



Participant Information Sheet for use of Blood Samples for Future Unspecified Research

Study title:	Healthy Foods for Your Heart Study	Use of Blood Samples for Future Unspecified Research
Locality:	Dunedin	Ethics committee ref.: 20/NTB/121
Lead investigator:	Andrew Reynolds	healthy_heart@otago.ac.nz

You have already agreed to take part in the Healthy Foods for Your Heart Study, - thank you. This information sheet tells you about an option to let us collect and store your blood samples in a tissue bank designed for future research. These samples would be collected during the Healthy Foods for Your Heart Study, at the beginning of the study and at 12 weeks

Whether or not you agree to contribute blood samples for future unspecified research is your choice. If you don't want to, you don't have to give a reason, and it won't affect the care you receive or your participation in Healthy Foods for Your Heart Study.

This Information Sheet sets out what it means to contribute blood samples for future unspecified use, what we are asking for, what it would involve, what the benefits and risks to you might be. You do not have to decide today. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers.

If you do decide to contribute blood samples for future unspecified use, you will be asked to sign an online consent form. You will be emailed a copy of both the Participant Information Sheet and the Consent Form to keep. This document is 4 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

Key Points:

- When you are taking part in the Healthy Foods for Your Heart Study you can choose to let us collect and store blood samples in a tissue bank for future unspecified research
- The collection of blood samples for future unspecified research has been approved by an ethics committee
- We ask to collect and store your samples because research and new tests develop quickly. There might be a question we want to answer next year, that we didn't know to ask today
- If you let us store samples they:
 - ✓ Will only be used in research that has ethical approval
 - ✓ May help us learn more about heart health
 - ✓ May be used in other types of research as well
 - ✓ Will not be identified with your name
- If you let us store samples you can:
 - ✓ decide if you permit us to send your samples overseas for analysis
 - ✓ withdraw your consent at any time

WHAT IS THE PURPOSE OF THE TISSUE BANK?

Why store my samples?

Scientific knowledge and new tests develop quickly. Often tests that are relatively new are very costly to perform. Over a number of years as new methods are developed these tests may become more affordable.

In addition, as we learn more about health conditions we develop new questions that can be answered by analysis of carefully stored samples. Using samples in this way can help us to learn more from the significant investment that you make when you contribute your time and help with research.

It is also recognised that many tissue samples are collected and often destroyed and yet could be used for new studies that might potentially benefit the health of New Zealanders without having to repeat collections all over again.

WHAT WILL GIVING SAMPLES TO THE TISSUE BANK INVOLVE?

If you agreeing to let us store a blood sample for future research, we will separate out and store some of the blood you are already providing as part of the Healthy Foods for Your Heart study. Doing this will not cost you anything. In the future we will not routinely contact you regarding the use of these samples, and the results of this future research will not be shared with you.

WHAT HAPPENS TO MY SAMPLES AFTER THEY HAVE BEEN COLLECTED?

Your samples will first be stored at Southern Community Laboratory facilities where it is taken from your arm, before being moved to the Department of Medicine Tissue Bank located in the Department of Medicine, University of Otago, Dunedin.

If the samples are being used in research led from New Zealand, the research project will be subject to ethical review in New Zealand. This review process requires that the researchers indicate how Māori have been consulted regarding the proposed research. However, if the research project is led from overseas the research is likely to be considered by an overseas ethics committee. Samples may be analysed either in New Zealand, or overseas. Please note we will not be performing unspecified genetic testing on any stored samples.

Your samples will be stored using a study ID, and the year of your birth and will be kept indefinitely. We will also record your NHI number, however this will not be recorded on the sample. Your NHI number is what links all of your health information together. We will store your NHI number as a code, so that we can only access future health information about you if an ethics committee approves this. This may include linking to information held about you by Statistics New Zealand in their database.

Your data, including the information that identifies that the samples came from you will be stored on secure databases overseen by the University of Otago indefinitely. If we need to send study information to other researchers who are analysing the samples or related data we will remove any details that can identify you before we send the data.

WHAT ARE MY RIGHTS?

You do not need to agree to give samples for future research. If you do not agree you will not be disadvantaged, and you can still participate in the Healthy Foods for Your Heart Study. You will not own any intellectual property that may arise from any future research done using samples you provide.

If you do consent but later change your mind, you can ask that your samples be destroyed by contacting healthy_heart@otago.ac.nz.

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

If you have any questions, concerns or complaints about the study:

During the study, you can contact:

healthy_heart@otago.ac.nz

To ensure ongoing cultural safety, the Southern District Health Board encourage those who identify as Māori, and who are participating in health research or clinical trials, to seek cultural support and advice from their own Kaumātua or Whaea in the first instance, or please contact Te Ara Hauora Māori Liaison Service in the Southern DHB:

Wendi Raumati
Kaiāwhina
Te Ara Hauora - Māori Health Liaison Service
Dunedin Hospital
(03) 474 0999 ext 58649

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

0800 555 050
advocacy@advocacy.org.nz

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:

0800 4 ETHIC
0800 4 38442
hdec@health.govt.nz

Consent Form



Use of Blood Samples for Future Unspecified Research

Please indicate you confirm the following

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.

I have been given enough time to consider whether or not to contribute samples to the tissue bank for future unspecified research.

I have had the opportunity to use whānau/ family support, a friend or a legal representative, to help me ask questions and understand contributing samples to the tissue bank for future unspecified research.

I am satisfied with the answers I have been given regarding the storage of my samples and I have been offered a copy of this consent form and information sheet.

I understand that agreeing to store my samples is voluntary (my choice).

I understand that that no material, which could identify me personally, will be used in any reports from any use of my tissue samples or related data.

I understand that any samples I contribute will be stored in the tissue bank indefinitely in a de-identified way by using a study code, and the date the sample was collected.

I know who to contact if I have any questions (healthy_heart@otago.ac.nz).

I understand that once these samples are no longer required, they will be disposed of using established guidelines for discarding biohazard waste.

I understand that in the future researchers may access health information about me if approved by an ethics committee.

I agree to my samples being stored indefinitely and used in future research of any type which has been properly approved. Yes

I would like a karakia to be said before my sample is stored Yes No

I agree to my samples being sent overseas. Yes No

Participant's name

Signature:

Date:
