# Participant Information Sheet

Study title: **Pilot study: Can a dairy based protein (IDP) enhance immune responses after influenza vaccination?**

Sponsor (if applicable): Dr Rod Claycomb, Quantec Ltd, Waikato Innovation Park, Ruakura Rd, PO Box 9466 Hamilton New Zealand

Lead Researcher: Associate Professor Rachel Page

Study Site: Massey University, Albany Campus, Auckland

Contact phone number: 04 801 5799 ext. 63462

Ethics committee ref.: 21CEN233

You are invited to take part in a study looking at consumption of a dairy protein complex (IDP), a supplement that has been in the marketplace for 10 years, is able to enhance antibody responses to the influenza vaccine. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form 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 11 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

## VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

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

## WHAT IS THE PURPOSE OF THE STUDY?

Immune Defense Proteins (IDP) is a complex of milk proteins that has been shown in a pilot study to have anti-inflammatory activity and provide protection from infection. However, thus far there have been no studies looking at whether IDP is able to enhance immune responses after an influenza vaccination in humans. This study aims to determine whether daily consumption of IDP for four weeks before, and four weeks after receiving the vaccination can enhance the antibody responses to the Influenza vaccine.

## HOW IS THE STUDY DESIGNED?

The study will involve 60 people from the Auckland region. You will undergo screening via a general health questionnaire to ensure suitability for the study. If you are eligible and once you provide consent to participate in the study you will be required to come to the Massey University Nutrition Research Facility, located at the Albany campus for **SIX** visits over a nine-week study period. Each of these six visits will take between 15 - 75 min each and will occur in the morning.

Participants will be randomly allocated to one of three testing groups. You will be required to consume a supplement in powder form containing Placebo or IDP (50 mg) or IDP (200 mg). The supplement (2 grams powder in each sachet) will be consumed with breakfast daily for 8 weeks, and after four weeks of consumption you will receive the influenza vaccine. We will collect 6 blood samples over the 9-week study period and we will require you to complete 3 questionnaires regarding general health and consumption of the supplement during the study.

## WHO CAN TAKE PART IN THE STUDY?

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

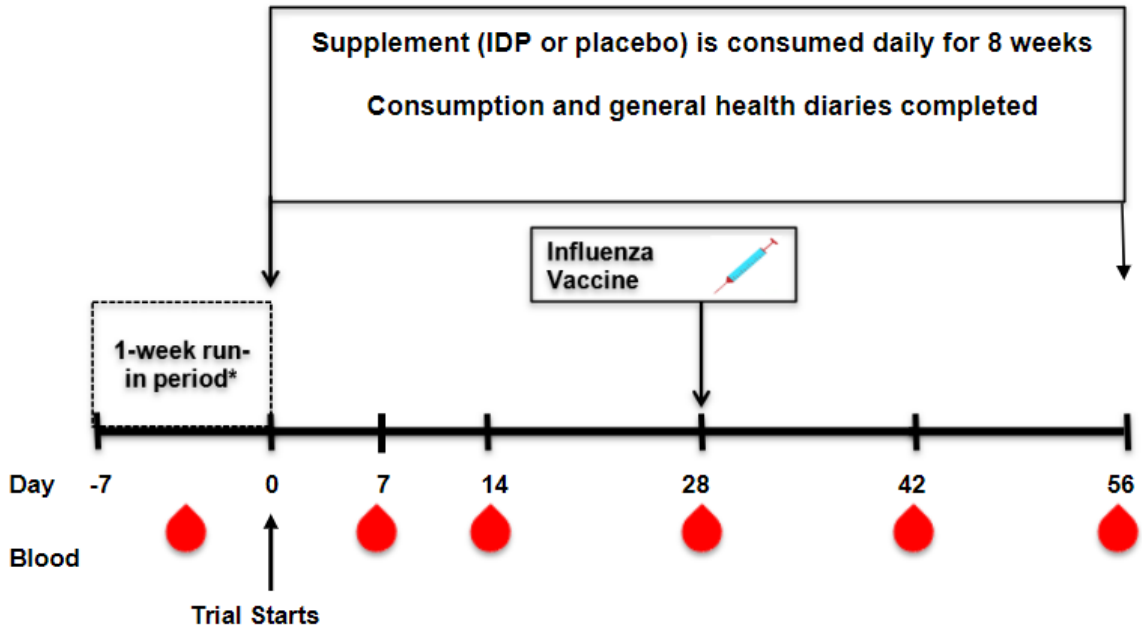
- 40-60 years of age
- Healthy
- Not having already received the influenza vaccination in 2022
- Not had an anaphylactic reaction to a previous influenza vaccination
- Not pregnant or breastfeeding
- Not lactose intolerant or allergic to dairy products
- Not allergic to starch, gluten or artificial sweeteners
- Not currently participating in another clinical trial
- Not had a recent cold
- Not have any chronic inflammatory conditions
- Able to communicate well in English

## WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You will be required to come to the Massey University Nutrition Research Facility, located at the Albany campus for **SIX** visits over a nine-week study period. Each of these six visits will take between 15 - 75 min each and will occur in the morning. You are not required to fast prior

to attending for visits, but we would recommend that you eat at least two hours before coming to the research facility as we will be collecting blood samples from you.

## Whole Study at a Glance




## First visit (1-7 days before trial starts)

During the first visit, we will require you to arrive at the Massey University Human Nutrition Research Unit in the morning for some baseline measures to be taken. Trained personnel will measure your height, weight and blood pressure and a trained phlebotomist will collect approximately 12 ml of blood. You will be allocated into one of the three testing groups and provided with sachets of the supplement, which you will consume daily with breakfast for eight weeks. The start date for your trial and subsequent visit dates and days will be determined. You will be provided with a daily consumption and general health diary to complete during the next four weeks while you are taking the supplement. If you have any questions about the study, you will be able to ask one of the researchers. The session should take approximately **60-75 min**.

## Second visit (Day 7)

We will require you to arrive at the Massey University Human Nutrition Research Unit in the morning for a trained phlebotomist to collect approximately 12 ml of blood. In addition, we will check completion of the daily consumption and general health diary and you will have an opportunity to ask any questions you may have. The session should take approximately **20-30 min**.

## Third visit (Day 14)

For the third visit, 14 days after commencing taking the supplement we will require you to arrive at the Massey University Human Nutrition Research Unit in the morning for a trained phlebotomist to collect approximately 12 ml of blood. We will also collect from you, the first two weeks of your daily consumption and general health diary. In addition, you will have an

opportunity to ask any questions you may have. The session should take approximately **15-20 min**.

**Fourth visit (Day 28)**

For the fourth visit, 28 days after commencing taking the supplement we will require you to bring your completed daily consumption and general health diary (weeks 3-4) and arrive at the Massey University Human Nutrition Research Unit in the morning for a trained phlebotomist to collect approximately 12 ml of blood. Following this you will receive the influenza vaccination by trained personnel. You will be asked to remain there for 30 minutes to ensure there are no allergic reactions. You will be given a new consumption and symptoms diary to complete during the next four weeks of the study. The session should take approximately **45-60 min**.

**Fifth visit (Day 42, and 14 days after receiving vaccination)**

For the fifth visit, 14 days after receiving the vaccination we will require you to arrive at the Massey University Human Nutrition Research Unit in the morning for a trained phlebotomist to collect approximately 12 ml of blood. We will also collect your consumption and symptoms diary for weeks 5 and 6. This session should take approximately **15-20 min**.

**Sixth visit (Day 56, and 28 days after receiving vaccination)**

For the sixth and final visit, 28 days after receiving the vaccination we will require you to bring your completed consumption and symptoms diary (weeks 7 and 8) and arrive at the Massey University Human Nutrition Research Unit in the morning for a trained phlebotomist to collect approximately 12 ml of blood. During this session we will also ask you to complete the final short questionnaire regarding consumption of the supplement over the 8 weeks of the trial. The session should take approximately **20-30 min**.

## WHAT WILL HAPPEN TO MY BLOOD SAMPLES?

Your blood samples will be identified using a code unique to you. The samples will be analysed at Massey University for the levels of antibody against the influenza vaccine and markers of inflammation (Interleukin 6, interleukin 10, interferon and Tumour Necrosis Factor α).

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

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

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

The cultural issues associated with storing your blood samples and analysis on them should be discussed with your family/whānau as appropriate. We are happy to meet with you and your whānau/family to discuss the study further. To avoid problems at a later stage, we suggest that your family/whānau is involved with you at all stages of the study. You may hold beliefs about a sacred and shared value of all or any blood samples removed. There 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 prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.

## WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

It is highly unlikely that you will be injured during this study. Phlebotomy is a safe and routinely used practice and will be performed by a trained phlebotomist. You may experience some mild discomfort during the drawing of blood. Qualified personnel and a first aider will be available during each study session and will assess for any adverse events you may experience (i.e., feeling nauseous, dehydrated or faint) during each blood sampling.

Administration of the influenza vaccine will be performed by a trained healthcare professional, and you will need to remain at Human Nutrition Research Unit for a further 30 mins after injection to ensure no adverse effects occur. You may feel discomfort at the injection site for the influenza vaccine. Sometimes, flu vaccination can cause mild side effects, such as pain, redness, and swelling at the injection site. Some people may experience low grade fever, headaches, and muscle aches after the **vaccination**, but these should only last 1–2 days.

If you feel you are experiencing longer term effects from the vaccination, please contact your Family doctor or Healthline (phone **0800 611 116**).

IDP has been in the marketplace for 10 years. If there are any side effects, they will be related to its dairy content. Lactose intolerance and known or suspected allergies to dairy, starch, gluten and artificial sweeteners are therefore noted as Exclusion Criteria for the study.

Participants may dislike the taste of the supplement; different suggestions will be made on ways to consume the supplement.

## WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Research is a big part of improving health outcomes or enhancing health and wellbeing and being involved can be very rewarding. You can learn a lot about the processes that are involved in research by actively participating and it can be satisfying to know that you are contributing to knowledge. Furthermore, by participating in the study, you will receive the influenza vaccination and have your blood pressure measured at no cost to you. In addition, there will be a koha (Westfield vouchers) for involvement in the study.

## WILL ANY COSTS BE REIMBURSED?

Participation in this study is free. The costs for the blood testing and the influenza vaccination will be covered by us.

In recognition of your time and participation in this study, you will receive a total koha of $150 in the form of Westfield vouchers for completing the whole study (six study visits). You will receive $75 in Week 4 and the remainder after completion of the final visit (week 8). If for any reason you are unable to complete the study, you will be reimbursed for the visits you completed.

## WHAT IF SOMETHING GOES WRONG?

*"Commercially sponsored" intervention studies:*

As this research study is for the principal benefit of its commercial sponsor Quantec Ltd, if you are injured as a result of taking part in this study you **won't** be eligible for compensation from ACC.

However, Quantec Ltd has satisfied the Health and Disability Ethics Committee that approved this study that it has up-to-date insurance for providing participants with compensation if they are injured as a result of taking part in this study.

New Zealand ethical standards require compensation for injury to be at least ACC equivalent. Compensation should be appropriate to the nature, severity and persistence of your injury and should be no less than would be awarded for similar injuries by New Zealand's ACC scheme.

Some sponsors voluntarily commit to providing compensation in accordance with guidelines that they have agreed between themselves, called the Medicines New Zealand Guidelines (Industry Guidelines). These are often referred to for information on compensation for commercial clinical trials. There are some important points to know about the Industry Guidelines:

- On their own they are not legally enforceable and may not provide ACC equivalent compensation.
- There are limitations on when compensation is available, for example compensation may be available for more serious, enduring injuries, and not for temporary pain or discomfort or less serious or curable complaints.
- Unlike ACC, the guidelines do not provide compensation on a no-fault basis:
- The Sponsor may not accept the compensation claim if:
    - Your injury was caused by the investigators, or;
    - There was a deviation from the proposed research plan, or;
    - Your injury was caused solely by you.

An initial decision whether to compensate you would be made the by the sponsor and/or its insurers.

If they decide not to compensate you, you may be able to take action through the Courts for compensation, but it could be expensive and lengthy, and you might require legal representation. You would need to be able to show that your injury was caused by participation in the trial.

You are strongly advised to read the Industry Guidelines and ask questions if you are unsure about what they mean for you.

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 WILL HAPPEN TO MY INFORMATION?

During this study the researchers will record information about you and your study participation. This includes the results of any study assessments.

Identifiable Information

Identifiable information is any data that could identify you (e.g., your name, date of birth, or address). Only researchers will have access to your identifiable information.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researchers or any study information sent to the sponsor. Instead, you will be identified by a code. The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

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

Security and Storage of Your Information.

The study data including your identifiable information 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 5 years, at which point it will be destroyed using University Security methods for removal of confidential material.

Risks.

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 (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.

Although we are collecting data on ethnicity, it will only be used to describe participant characteristics, and no analyses will be carried out using this data.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access the results of your screening and safety tests during the study.

If you have any questions about the collection and use of information about you, you should ask one of the researchers.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing one of the researchers.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you. If you withdraw from the study during the trial, all of the data that was related to you will be shredded/destroyed, any blood samples collected will be either returned to you upon request or destroyed/disposed of.

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

You are able to withdraw from the study at any time by contacting one of the named researchers and will be compensated accordingly for your time. Furthermore, 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 withdraw from the study during the trial, all of the data that was related to you will be shredded/destroyed, any blood samples collected will be either returned to you upon request or destroyed/disposed of.

The IDP supplement will not be available to any participant after the study.

At the end of the study after analysis of the results participants can request a copy of the final study report and can be told which trial arm they were part of if they request it.

## CAN I FIND OUT THE RESULTS OF THE STUDY?

Participants are welcome to discuss the findings of this study with the researchers at any time. You will also be provided with a full copy of the final study report, within 1 year of completion of the study if requested.

It is also very likely that the results of this study will be written up for publication in a peer-reviewed journal. If this happens no participant identification information will be included.

## WHO IS FUNDING THE STUDY?

This study is being funded by Quantec Ltd, who will also be providing the placebo and IDP supplements.

The researchers are all employed by Massey University New Zealand.

## WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards.

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

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

**A/Prof Rachel Page:** Head of School of Health Sciences, Massey University, Wellington
Phone: 04 979 3462
Email: R.A.Page@massey.ac.nz

**A/Prof Kay Rutherfurd-Markwick:** Associate Professor, School of Health Sciences, Massey University, Albany
Phone: 09 414 0800 ext. 43646

Email: k.j.rutherfurd@massey.ac.nz

**Dr Cheryl Gammon:** Lecturer, School of Health Sciences, Massey University, Albany
Phone: 09 2136437
Email: C.Gammon@massey.ac.nz

**Dr Judy Thomas:** Lecturer, School of Health Sciences, Massey University, Albany
Phone: 09 2136665
Email: J.Thomas1@massey.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

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| Phone: | 0800 555 050 |
| Fax: | 0800 2 SUPPORT (0800 2787 7678) |
| Email: | advocacy@advocacy.org.nz |
| Website: | https://www.advocacy.org.nz/ |

For Māori Health support please contact:

Dr Bevan Erueti, Associate Dean for Māori, College of Health
Telephone number: +64 69516087
Email: B.Erueti@massey.ac.nz

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

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