DATA AND TISSUE MANAGEMENT PLAN

Version: 1

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Protocol: A flourishing biome for gut health – Promoting a diverse microbiome through bread
BREAD STUDY

Site: University of Otago, Christchuch

Co-ordinating Investigator: Dr. Simone Bayer

CONTENTS

1 INTRODUCTION

This Data and Tissue Management Guide outlines how data and tissue will be handled during the study (BREAD) and after its completion.

2 STUDY STRUCTURE

The Sponsor is responsible for supervising any and all outsourced activities.

TABLE 1. STUDY STRUCTURE

Sponsor	University of Otago, Dr Martin Gagnon, Director, Research and Enterprise, Department: Research and Enterprise, Centre for Innovation, 87 St David Street, Dunedin research@otago.ac.nz
Lead Site (New Zealand)	University of Otago, Christchurch.
Principal Investigator	**Prof. Richard Gearry,** Head of Department Department of Medicine, University of Otago, Christchurch Riccarton Avenue Christchurch Central Christchurch 8011. **Prof. Nicole Roy,** Department of Human Nutrition, University of Otago, Dunedin.
Study Coordinator	Dr Simone Bayer, Department of Medicine, Gastrointestinal Unit for Translational Studies, University of Otago, Christchurch Tel: +64 3 364 1790, Email: Simone.Bayer@otago.ac.nz
New Zealand Laboratory(ies)	1) The University of Otago, Christchurch 2) Canterbury District Health Laboratories (Hagley Avenue, Addington, Christchurch 8011) 3) AgResearch (1365 Springs Road, Lincoln 7674) 4) Riddet Institute (University Avenue, Fitzherbert, Palmerston North 4474 5) Plant & Food Research (Gerald St, Lincoln 7608)
Overseas Laboratory(ies)	6) Teagasc (Agriculture and Food Development Authority), Oak Park, Carlow R93 XE12, Ireland (sequencing) 7) Atmo Bioscience, 436, Elgar Rd, Box Hill Victoria, Australia.

3 ORGANISATIONAL DATA GOVERNANCE OVERSIGHT

The following institutional data policies apply for the Study:

- National Ethical Standards: Health Data (https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health)
- Responsible Practice in Research -Code of Conduct (University of Otago): https://www.otago.ac.nz/administration/policies/otago003211.html
- Allegations of Misconduct in Research Procedures (University of Otago): https://www.otago.ac.nz/administration/policies/OTAGO028903.html
- Research Consultation with Māori Policy (University of Otago): https://www.otago.ac.nz/administration/policies/otago003272.html

4 CONSENT FOR DATA AND TISSUE COLLECTION AND USE

All participants will be informed of, and provide consent for, the collection and use of their data for the purposes of this study, and for any mandatory secondary uses.

5 DATA AND TISSUE COLLECTION

Data will be collected from the following sources:

- Direct communication with the participant
- Study assessments, including laboratory test results, imaging, biomedical monitoring, questionnaires, interviews, and data downloaded from apps

Tissue will be collected as follows: Type of tissue samples, e.g., blood and faecal samples will be collected from the participant during the study.

Data and tissue will be collected primarily by the Investigator or designated study staff. All study personnel involved in data and tissue collection will be trained in GCP, study protocol, and collection requirements.

Collection of data and tissue will be limited to that necessary for the specified purposes of the study, or for additional purposes that the participant has explicitly consented to.

6 PRIVACY AND CONFIDENTIALITY

Participants' privacy and confidentiality will be respected through the protection of their data and tissue as outlined in this plan. The investigator will comply with legal and regulatory requirements regarding the privacy and confidentiality of participants' data and tissue.

Participants have the right to access and correct personal data held by the site. This includes screening and safety results. Other results may be available on request and will not result in the participant being withdrawn from the study.

Breach of Privacy / Confidentiality

A breach of privacy means unauthorised or accidental access to, or disclosure, alteration, loss, or destruction of a participant's information.

In the event of a participant privacy and confidentiality breach during the study, the following steps will be taken:

- Action will be taken to reduce the risk of harm following the breach. Where possible, the recipient will be contacted and asked to destroy or return any electronic disclosed material.
- The participant will be informed of the breach as soon as practicable and provided with support as required, except for when the participant is under the age of 16 and notification would be contrary to his/her interests; or when notification would be likely to prejudice the health of the participant (after consultation with the participant's health practitioner, where practicable).
- In accordance with the University of Otago disciplinary and research misconduct processes, a quality review will be conducted to ascertain factors contributing to the breach, and any corrective action required to prevent future breaches.
- The approving University of Otago Human Ethics Committee will be informed.
- For notifiable privacy breaches of privacy under the Privacy Act 2020, the New Zealand Privacy Commissioner will be notified in accordance with that Act.

7 Forms of Data and Tissue

Identifiable Data and Tissue

Some study data will be collected in identifiable form to allow the research team to link participants with unique study codes and to allow provision of individual study results. Identifying data will be kept on a separate excel file. National Health Index numbers will not be collected, however personal information (name, date of birth, gender, ethnicity, contact details) of all participants will be collected.

Source documents refer to identifiable data collected for the purposes of this study. Source documents include screening questionnaire, consent form and demographics, as detailed in the study protocol.

All data will be stored on password protected files, backed up to University of Otago servers and stored on computers on locked premises.

De-identified Data and Tissue

De-identified data and tissue in this study includes but is not limited to:

- Tissue samples i.e., blood and faeces
- Self-reported study questionnaire
- Safety and screening results as entered to the analysis data set.
- Communications from the site to the CRO, Sponsor, imaging vendor or [New Zealand/ overseas] laboratory.
- Data generated by the food diary
- Data generated by the [New Zealand/ overseas] laboratory.

- Data downloaded from Atmo Cloud app.
- Data downloaded from bowel health app.
- Data downloaded from bread diary app.
- Data generated from personal communication with the participants.

De-identified tissue and data will carry the participant's unique study code. The investigator will retain a log linking participant code with identifiers. This log will not be made available other collaborators and co-investigators including the New Zealand laboratory, imaging vendor, CRO or Sponsor.

All data and/or tissue sent to the New Zealand laboratory, central imaging vendor, CRO and Sponsor will be de-identified. All data generated by these parties will be in de-identified form. No attempt will be made to re-identify participants.

Anonymous / Anonymised Data [and/or Tissue].

Not applicable

8 Access to and Use of Data and Tissue

Collected data and tissue will be used to answer the research questions and fulfil the study requirements described in the study protocol, and for the secondary purposes outlined in Sections 8.5 and 8.6.

Identifiable Data and Tissue

Identifiable data and/or tissue may be accessed by the following groups:

- The investigator and designated study staff, to fulfil protocol requirements.
- Study monitor(s), for eligibility confirmation and source data verification purposes.
- The sponsor for audit purposes.
- The sponsor and its authorised representatives, in the event of a compensation claim by a participant.
- The Health and Disability Ethics Committee, for legal and regulatory purposes.
- Health, regulatory, or government agencies, for legal and regulatory purposes.

Rarely, it may be necessary for the investigator to share identifiable data with people or groups not listed above – for example, in the event of a serious threat to public health or safety, or to the life or health of the participant or another person; or if the data is required for certain legal situations.

De-identified Data and Tissue

De-identified data and tissue will be accessed and used by the following groups:

- The investigator and suitably trained and experienced study staff, to conduct the study.
- Sponsor / CRO study monitor(s), for source data verification purposes.
- The New Zealand laboratories, for sample processing, analysis, and reporting purposes.
- The imaging vendor, for analysis and reporting purposes.

- Third parties working with or for the sponsor, including the sponsor's subsidiaries and affiliates and third-party researchers, may also have access for these purposes.
- The Health and Disability Ethics Committee, to comply with legal and regulatory duties.
- Health, regulatory, or government authorities, to comply with legal and regulatory duties.

De-identified tissue will be used for analyses as described in the protocol [and laboratory manual].

De-identified data may be included in published study results including, but not limited to, peer-reviewed publications, clinical trial registry websites, scientific meetings, and regulatory/ marketing submissions.

De-identified data may be included in clinical trial registries.

[ANONYMOUS/ANONYMISED] DATA [AND/OR TISSUE]

Not applicable

SENDING OF DATA AND TISSUE OVERSEAS

De-identified data will be sent overseas to the United Kingdom and Australia. De-identified tissue samples (faecal) will be sent overseas to Ireland.

Participants will be informed of the potential risks and cultural issues associated with sending and storing data overseas, and that there may be no New Zealand representation on overseas governance committees.

FUTURE USE OF DATA AND/OR TISSUE

De-identified data will be used by the sponsor for future medical or scientific research as specified below:

- unspecified purposes which are related directly to the study question(s)
- unspecified purposes which are related to the item and/or condition under study

If participants provide optional additional consent, de-identified data will be made available to other researchers on request for future research as specified above and/ or will be added to data from other sources to form larger datasets.

In all cases, the sponsor must be satisfied that appropriate Data Management Plans are in place and that ethical approval for use has been obtained in accordance with local laws and regulations.

COMMERCIAL USE OF DATA AND/OR TISSUE

Study data analysis may lead to discoveries/ inventions or development of a commercial product or benefits to the producers. The rights to these will belong to the sponsor. Participants will not receive any financial benefits or compensation from, nor have any rights to, any developments, inventions, or other discoveries arising from this analysis.

DATA LINKING

Not applicable

9 STORAGE AND DESTRUCTION OF DATA

9.1 IDENTIFIABLE DATA AND SOURCE DOCUMENTS

During the study, study-specific source documents will be maintained and kept on paper, Microsoft word or excel spreadsheets during the study, either in locked filing cabinets in locked rooms or as password protected Otago OneDrive files on computers in locked rooms.

Post-study, study-specific source documents will be archived on Department of Medicine, University of Otago, Christchurch premises or on password protected OneDrive files of the study coordinator.

All raw data collected in hard copy will be held for 10 years in locked cabinets on locked premises of the University of Otago. Electronic files will also be retained for 10 years on a secure storage space provided by the University of Otago, as per the University of Otago Policy on the Responsible Practice in Research Code of Conduct.

De-identified tissue samples will be stored until publication of the results, but not longer than 10 years. The samples will be stored in secure facilities with restricted access.

9.2 DE-IDENTIFIED DATA

Identifiable data will be converted to a de-identified form at the study site, at which point it is entered into a secure data platform. The data platform complies with international and national regulatory requirements for electronic data capture systems in the countries where it is used. Data entry will be limited to designated study staff trained and experienced in transcribing data for this purpose.

De-identified data will carry a participant ID code. The investigator will retain a log linking participant ID codes with identifiers. This log will not be made available to overseas co-investigators or the sponsor.

10 STORAGE AND DESTRUCTION OF TISSUE

10.1 NEW ZEALAND LABORATORY(IES)

Named laboratories (Canterbury District Health Laboratories, AgResearch, Riddet Institute, Plant and Food Research) are responsible for the storage, testing/analysis, and destruction of the tissue samples described in section 7.1 and 7.2.

Tissue samples will be labelled as detailed in Section 6.

Tissue samples will be transported to the laboratory as per the study protocol. Chain of custody will be recorded.

All laboratories are Good Laboratory Practice (GLP) compliant. The facilities are secure with tissue access restricted to those staff directly involved in their analysis.

10.2 Overseas Laboratory(ies)

10.2.1 Tissue Samples – Mandatory Research

Mandatory tissue samples will be labelled as detailed in Section 6.

The samples, as described in Section 7.2, will be sent in the care of specialised courier companies in compliance with IATA guidance, to the overseas laboratories for the tests/analyses as described in the protocol.

All laboratories where samples are stored or processed follow GLP principles and are appropriately accredited with the relevant body of the country in which they are located. Laboratory facilities are secure, with tissue access restricted to those staff directly involved in their analysis.

The following laboratory(ies) will be utilised for the current study:

- Teagasc (Agriculture and Food Development Authority), Oak Park, Carlow R93 XE12 Ireland. Processed stool samples will be sent for stool microbiome analysis (DNA and RNA sequencing).
- Tissue samples will be retained for analysis, during which the sample is destroyed.

Tissue use is restricted to the mandatory uses specified in the study protocol.

11 Consultation

No formal consultation regarding data management will be undertaken within the community. However, the research team includes people from diverse backgrounds and experiences. All the data management strategies will be discussed and agreed by the research team. The research team meets weekly to raise any issues and concerns with the project. If need arises for formal data management input, the research team will seek advice of the professional Data Management team within the University of Otago.

Māori Data and Tissue Sovereignty

During the study, data and tissue may be collected from participants identifying as Māori. Taking of tissue is a major cultural issue for Māori as it is linked to whakapapa and continuation of Māori as a nation. For some Māori, tissue is considered tapu and imbued with wairua.

Options for karakia will be discussed with participants during the informed consent process.

Personal and health information is a taonga (treasure) and will be treated accordingly.

Formal Māori health Advancement Review for this study will be completed as part of the Locality Approval Process for New Zealand studies. Any recommendations for additional measures to improve Māori rights and interests in relation to data and tissue will be acted upon.

12 Return of Results

Screening and safety results will be provided to participants on request.

Participants have the right to request a lay summary of study results.

Incidental Findings

In the event of a study assessment returning a result of potential clinical significance, the participant will be informed. The participant's usual doctor and/ or an appropriate specialist will be notified, and follow-up will be arranged.

Results Arising from Future Research

Data

Results will not be made available to participants of any future research conducted using data collected in this study. Participants are informed of this in the PISCF.

Databank / Registry /Biobank submission

Not applicable

13 Withdrawal of Data and/or Tissue

Participants may withdraw consent for the collection of data at any time, without providing a reason. Should a participant withdraw consent, no further data will be collected by study staff. Data collected prior to the participant's withdrawal will continue to be used and analysed.