NZ Spinal Cord Injury Registry
Te Rēhita Whara Aho Tuaiwi ā-Motu

Information Booklet

New Zealand Spinal Cord Injury Registry (NZSCIR)

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Study Sites:	Te Whatu Ora Counties Manukau Middlemore Hospital/Auckland Spinal Rehabilitation Unit) Te Whatu Ora Waitaha Canterbury (Christchurch Hospital/Burwood Spinal Unit)
Contact phone numbers:	Auckland NZSCIR Coordinator 0211920377 Burwood NZSCIR Coordinator 021594291
Ethics committee ref.:	16/STH/84

Nau mai

You're invited to participate in the New Zealand Spinal Cord Injury Registry (NZSCIR) because you have sustained a spinal cord injury (SCI) through an accident or non-traumatic cause.

The NZSCIR stores information about individuals who have SCIs in a national database. NZSCIR Coordinators work from the New Zealand (NZ) spinal specialist services (acute and rehabilitation). These are Middlemore Hospital and Auckland Spinal Rehabilitation Unit in the north, and Christchurch Hospital and Burwood Spinal Unit in the south. The NZSCIR partners with the Praxis Spinal Cord Institute, who has managed the Canadian national Rick Hansen Spinal Cord Injury Registry (RHSCIR) since 2004.

This booklet sets out the purpose of the NZSCIR, what your participation would involve, and what the benefits and risks to you might be. Please keep this booklet. Take time before making a decision. Feel free to talk with others, such as family, whānau, friends, or healthcare providers.

Voluntary participation and withdrawal from the NZSCIR

Participation in the NZSCIR is voluntary. It is up to you to decide whether to take part. You don't have to give a reason if you don't wish to participate.

If you want to participate, you (or someone on your behalf) will be asked to sign a consent form. By signing the consent form, you are not waiving any of your legal rights. You are welcome to request a copy of the consent form from the NZSCIR Coordinator.

If you take part in the NZSCIR, you may withdraw at any time without giving a reason. All data collected up to the point of your withdrawal will be kept in the database for analysis, but no further data will be collected or entered.

If you decide not to participate, it won't affect the care you receive.

There is no monetary compensation for participating.

Research

Innovation

Improvement

What is the purpose of the NZSCIR?

The NZSCIR aims to record every new SCI in NZ each year. Basic statistics are collected to help SCI services track how many people have a SCI, what the causes are, the severity and what treatments achieve better outcomes.

By collecting a person's demographic information (age, gender, ethnicity etc.) and clinical data (level and type of injury, admission and discharge dates, complications, etc.), it lets clinicians, researchers and healthcare providers see trends and answer questions about how patients are being treated. This information is used to improve SCI care within spinal services and also helps to develop evidence-based practices.

SCI is considered an uncommon, high-cost medical condition which varies a lot from person to person. Registries let us study variations, complications and outcomes. Without this information, there is no way to know how to improve care or introduce new therapies.

The main objective of NZSCIR is to collect demographic and clinical information about the New Zealanders' who sustain a SCI, then combine that information to:

- Measure how well current treatments work
- Develop better treatments and therapies
- Make clinical care and hospital administration processes across NZ better to improve health outcomes for individuals with SCI
- Plan directions for future research
- Answer local and national research questions
- Create collaborations between health care centres across the country to help ensure that all individuals with SCI receive the best and similar types of clinical care
- Understand gaps in care and services, and gather information to help advocate for resources to fill these gaps.

NZSCIR has a partnership with Te Ao Mārama Aotearoa Trust (TAMA). This is an independent group which sits alongside the Ministry of Health providing a voice for Tāngata Whaikaha (Māori persons with lived experience of a disability). It allows the NZSCIR to collaborate and kōrero to support the disability sector and take necessary steps to achieve equity. It also helps guide the NZSCIR with tikanga and building partnerships.

How is the NZSCIR designed?

The NZSCIR collects basic information (i.e. age, gender, ethnicity, cause of SCI, neurological level, if surgery is performed) from medical records on every person with a new SCI. This basic information (known as a Minimal Data Set) does not require consent and is essential to accurately report how many people have a SCI in NZ.

If you consent, further information is collected and added to the NZSCIR. This allows more in-depth analysis to help us understand what our population looks like and what their needs are, such as the type of equipment used and the most common complications.

Hospital Data Collection

After agreeing to participate in the NZSCIR and signing the consent form, a NZSCIR Coordinator will meet with you to gain a good picture of your health status. The brief interview includes short questions about you, such as your education level, occupation, height and smoking history. You may refuse to answer any of the questions that you are not comfortable with.

Clinicians already involved in your care (nurses, therapists, doctors or surgeons) and NZSCIR Coordinators will provide information from your medical record for the NZSCIR. This covers demographics, medical history, admission and discharge dates and times, diagnosis, neurology, procedures, interventions and outcomes relating to this hospital journey.

Prior to your discharge from hospital, a NZSCIR Coordinator will meet with you to collect additional information about your social circumstances (sociodemographics), what interventions and services you had, any complications, and your contact details.

Data are entered into a secure information management system. This system is a secure, cloud-based platform in Canada. The privacy and security of your information is managed using a set of administrative, technical and physical safeguards. All participants have the right to access and review their own data to confirm the information and make corrections. Requests for access to your data are managed by your NZSCIR Coordinator.

Follow-up Data Collection

After you have been discharged from hospital, we aim to contact you periodically in the community. This can be by telephone, mail, or email link to a secure website, or in person. We ask you to complete a questionnaire related to your health and quality of life.

This follow-up data is very important as it allows us to see how participants are reintegrating into the community, the issues they are facing and what their needs are. Services can then see how to improve, whilst tracking changes in the SCI population that occur overtime.

Follow-up data includes:

- updating contact information, sociodemographics, medical history and health care use
- gathering information related to independence in daily activities, quality of life, community and environment accessibility, health conditions, pain and any secondary complications.

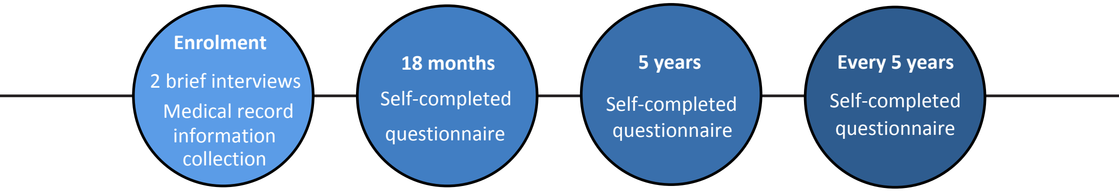
Who can take part in the NZSCIR?

To participate in NZSCIR you need to have sustained a spinal cord injury or cauda equina as a result of an injury or non-traumatic cause.

What will my participation in the NZSCIR involve?

You will be giving the information by completing two questionnaires with a NZSCIR Coordinator. The initial interview may take 5-15 minutes, and the discharge interview maybe 15-25 minutes.

You will be giving the information by answering questions during brief interviews and filling out questionnaires with a NZSCIR Coordinator. You will be followed up within the community and information will be collected starting now and continuing throughout your life (unless you later decide you no longer wish to participate).



What are the possible risks?

There are risks associated with completing questionnaires and providing information to the NZSCIR.

- Questionnaires may ask for information that makes you feel sad or anxious. This risk is considered low because every effort is made by the NZSCIR to be sensitive in the questions asked. You may refuse to answer any question.
- Unauthorised users may attempt to access or misuse your health information. This risk is considered low because the NZSCIR uses the most advanced security measures to protect your privacy.
- Researchers with ethical approval to use identifiable data may not hold this securely, breaching your privacy. This risk is considered low because any identifiable data requires a rigorous ethical process to be followed to hold all data securely and not to misuse it in any way.
- Researchers might combine or link data. The result of combining the data may mean its interpretation isn't quite right. This risk is considered low because researchers need to get ethical approval and have their research methods and results reviewed and approved.

What happens to my information?

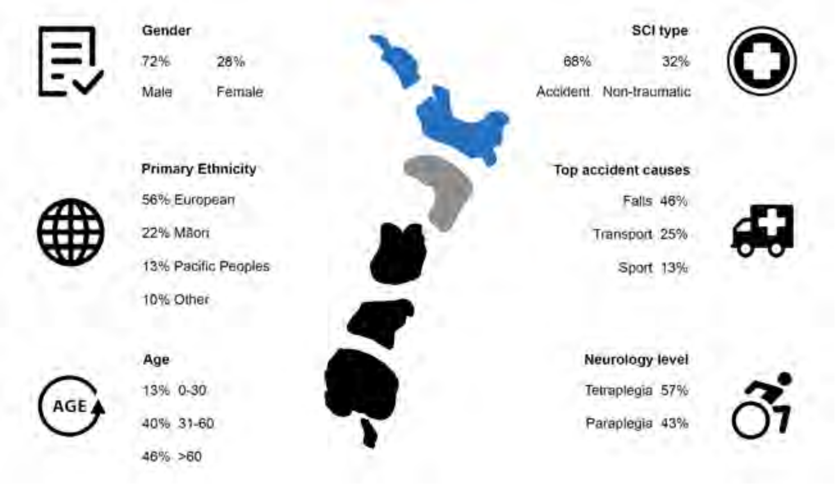
Your confidentiality is respected. Protecting your privacy is of primary importance to the NZSCIR. Any publicly available reports (such as an annual SCI report) or publications resulting from the NZSCIR are de-identified and data may also be grouped so individuals cannot be identified.

NZSCIR Coordinators and clinicians involved with your SCI care record information about you in the NZSCIR. This includes the questionnaires you complete.

Information from the NZSCIR is shared with researchers, clinicians and service providers through a Data Access Request process. Strict rules are in place to ensure information is kept safe and used in the appropriate way.

Dashboard information

The NZSCIR has electronic dashboards where information can only be accessed by the NZSCIR Coordinators. Dashboards are used to view and analyse information across the NZSCIR. Limited information can be given to researchers or clinicians on request. For example, dashboards are used to answer clinical questions, help determine if research is feasible, and contribute visual information to presentations. When this information is de-identified and grouped with others (by age group, gender, ethnicity), it makes it very difficult (but not impossible) to identify the information that belongs to you. An example of 2020 dashboard data is shown below.



De-identified (coded) information

To make sure your personal information is kept confidential, information that identifies you is not included in any NZSCIR report. When releasing de-identified data to clinicians and researchers, your information is identified by a unique code only. NZSCIR Coordinators keep a list linking your code with your name, so that you can be identified by your coded data if needed. The results of any study using your data may be published or presented, but not in a form that would reasonably be expected to identify you.

Identifiable information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or National Health Index number). NZSCIR Coordinators and clinicians already involved with your care have access to your identifiable information to ensure the correct required data is being entered under the correct person.

The NZSCIR has an agreement with St John to share data. St John provide the ambulance data (date/time of injury, time of 111 call, ambulance arrival time etc.) to the NZSCIR. St John requires identifiable information to ensure ambulance records are correct. The NZSCIR shares data with St John about the participant's level and severity of SCI to allow cross checking of processes for quality purposes.

Researchers with the appropriate ethical approval may request NZSCIR identifiable data. Approval is obtained through a rigorous NZ Ethics Committee process to facilitate SCI research. This process ensures researchers comply with ethical guidelines. Using this type of information allows New Zealand based researchers to compare NZSCIR data with other sets of health data. Researchers have to hold data securely and cannot publish individual level identifiable data.

NZSCIR collaborates with Canadian-based RHSCIR, therefore overseas researchers may request NZSCIR data. Any overseas researchers will need to meet NZ Ethics standards and will not have access to identifiable data.

Security and Storage of Your Information

Your identifiable information is held on a secure, cloud-based storage platform based in Canada. Canada abides by strict privacy requirements which are as secure as in New Zealand. Decisions about the use and access of this data can only be made by the NZSCIR which is governed by New Zealand ethical approvals.

Any information recorded on paper forms is kept secure by key access and shredded when entered into the NZSCIR. All physical and cloud-based storage complies with local and international data security and privacy guidelines. Once data is entered into the NZSCIR, it remains on the system in identifiable form for the lifetime of the participant.

The NZSCIR was established with consultation with Māori Health Services from both Tw Whatu Ora Counties Manukau and Te Whatu Ora Waitaha Canterbury. A partnership with Te Ao Mārama helps ensure the principles of Māori Data Sovereignty are observed.

Rights to Access Your Information

You have the right to request access to your information held by the NZSCIR. You also have the right to request that any information you disagree with is corrected.

If you have any questions about the collection and use of information about you, please ask your NZSCIR Coordinator.

Can I see the NZSCIR reports?

Yes! We publish NZSCIR annual reports on the NZ Spinal Trust website each year. You can view and download them from here: www.nzscir.nz

We include information on articles written and published using NZSCIR data on this site.

Who is funding the NZSCIR?

NZSCIR is jointly funded by the Accident Compensation Corporation (ACC), Te Whatu Ora Waitaha Canterbury and Te Whatu Ora Counties Manukau (CMH). The NZSCIR works in partnership with the Canadian Praxis Spinal Cord Institute.

Who has approved the study?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Southern HDEC has approved this study.

You can contact HDEC that approved this study on:

Phone:	0800 4 ETHIC
Email:	hdecs@health.govt.nz

Who else can I talk to?

If you want to talk to someone who isn't involved with the NZSCIR, you can contact an independent health and disability advocate on:

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@advocacy.org.nz
Website:	https://www.hdc.org.nz/advocacy

If you have any questions, concerns or complaints about the NZSCIR at any stage, you can contact:

Burwood NZSCIR Coordinator

021594291

NZSCIR@cdhb.health.nz

Auckland NZSCIR Coordinator

0211920377

NZSCIR@middlemore.co.nz

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Waitaha Canterbury

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