**DATA AND TISSUE MANAGEMENT PLAN**

**Version: [version number]**

 **Date: [version date]**

**Protocol [Insert Formal Protocol Title & Protocol Number]**

**Sponsor:** **[If applicable - Sponsor name]**

**Site [Insert study site(s)]**

**Co-ordinating Investigator [name]**

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**Note to researchers**

This data and tissue management guide is a template only. Not all sections may be applicable to all studies. If a section is not applicable to your study, please simply write ‘not applicable’ under the section heading, delete the templated text, and move on to the next section.

In some studies, greater detail may be required. Researchers should add further information if this is indicated. For guidance, refer to Chapters 12, 13 and 14 of the National Ethical Standards for Health and Disability Research and Quality Improvement (2019).

For return of results, researchers are directed to Standards 11.45 – 11.49 for general guidance about return of results and incidental findings; Standards 14.23 – 14.26 (in relation to incidental findings arising from tissue) and Standards 14.37 – 14.41 (in relation to incidental genetic results).

Researchers must also comply with other data and tissue legislation, regulations, and codes.

For data, these include: The Privacy Act 2020 and The Health Information Privacy Code 1994, The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, HISO 10029:2015 Health Information Security Framework, HISO 10064:2017 Health Information Governance Guidelines, and Digital and Data Technology Services (2020).

For tissue, these include: The Human Tissue Act 2008, the Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes (Ministry of Health. 2007) and Standards for the collection of human tissue for non-therapeutic purposes (eg, NZS 8135:2009).

# Introduction

This Data and Tissue Management Guide outlines how data and tissue will be handled during the study ([Insert study title or protocol number]) and after its completion.

# Study Structure

*Add if appropriate:* The Sponsor will enlist the support of the named Contract Research Organisation (CRO) to co-ordinate the Study. The Sponsor is responsible for supervising any and all outsourced activities.

**TABLE 1. STUDY STRUCTURE** *Add, modify, or delete as appropriate:*

|  |  |
| --- | --- |
| Sponsor | [name] |
|  | [address] |
| Contract Research Organisation | [name] |
|  | [address] |
| Lead Site (New Zealand) | [name] |
|  | [address] |
| Co-ordinating Investigator | [name] |
|  | [address] |
| New Zealand Laboratory(ies) | [name][address] |
| Overseas Laboratory(ies) | [address] |
|  | [address] |
| Imaging Vendor | [address] |
|  | [address] |

# Organisational Data Governance Oversight

The following institutional data policies apply for the Study:

* *Enter the data policies applicable to your study*

# 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.

*Add if applicable:* Additional written consent will be sought for optional secondary uses of data [and tissue].

*OR*

*Non-Consenting:* A waiver of consent has been granted by the approving HDEC for the study [insert HDEC number]. Participants will therefore not be informed of, or consent to, the collection and use of their data and tissue for the purposes of the study *Add if applicable*, or for secondary uses.

*OR*

*Opt-Out Consent:* All participants will be informed of the collection and use of their data and tissue for the purposes of the study. Explicit consent will not be obtained; however, participants will be given the opportunity to refuse to allow the collection and use of their data and tissue (‘opt out’ consent). This approach has been agreed to by the approving HDEC for the study [insert HDEC number].

# Data and Tissue Collection

Data will be collected from the following sources: *Add, modify, or delete as appropriate:*

* Direct communication with the participant
* Study assessments, including laboratory test results, imaging, biomedical monitoring, questionnaires, interviews, and data downloaded from apps
* Participant medical records (if indicated)
* Communications with participant’s clinical care team (if indicated).
* The [Databank / Registry name] Databank / Registry

Tissue will be collected as follows: *Add, modify, or delete as appropriate:*

* [Type of tissue samples, e.g., blood, urine, bone marrow, cerebrospinal fluid, tumour] samples will be collected from the participant during the study.
* Existing stored [type of tissue] samples from the participant
* The [Biobank Name] Biobank

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.

*Add if applicable:* [data generating assessment/procedure [or tissue collection procedure] will be performed by external third parties suitably qualified by education, training, and experience.

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.

# 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. *Add if applicable:* Other results may be available on request, and [will/will not/may] 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 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 the 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.
* *(add, modify, or delete as appropriate)* A site and/or CRO and/or Sponsor (as appropriate) quality review will be conducted to ascertain factors contributing to the breach, and any corrective action required to prevent future breaches.
* 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.

# Forms of Data and Tissue

## Identifiable Data and Tissue

[Some] Study data [and tissue] will be collected in identifiable form.

Source documents refer to identifiable data collected for the purposes of this study. *Add if applicable:* For the purposes of this data management plan, identifiable data includes the participant’s existing medical / clinical records.

Source documents will be held at the site in identifiable form.

*Add if applicable:* [Some] Screening and safety tissue samples (and their results) will be labelled with identifiers. Results will be held in source, to optimise participant safety.

## De-identified Data and Tissue

De-identified data and tissue in this study includes but is not limited to *(Add, modify, or delete as appropriate)*:

* Tissue samples and requisition forms not included in Section 6.1.
* Case Report Forms.
* Safety and screening results entered into the analysis data set.
* Communications from the site to the CRO, Sponsor, imaging vendor or [New Zealand / overseas] laboratory.
* Data generated by the [New Zealand / overseas] laboratory.
* Data sent to and generated by the imaging vendor.

De-identified tissue and data will carry the participant’s unique study code [or state how de-identified data and tissue will be labelled]. The Investigator will retain a log linking participant code with identifiers. This log will not be made available to *(add, modify, or delete as appropriate)* the [New Zealand / overseas] laboratory, imaging vendor, CRO or Sponsor.

All data and/or tissue sent to *(add, modify, or delete as appropriate)* the [New Zealand / overseas] 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].

*Add if applicable:* Data [and tissue] will be collected anonymously, i.e., it will not contain any identifiers. *Add if applicable:* The signed consent form and contact information (if provided) will not be linked in any way to data [and tissue] collected for study purposes.

*OR*

De-identified data [and tissue] may be anonymised prior to being made available for future research (see Section 7.2.1). Anonymised data and tissue will be irreversibly stripped of the unique participant code and any other identifiers.

*Add if applicable:* Tissue may be added to or mixed with other tissue samples, rendering it non-identifiable.

Participants will be informed that anonymous / anonymised data [and tissue] is unable to be accessed, corrected, or withdrawn; and that return of individual results will not be possible.

# 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.

## Identifiable Data and Tissue

Identifiable data and/or tissue may be accessed by the following groups: *Add, modify, or delete as appropriate:*

* The Investigator and designated study staff, to fulfil protocol requirements.
* Local laboratory staff, to process, analyse and report [insert type of samples] samples.
* Local radiology staff, to process, analyse and report images.
* Study monitor(s), for eligibility confirmation and source data verification purposes.
* The Sponsor and CRO, 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.
* The participant’s GP or appropriate specialist, to inform them of study participation, and in the event of an incidental finding of potential clinical significance.
* The Medical Office of Health, in the event of a positive result for a notifiable disease.

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.

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

## De-identified Data and Tissue

De-identified data and tissue will be accessed and used by the following groups: *Add, modify, or delete as appropriate:*

* 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 / overseas] laboratory, for sample processing, analysis, and reporting purposes.
* The imaging vendor, for analysis and reporting purposes.
* The CRO and Sponsor, for study conduct, data analysis and pharmacovigilance purposes, product registration and marketing, or as otherwise permitted by applicable local and international laws and regulations. *Add if applicable:* 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.

*Add if applicable:* The [New Zealand / overseas] laboratory and / or imaging vendor will not be authorised to share data and/or tissue with third parties unless explicitly directed to do so by the Sponsor.

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.

*Add if applicable:* De-identified data [may / will] be included in clinical trial registries and data banks (refer to Section 8.7).

*Add if applicable:* De-identified tissue [may / will] be included in biobanks (refer to Section 8.7).

## [Anonymous/Anonymised] Data [and/or Tissue]

*Add if applicable:* [Anonymous/Anonymised] data [and/or tissue] may be accessed and used by the groups described in Section 8.2.

*Add if applicable:*  Anonymised data [and/or tissue] may also be made available to other researchers, as described in Section 8.5.

## Sending of Data and Tissue Overseas

*Add if applicable:* [Identifiable / de-identified / anonymised] data will be sent overseas to [state main countries].

[Identifiable / de-identified / anonymised] tissue [describe type] will be sent overseas (see Section 2 for details) for analysis [and storage].

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

## Future Use of Data and/or Tissue

*Add if applicable:* De-identified [and/or anonymised] data [and tissue] will be used by the Sponsor for future medical or scientific research as specified below: *select as appropriate:*

* unspecified purposes which are directly related to the study question(s)
* unspecified purposes which are related to the item and/or condition under study
* unspecified medical or scientific purposes which are not related to the study questions
* other unspecified research

*Add if appropriate:* [If participants provide optional additional consent] De-identified [and/or anonymised] data [and tissue] 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 [and Tissue] 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

*Add if applicable:* Study data [and tissue] analysis may lead to discoveries and inventions or development of a commercial product or producers. The rights to these will belong to the Sponsor *(amend as appropriate).* Participants [will / 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

*Add if applicable:* The study will link data obtained from [describe the data sets that will be linked]. This data linking is [mandatory / optional] for participants.

*Provide details of planned data linking:*

* *The method of linking (e.g. deterministic or probabilistic)*
* *What variables will be used for linking*
* *Who is undertaking the linking and who is accountable for it*
* *How participants’ privacy will be protected including any risks of re-identification or inference risks*
* *How any participant conditions concerning data-linking will be respected.*
* *How any bias will be considered and mitigated*
* *Who will have access to the linked data and for what purpose*
* *Security measures including how the confidentiality of the link between collected data and personal identifiers will be maintained*
* *How the linked data will be stored including an accounting of the risks of storage and plans to mitigate the risks*
* *How the linked data will be destroyed, or the rational for archiving it and whether it will be accessible for future research and if so how*

## Databank / Registry and/or Biobank

*Add if applicable:* [Identifiable / de-identified / anonymised] data [and [ Identifiable / de-identified / anonymised] tissue] collected in the study will be submitted to [Data Bank/Registry/Biobank name and address]. This [Databank / Registry/Biobank] submission is [mandatory / optional] for participants.

*Provide details of the Databank / Registry/Biobank:*

* *Purpose*
* *Type of research for which submitted data [and tissue] will be used, for example, for future specified or future unspecified research and including whether genetic testing may be carried out*
* *Any restrictions to types of research permitted using the Databank / Registry/Biobank*
* *How any restrictions participants place on future use of data [and tissue] submitted to the Databank/Rregistry/Biobank will be respected and how that will be audited*
* *How participants’ privacy and rights will be protected*
* *The rules of access to the data [and tissue] held in the Databank / Registry / Biobank including who will have access to it and the purpose of that access*
* *Procedures for how participants may withdraw consent, and the circumstances in which it is not possible to withdraw consent*
* *Procedures for how participants may request corrections and omissions to their data and how enquiries and complaints will be received and addressed*
* *Procedures for returning results, including incidental findings and how participants will be re-contacted*
* *How participants will be kept informed of research outcomes, if at all*
* *Who is responsible for governance and whether there is any New Zealand representation*
* *Who is accountable for unauthorised access to, or inappropriate or unauthorised use of, participants’ data [and tissue] and how privacy breaches will be reported*
* *What happens if the Databank/Registry/Biobank changes ownership or closes and how data [and tissue] will be dealt with including transfer or disposal*
* *Procedures for participatory engagement with patient groups or the wider community, if any*
* *How the operations of the Databank/Registry/Biobank will be made transparent*
* *Security Measures*
* *Storage details (site / duration/destruction)*
1. **storage and Destruction of Data**
	1. **Identifiable Data and Source Documents**

During the study, study-specific source documents will be maintained [state location where source documents will be stored during the study – eg, locked file cabinets in locked rooms, password protected databases located on computers in locked rooms, password protected databases via password protected computers].

Post-study, study-specific source documents will be archived [state location where source documents will be stored long-term]. *Add if applicable:* The maintenance and archiving of source documents are described in [give titles of applicable Standard Operating Procedures or documents].

Source documents will be retained for at least [duration], then destroyed by [state destruction method].

*Add if applicable:* The following forms of data will be retained by [state who will store applicable data, e.g. imaging data] and will form part of the participant’s clinical record. These documents will not be archived or destroyed as described above:

* *[add as appropriate]*
	1. **De-identified Data**

Identifiable data will be converted to a de-identified form at the study site, at which point it is entered into [state where de-identified data is entered and its security (e.g. ‘electronic case report forms using 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.

*Add if applicable:* De-identified data generated by the [New Zealand / overseas] laboratory will be entered into [state where de-identified lab data is entered and its security].

*Add if applicable:* Study imaging data will be transferred to the imaging vendor using [state imaging system name and summarise security].

De-identified data will carry [state how de-identified data will be labelled]. The Investigator will retain a log linking participant code with identifiers. This log will not be made available to *(add, modify, or delete as appropriate)* the [New Zealand / overseas] laboratory, imaging vendor, CRO or Sponsor.

*Add if applicable:* The de-identified database will remain on [insert platform name] servers for up to approximately [insert duration].

De-identified data is stored long-term by the Sponsor in [state where data will be stored long-term, e.g. ‘in secure cloud-based servers’].

De-identified data will be retained for [state retention time].

1. **Storage and Destruction of Tissue**
	1. **New Zealand Laboratory(ies)**

[Laboratory name] is 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 by [state how samples are transported]. Chain of custody is recorded *(add or modify if required).*

The laboratory is Good Laboratory Practice (GLP) compliant *(ensure this information is verified).* The facilities are secure with tissue access restricted to those staff directly involved in their analysis *(add or modify as required).*

Tissue samples will be retained for up to [state duration], then destroyed by [state method of destruction]. *Add if applicable:* or returned to the participant on request.

* 1. **Overseas Laboratory(ies)**
		1. **Tissue Samples – Mandatory Research**

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

The samples, as described in Section 7.3, 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 (ensure this information is verified). Laboratory facilities are secure, with tissue access restricted to those staff directly involved in their analysis (add or modify as required).

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

* *Provide name of (each) laboratory, and type of tissue samples handled*

Tissue samples will be retained for up to [state duration], then destroyed by [state method of destruction]. *Add if applicable:* or returned to the participant on request.

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

* + 1. **Tissue Samples – Optional Research**

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

Where the participant has consented to optional research, [left-over samples] and / or [tissue samples] will be transferred to the following laboratory(ies):

* *Provide name of (each) laboratory, and type of tissue samples handled*

*Add if applicable:* Where participants have provided explicit consent, tissue samples may be shared with other researchers or companies at unspecified laboratories, as detailed in a PISCF. For this to occur, the Sponsor must be satisfied that appropriate Tissue Management Plans are in place and that ethical approval for use has been obtained in accordance with local laws and regulations.

Tissue samples will be retained for up to [state duration], then destroyed by [state method of destruction].

Tissue use is restricted to those uses specified in the applicable optional PISCF document(s).

# Consultation

Consultation regarding data [and tissue] management will be undertaken with the following relevant communities/stakeholders [describe].

*If consultation will not be undertaken with relevant communities/stakeholders, explain why.*

## 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(s). Any recommendations for additional measures to improve Māori rights and interests in relation to data [and tissue] will be acted upon.

*Add if applicable:* The principles of whakapapa, whanaungatanga, rangatiratanga, kotahitanga, manaakitanga, and kaitiakitanga are applied in the following ways:

*State how these principles are recognised / respected / actioned for the current study.*

# 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.

*If data is collected anonymously, replace the above text with:* As data is collected anonymously, or has been anonymised, participants are unable to receive results of their individual study assessments. A lay summary of study results will be available [state where lay results will be made available].

## 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.

*Add if applicable:* Analyses may provide an individual result that is clinically significant but not clinically actionable. Participants are informed of this possibility in the PISCF, and will be notified in accordance with the protocol and the participant’s stated wishes in the PISCF.

*Add if applicable:* In the event a study assessment returns a genetic result of potential significance to the participant or his / her family, the participant will be notified in accordance with the protocol and the participant’s stated wishes in the PISCF.

## Results Arising from Future Research

### Data

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

*OR* Results [will/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.

### Tissue

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

*OR* Participants [will/will not] be provided with the results of optional (*add, modify, or delete as appropriate)* [pharmacogenomic/genetic/biomarker/future related/future unspecified] research conducted on tissue collected in this study. Participants are informed of this in a PISCF.

### Databank / Registry /Biobank submission

For return of results from data [and tissue] submitted to Data Banks, Registries/Biobanks, refer to Section 7.4.

# 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 and/or tissue will be collected by study staff.

Data collected prior to the participant’s withdrawal [will/will not] continue to be used and analysed. *(modify this statement as appropriate).*

Tissue collected prior to the participant’s withdrawal [will/will not] continue to be used and analysed for the purposes of the study *(modify this statement as appropriate).*

*Add if applicable:* Tissue collected and/or stored for future research will be destroyed provided it his still able to be traced.

*Add if applicable:* For withdrawal of data [and tissue] submitted to Data Banks, Registries/Biobanks, refer to Section 7.7.

**AppendiX**

*Append any data-sharing agreements as appendices to this document.*