ray, similar to the radiation dose that you would be exposed to on a 1-hour flight – e.g. between Auckland and Wellington. At the end of the

scan we will print a picture of you showing an image of the bone, fat and lean tissue in your body for you to take home with you.

## 8. What are the possible benefits of this study?

There will be no benefits from participating in this project other than obtaining valuable information pertaining to your health. You will also importantly be contributing to scientific knowledge in the field of nutrition and health.

## 9. Will I be compensated for my participation?

In recognition of your participation, we will provide you with a $10 voucher for completion of the screening visit. In addition, if you are eligible and consent to participate in the study, you will receive $10 after completion of the DXA body composition visit, and $75 in vouchers for each study visit (i.e., $245 for completing the screening visit, DXA scan + three study visits).

Aside from this, you will also have access to your results from this study. At the end of the study, you will receive results from your blood tests such as your glucose, insulin, and lipid profile. It may take a while before you receive these blood results as we will need to wait until all participants have completed their visits to analyse all the collected blood samples together. You will also receive your body composition scan results.

## 10. What if something goes wrong?

If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC, just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. 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.

## 11. What will happen to my information?

During this study the researchers and nurses will record information about you and your study participation. This includes the results of any study assessments. You cannot take part in this study if you do not consent to the collection of this information.

## 12. Identifiable information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Your identifiable information can only be accessed by (i) researchers at the Human Nutrition Unit working on this research project; (ii) laboratory staff who process, analyse and report your blood samples to us during the screening process (to check your eligibility); (iii) an approved auditor chosen by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative for the sole purpose of checking the accuracy of the information recorded for the study; (iv) your GP, in the event of unexpected findings that could significantly impact your health. We will not provide your identifiable information to other researchers (including the other researchers within the University of Auckland).

## 13. Data confidentiality

To protect your privacy and confidentiality of your identity during and after your participation in the study, you will be allocated a unique study ID number upon your enrolment. This ID number will be used to label your samples, any data collected and your results throughout the study. Research files and all other information that you provide will remain de-identified and strictly confidential. No material that could personally identify you will be used in any reports throughout the course of this research project. Moreover, all computer records will be password protected throughout.

The researcher will keep a password-protected list linking your code with your name, so that you can be identified by your coded data if needed.

## 14. Future research using your information

Your coded (de-identified) information may be used for future research related to the outcomes of this study. We will not share any identifiable information with anyone else other than the HNU research team.

## 15. Security and storage of your information

Your identifiable information will be held at the HNU during the study and will be accessible only to members of the HNU research team. After the study is completed it will be transferred to a secure archiving site and stored for at least 10 years, then destroyed.

## 16. Risks associated with data

Although robust 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 (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

## 17. Rights to access your information

As a participant in the present study, you preserve all rights to access information about yourself as collected for the study. Upon request, this information will be disseminated as soon as it is available, such as described with the blood test data in Section 5. You also have the right to request that any information you disagree with is corrected.

Given your consent, you will be informed of any new information which arises regarding adverse or beneficial effects related to the study which could have an impact on your health (i.e. that which becomes available during the study), as described in Section 20. If you have any questions

about the collection and use of information about you, you should ask Jia Jiet Lim, the primary study coordinator.

## 18. Rights to withdraw information

You may withdraw your consent for the collection and use of your information at any time, by informing someone on the study team.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

All of your data will be securely stored at the Human Nutrition Unit in Auckland. Data will be both written and also on computer files which can be accessed only by the study staff, using security codes. No one else at the University or outside the University will have access to your information. If you drop out of the study at any time, we ask that all of the data that we have collected can remain in the database in Auckland – we respect your right to withdraw from the study. All data collected from you to that point will remain in our database and be analysed as part of the study however, we will collect no other samples and data from you from that point onwards. The research team will need data from all study participants in order to report to regulatory authorities and also to publish the findings from the study.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have already been undertaken.

## 19. What if the researcher discovers incidental or unexpected findings?

If there are any results from the blood tests that are outside the reference ranges, we will first discuss this with you.

It is possible that you may have abnormal blood results, such as prediabetes or diabetes, low iron, or abnormal level of liver enzymes, during the study. If so, you will be informed, provided with the results, and advised to contact your GP directly. Our research staff will discuss with you the significance of any abnormal result and will suggest that you contact your GP or specialist to ensure adequate follow-up is in place, since these

disorders can have significant impact on your health. If you were to request that we discuss the results with your GP then we could do so.

## 20. Will I get my test results?

If you wish, you will get results of certain body measurements including weight, BMI, blood pressure, metabolic rate and DXA scan. At the end of the study, we can also give you your own information on blood tests such as blood sugar, HbA1c (diabetes test), and cholesterol.

Other tests will be performed in a research laboratory and the results will not routinely be made available to you. This is to safeguard you from Insurance companies who demand to know ANYTHING you know about your health. While these tests may give research information about how you might respond to different beverages, they will not provide information that is useful to your own health or wellbeing or could be used for medical treatment in any way. These measurements are for research purposes and are not diagnostic. However, you have a right to specify on your consent form if you want to receive information about findings that may indicate potential or actual risk to health. Such results will however be available only at the end of the study.

## 21. Can I find out the overall results of this study?

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

You can request a letter telling you about the study results. The letter will be sent to you once the final study report is available (this can take 1–2 years). A description of this trial will also be available on the Australian New Zealand Clinical Trials Registry (ANZCTR) website (https://www.anzctr.org.au/). This website will not include information that can identify you. At most, it will include a summary of study results.

## 22. Who has approved the study?

This study has been approved by an independent, national group of people called a Health and Disability Ethics Committee (HDEC), who check that

studies meet established New Zealand and international ethical standards. The Central HDEC has approved this study (Reference: 2022 EXP 13859).

## 23. 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:

**Dr Jia Jiet Lim (Primary contact for participants)**
*Research Fellow & Study Co-ordinator*

Human Nutrition Unit, University of Auckland,
18 Carrick Place, Mount Eden,
Auckland 1024

Email: jia.jiet.lim@auckland.ac.nz
Contact number: 09 630 1162

For Māori cultural support please contact:

**Mr Teariki Tuiono**
Kaiarahi
Faculty of Science, University of Auckland
Contact number: 09 923 5722
Email: teariki.tuiono@auckland.ac.nz

If you have further *unresolved* questions, concerns or complaints about the study at any stage, you can contact:

**Dr Jennifer Miles-Chan**
*Director, Associate Professor*

Human Nutrition Unit, School of Biological Sciences,
University of Auckland
Email: j.miles-chan@auckland.ac.nz
Contact number:09 923 4322

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@advocacy.org.nz
Website: https://www.advocacy.org.nz/

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC
Email: hdecs@health.govt.nz

The research investigators are:

## Principal Investigators

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**Thank you for considering to take part in this study.**

# Informed Consent Form (ICF)

**Effects of a dairy protein (whey) hydrolysate on blood sugar, metabolic rate, gut and immune function after eating**

| | |
|---|---|
| I wish to have an interpreter to translate the study requirements from English into my preferred language. | Yes ☐<br>No ☐ |
| I have read, or have had read to me, and I 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 consent to my GP or current provider being informed of any significant abnormal results obtained during the study. | |
| I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, 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 the compensation provisions in case of any injury during the study. | |

| | |
|---|---|
| I consent to my coded information being used for future research. This is completely optional and will not determine your eligibility for the current study. | Yes ☐<br>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. | |
| I know who to contact if I have any questions about the study in general. | |
| I understand my responsibilities as a study participant. | |
| I wish to receive a summary of the results from the study. | Yes ☐<br>No ☐ |
| I consent for research staff at the HNU to contact me at a later date if there are future studies for which I am eligible | Yes ☐<br>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:

***A copy of this consent form is to be given to the participant and a copy to be kept in a research file by the investigator.***