Participant Information Sheet
Optional storage and use of blood samples for future unspecified research

Main study title:	Dietary fibre and its potential role in mitigating the health effects of dietary intakes high in processed foods	
Principal investigator:	Professor Sheila Skeaff Department of Human Nutrition University of Otago	Contact phone number: +64 3 479 7944

Introduction

You are being invited to consider allowing some of the blood collected for the main study to be stored and used in future research. Please read this information carefully and discuss it with your family, whānau, friends, or healthcare provider if you wish.

This is optional. You can take part in the main study without agreeing to future use of your samples. Your decision will not affect your participation, reimbursement, academic relationship, access to University services, or relationship with the University of Otago.

Key points

- No extra blood will be taken for future research. Only remaining plasma (the liquid part of blood) from samples collected for the main study will be stored.
- Future use of your samples is optional. You can take part in the main study without agreeing to this.
- Samples will be labelled with a study code rather than your name.
- Future projects must receive appropriate ethical approval before your samples are used. You will not be contacted for consent for each individual future project.
- You may withdraw your consent for future use of your remaining samples before 30 August 2027. After this date, it may no longer be possible to identify or destroy your samples.

Why are we asking to store samples?

Scientific methods continue to develop, and future researchers may be able to measure substances in blood that cannot be measured easily or affordably now. Storing remaining plasma may allow future ethically approved research to answer new questions about diet and health without asking participants to provide another blood sample.

What samples will be stored?

During the main study, approximately 14 mL of blood will be collected at each of four blood collection visits. One blood sample will be used for routine cardiometabolic tests. The second sample will be processed into plasma for the analyses described in the main study. Only plasma remaining after all main-study analyses and any necessary repeat analyses have been completed may be stored for future research. No additional blood will be collected for this purpose.

How may the samples and information be used?

Future research will be limited to ethically approved studies measuring blood metabolites or similar markers related to diet, nutrition, metabolism, or cardiometabolic health. Relevant coded information collected during the main study may also be used to help researchers interpret the sample results. This may include information such as your age, gender, ethnicity, dietary intake, and other blood test results. This information will be identified only by your study code and not by your name.

Your samples will not be used for unspecified genetic testing. Any proposed use outside this scope before permanent de-identification would require additional ethical approval and new consent.

Who may use the samples?

Approved researchers at the University of Otago or collaborating research laboratories may use coded samples and related coded data. Researchers receiving the samples will not be given your name or contact details.

How will the samples and information be stored?

After initial clinical processing by Awanui Labs, plasma retained for research will be transferred to a secure University of Otago laboratory and stored in a locked freezer facility. The samples will be labelled with a study code rather than your name. The file linking your name to the study code will be kept separately on a secure, password-protected University server and will only be accessible to authorised study staff. This linking file will be kept until 30 August 2027 so that you can withdraw your consent and ask for your remaining samples to be destroyed. After this date, the linking file will be securely destroyed and your samples will be permanently de-identified.

Samples may be stored for up to 10 years after completion of the main study. Any remaining samples will then be disposed of using approved biohazard procedures. You may request that a karakia is said before your samples are disposed of.

Will my privacy be protected?

Awanui Labs requires identifying information, including your name and date of birth, to make sure your blood sample is matched to the correct person and to report the clinical test results. Once samples are transferred for research storage, they will be identified by a study code. Publications and presentations will not identify you.

Are there any risks or benefits?

There is no additional physical risk because no extra blood will be collected. There is a small privacy risk whenever samples and information are stored, but this risk will be reduced through coding, secure storage, restricted access, and ethical review of future projects.

You are unlikely to receive any direct personal benefit from allowing your samples to be used for future research. However, the samples may help researchers better understand how diet affects health and may contribute to future nutrition and health research.

Results from future research will not be returned to you. Before 30 August 2027, future research results are unlikely to have a clear or clinically useful meaning. After 30 August 2027, the file linking your personal details to the study code will be destroyed, so it will no longer be possible to identify which results came from your samples.

Will I receive payment or have ownership of future discoveries?

You will not receive additional payment for allowing your samples to be stored. You will not own intellectual property or receive financial benefits arising from future research using the samples. Any future use will be for approved research purposes.

Can I change my mind later?

Yes. You may withdraw your consent for future use of your remaining samples at any time before 30 August 2027 by contacting the research team. If you withdraw before this date, any remaining samples that can still be linked to you will be destroyed and will not be used in any new research. You may request that a karakia is said before your samples are disposed of.

It may not be possible to retrieve samples or remove information that has already been used in an analysis or transferred to an approved research project before your withdrawal request is received.

After 30 August 2027, the file linking your personal details to your study code will be destroyed and your samples will be permanently de-identified. After this date, it will no longer be possible to identify or destroy your individual samples or remove results produced from them.

How do I give consent?

If you agree, you will complete a separate consent form. The consent form will also ask whether you agree to your coded samples be analysed. You can choose not to agree to future storage and still take part in the main study.

Any questions?

If you have questions now or in the future, please contact one of the research team members below:

Professor Sheila Skeaff Principal Investigator Department of Human Nutrition	Contact: +64 3 479 7944
Associate Professor Andrew Reynolds Co-principal Investigator Department of Medicine	Contact: +64 27 956 5826
Aaron Hao Student Investigator (PhD student) Department of Human Nutrition	Contact: +64 28 8518 4352

This study has been approved by the University of Otago Human Ethics Committee (Health) - Te Pae Matatika Tangata (Hauora), Ōtākou Whakaihu Waka. If you have concerns about the ethical conduct of the research, you may contact the Human Ethics Committee Administrator (phone +64 3 479 8256 or email humanethics@otago.ac.nz). Any issues you raise will be treated in confidence, investigated, and you will be informed of the outcome.