**DATA AND TISSUE MANAGEMENT PLAN**

**Version: 1.25**

**Date: 26/12/21**

**Protocol: Effect of Carbohydrate Energy Replacement on Glycaemic Control Following High-Intensity Interval Training. Does Lactose Improve Glycaemic Control in Comparison to Sucrose?**

**Sponsor: Massey University Research Funding**

**Site: School of Sport, Exercise and Nutrition, Massey University, Albany**

**Co-ordinating Investigator: Dr David Rowlands and Miss Rose Stirling**

1. **Introduction**

This Data and Tissue Management Guide outlines how data will be handled during the study- High-Intensity Exercise Benefits to Blood Glucose Control – Is the Milk-Sugar Lactose better than Sucrose and after its completion.

1. **Study Structure**

**TABLE 1. STUDY STRUCTURE**

|  |  |
| --- | --- |
| Sponsor  | School of Sport, Exercise and Nutrition  (Funding) Massey University Research Funding (MURF)    |
|   |   |
| Contract Research Organisation  | School of Sport, Exercise and Nutrition, Massey University  Massey University East Precinct Albany Expressway, SH17 Auckland 0632  |
| Contact Person   | Andy Foskett – Head of School  a.foskett@massey.ac.nz  |
|   |   |

1. **Consent for Data and Tissue Collection and Use**

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

1. **Data and Tissue Collection**

Data will be collected from the following sources:

* Direct communication with the participant
* Study assessments, including laboratory test results and a questionnaire

Tissue will be collected as follows:

* Venous blood sample 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.

1. **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. Other results may be available on request, and will not result in the participant being withdrawn from the study.

1. **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 participant privacy and confidentiality is breached 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 (unless the participant is under the age of 16 and notification would be contrary to his/her interests; or notification would be likely to prejudice the health of the participant (after consultation with the participant’s health practitioner, where practicable), and provided with support as required.
* The approving HDEC 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.
1. **Forms of Data and Tissue**
2. **Identifiable Data  and tissue**

Study data and tissue will be collected in identifiable form which only Miss Rose Stirling, Dr David Rowlands, Dr Claire Badenhorst and Dr Wendy O’Brien have access to.

Source documents refer to identifiable data and tissue collected for the purposes of this study.

All information will be stored in password protected files and computers with access only by the researchers on the project.

1. **De-identified Data and tissue**

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

* Screening  results: Age, gender, BMI, VO2 max, activity level, COVID-19 results / symptoms.
* Testing results: Glycaemic response following ingestion of lactose, sucrose and placebo beverages.

To make sure your personal information is kept confidential, information that identifies the participant will not be included in any report generated by Drs David Rowlands, Wendy O’Brien and Claire Badenhorst and masters student, Miss Rose Stirling (researchers). Participants will be identified by a code only, with a master code file linked to participant stored in password protected files and computers with access only by the researchers on the project.

1. **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 7.4 and 7.5.

1. **Identifiable Data and tissue**

Identifiable data comprises of the participant's name, date of birth, contact details, address, GP, emergency contacts and any other relevant information which may distinguish the participant.

Identifiable data may be accessed by the following groups:

* The Investigator and designated study staff, to fulfil protocol requirements; Miss Rose Stirling, Dr David Rowlands, Dr Claire Badenhorst, Dr Wendy O’Brien.
* Auditors of Health and Disability Ethics Commitee (HDEC) and regulatory bodies for audit purposes.
1. **De-identified Data and Tissue**

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

* The Investigator and suitably trained and experienced study staff, to conduct the study; Miss Rose Stirling, Dr David Rowlands, Dr Claire Badenhorst, Dr Wendy O’Brien.

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 tissue will be used for analyses as described in the protocol.

De-identified data may be included in clinical trial registries and data banks (refer to Section 8.7).

1. **Future Use of Data and Tissue**

Pending participant consent, coded information may be used for future research related to lactose or other metabolic or nutrition studies.

1. **storage and Destruction of Data**
2. **Identifiable Data and Source Documents**

During the study, study-specific source documents will be maintained. Health Screening Questionnaire will be stored in locked filing cabinet in the laboratory during the duration of the study. Following data collection it will be moved into secure storage.

The only identifiable data will be in Health Screening Questionnaire and an Excel spreadsheet title Participant Details, which will contain the participant code.

Identifiable information is held at exercise science laboratory at Massey University, Albany Campus during the study. After the study, it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Your coded information will be entered into electronic spreadsheets and stored in a secure sever and kept by the researchers indefinitely. All storage will comply with local and/or international data security guidelines.

1. **De-identified Data**

Study deidentified data will be recorded on datasheets and transferred to Excel worksheets and SAS datasets for storage and processing.

Data entry will be limited to designated study staff trained and experienced in transcribing data for this purpose.

The spreadsheets and stored in a secure sever and kept by the researchers indefinitely. All storage will comply with local and/or international data security guidelines.

1. **Storage and Destruction of Tissue**
	1. **New Zealand Laboratory**

School of Sport, Exercise and Nutrition, Massey University, Albany is responsible for the storage, testing/analysis, and destruction of the tissue samples described in sections 6.1 and 6.2.

Tissue samples will be labelled as detailed in Section 6.

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

Tissue samples will be retained for up to 3 years then destroyed by biohazard disposal or returned to the participant on request.

1. **Consultation**

Consultation regarding data and tissue management is outlined in the participant information sheet in which the participant consents to understanding and agreeing with when signing the consent form.

1. **Māori Data and Tissue Sovereignty**

During the study, data and tissue may be collected from participants identifying as Maori. 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 & imbued with wairua.

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

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

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

1. **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.

1. **Incidental Findings**

In the event that a study assessment returns 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.

1. **Results Arising from Future Research**
2. **Data**

Participants will not be told when future research is undertaken using the study (de-identified) information. De-identified data may be shared with other researchers or companies. Information may also be added to information from other studies, to form much larger sets of data.

Information may be used indefinitely for future research unless participant consent is withdrawn. It may be extremely difficult or impossible to access individual participant information, or withdraw consent for its use, once information has been shared for future research.

### Tissue

No future unspecified research is planned for tissue collected in this study.

**Withdrawal of Data and 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 and tissue will be collected by study staff.

Data collected prior to the participant’s withdrawal will continue to be used and analysed, depending on the stage of withdrawal. If enough data has been collected then data will still be used if not enough this data will be discarded.

Tissue collected prior to the participant’s withdrawal will continue to be used and analysed for the purposes of the study.