



## DATA MANAGEMENT PLAN (Low-Risk)

Starship Child Health – Te Toka Tumai Auckland

Template available from: <https://starship.org.nz/health-professionals/research-study-templates>

<b>1. Project</b>	
a. Project title	
b. Protocol Number	
c. Ethics Number	
d. PI Name(s)	
e. DMP Author Name	
f. Service / Directorate	
g. Global Project Sponsor	
h. NZ CRO	
i. Project start & end dates	DD/MM/YYYY - DD/MM/YYYY (or ongoing)
j. Project description	
k. Related policies & guidelines	National Ethics Advisory Committee (NEAC), Health & Disability Ethics Commission (HDEC), Privacy Act 2020 and Health Information Privacy Code 2020
l. DMP creation date	DD/MM/YYYY
m. Current form version number	
n. Date form last updated	DD/MM/YYYY
o. Updated by	Name and affiliations

<b>2. Data</b>	
a. Type of Data	Include details on: <ul style="list-style-type: none"> <li>• <a href="#">Methods of data capture and sources of information (i.e. clinical records,</a></li> </ul>

Capture Fields	<p>medical databases, questionnaires, scheduled assessments)</p> <ul style="list-style-type: none"> <li>Who is included in data capture (e.g. patients, whanau, healthcare providers)</li> <li>Data fields/variables collected</li> </ul>
b. Data storage and organisation of data	<p>The REDCap (Research Electronic Data Capture) secure electronic data capture tool is the platform of choice for secure, flexible and fast data management to include case report form, registry and questionnaire designed instruments. For more details, refer to section 5a Security.</p> <p><i>Information here regarding storage on secured Te Toka Tumai Auckland network drives, or in the case of hardcopies, in secured lockable cabinets.</i></p> <ul style="list-style-type: none"> <li>All extracted and linked data will be stored in a secure restricted network drive at Te Toka Tumai Auckland.</li> <li>The access will be controlled by Study PI only and kept for a minimum of 10 years, from age of 16 years, as per GCP and will then be destroyed securely.</li> <li>Health data at Te Toka Tumai Auckland is in electronic form, staff members have personal logons for access, which is audited regularly, and clinical records are retained indefinitely. Te Toka Tumai Auckland recognises a patient's right to access their information in the clinical record as per Rule 6 of the <a href="#">Health Information Privacy Code</a></li> <li>Te Toka Tumai Auckland recognises that patients have a right to correct information held about them in the clinical record as per Rule 7 of the <a href="#">Health Information Privacy Code</a></li> </ul>

### 3. Ethics

a. Ethics	<ul style="list-style-type: none"> <li>Which ethics committee it has been approved by (or sent to/will be sent to if not yet approved)</li> <li>Hospital locality approval number(s) (usually obtained following full HDEC approval; will need approval for each data collection site)</li> <li>Who has/will perform Māori research review and approval</li> </ul>
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### 4. Māori Health Data

a. Custodial arrangements for data	<p>Include details here about Māori consultation in project design and execution.</p> <p>Māori data refers to data produced by Māori or that describes Māori and the environments they have relationships with. Māori data includes but is not limited to:</p> <ul style="list-style-type: none"> <li>Data from organisations and businesses</li> <li>Data about Māori that is used to describe or compare Māori collectives</li> </ul>
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- Data about Te Ao Māori that emerges from research

Include any details here regarding anyone on research team who has Māori research knowledge, or any ongoing consultations to ensure Māori responsiveness is adhered to throughout lifecycle of study.

Māori should be involved in decisions about the primary collection, analysis, and interpretation of Māori data in research contexts and the Māori data sovereignty rules will be used as a framework for custodial requirements and access. Address each of the Māori data sovereignty principles below based on the study protocol:

**Whakapapa** –

**Tika** –

**Manaakitanga** –

**Mana** –

*For further guidance about on Māori data sovereignty, visit:*

<https://www.temanararaunga.maori.nz/>

## 5. Security

### a. Security

New Zealand laws require the study doctor to protect the privacy of the participant's records. In New Zealand, data is protected under the [New Zealand Privacy Act](#) (2020, specifically part 3). Starship Child Health will do everything we can to make sure that no one, except the study doctor/hospital/clinic and study inspectors know who the participant is. We do this by using a code instead of the child's name and only these people will have the key to the code. However, absolute confidentiality cannot be guaranteed because of the need to disclose information in certain instances (as outlined in the study protocol).

The platform of choice for secure, flexible and fast data management is REDCap. This also includes case report form, registry and questionnaire designed instruments. REDCap is used by overseas study sites and sites within New Zealand allowing consistency in data management and safe data sharing. Te Toka Tumai Auckland research related data access and use are managed by stringent user privileges within REDCap through a delegation hierarchy built into the bespoke design for every study protocol. REDCap held data can be exported in anonymous form to various statistical packages for data analysis. Data access can be audited for tracking data manipulation and user activity, and the data is stored and backed up each evening on a healthAlliance managed infrastructure.

To keep the child's identity private, all data that is sent or provided outside of the study centre will show only a coded identification number instead of the child's name. Only the study doctor and authorised

personnel will be able to connect this code to the name, able to be re-identified only at site by a list kept in the study folder within the Starship Research unit. The code list and the child's study data may be retained by Te Toka Tumai Auckland for at least 10 years following the completion of the study, or from when the child turns 16 year's old, whichever comes first.

The coded data from the research study showing the child's involvement will be provided to the Sponsor and other individuals and/or companies that act on the Sponsor's behalf (mention the name of the Sponsor)

The paper files will be stored in a locked cabinet, in the Starship Clinical Research Department.

The data will be destroyed in compliance with Te Toka Tumai Auckland data management guidelines.

## 6. Sharing Data

### a. Disclosing

Te Toka Tumai Auckland has a data sharing agreement that outlines the responsibilities of the recipient (data host) and the provider. This complies with Te Toka Tumai Auckland legal review for organisational compliance.

## 7. Breach

### Breach

If a breach is identified and patient identifiable data has been sent outside of Te Toka Tumai Auckland then the recipient is informed if they were not yet aware and requested to delete the information. A CAPA is raised and the reason for the breach is reviewed and any corrective/preventative action is put in place. As per the Te Toka Tumai Auckland policy; These are five key steps in dealing with a privacy breach:

1. **Contain** the breach and make a first assessment
2. **Log the incident** and notify the Privacy Officer
3. **Evaluate** the risks
4. **Notify** the affected people if necessary
5. **Prevent** a repeat