

Participant Information Sheet and Consent Form

Study title:	The New Zealand Cerebral Palsy Register		
Locality:	New Zealand	Ethics committee ref.:	13/NTA/130
Lead investigator:	Professor Susan Stott	Contact phone number:	09 373 7599 Ext 82561

You are invited to contribute you or your child's / tamariki health information to the NZ Cerebral Palsy Register.

What is the NZ Cerebral Palsy Register?

The register is a database of clinical information about Cerebral Palsy (CP). We aim to collect health information about everybody with CP in New Zealand. Information will include birth details; description of your CP and how it affects your physical functioning.

The NZ CP Register will collect information via the Australian Cerebral Palsy Register website (ACPR). The Australian Register is a well established Register and is one of the largest in the world. NZ information will only be visible to NZ CP Register staff. On a yearly basis we will contribute our de-identified details (that is with no names) from the NZ Register to the Australian Register; this allows us to see how we are doing compared to the rest of the world.

Why is the NZ CP Register needed?

CP is the most common cause of physical disability in childhood. There is no known cure and the rates of CP have remained unchanged despite recent advances in medicine. Most CP occurs as a result of factors prior to birth, however little is known about these factors and for 80% of people with CP the cause is unknown. While people with cerebral palsy can lead fulfilling lives, having a better understanding on the causes and impact of CP can help improve the current health services and interventions available.

The NZ CP Register provides a coordinated data collection system that will increase our knowledge of people with CP in NZ to help with better planning of health services and benchmark our experiences with those of other countries, such as Australia

What are the aims and potential benefits of the Register?

If everyone contributes their data we will be able to:

- Know how many people have CP in NZ and how this affects them
- Begin to improve health and education planning in NZ for people with CP
- Promote research that can assess interventions and preventative strategies
- Allow us to compare our practice to overseas experience

How can I participate?

People with CP and their whānau / families can enrol in a number of ways:

- Log on to the NZ CP Website: www.cpregister.com to self register
- Contact the NZ CP Register and they can register your details
- Contact your local physician / therapist to obtain a consent form

There will be no payment of any kind for your participation in the Register, we hope that contributing information to the Register requires little time or inconvenience to you.

What about consent and withdrawal of consent?

- Joining the NZ CP Register is your choice. If you don't want to take part, you do not have to give a reason, and it won't affect the care you receive.
- If you would like to contribute information you will be asked to provide written consent. You can get a consent form online from: www.cpregister.com or contact the NZ CP Register.

There are different levels of consent on the Register.

You will be asked to consent to:

1. The collection of clinical details on your CP diagnosis. (You will not need to complete any additional tests or measures). This includes birth history and functional ability questions
2. The collection of information on your CP diagnosis from health professionals that you nominate and from accessing your current medical records. This is to assist with completing and verifying the Register information you provide.
3. Consent to your regional register representative receiving information for the purposes of service planning in the local area.
4. Receiving information from the NZ CP Register on future relevant research projects.
5. The transfer of de-identified information to the Australian CP Register for yearly reports.

If in the future you change your mind about participating in the register, you can withdraw consent and your name will be removed from the register.

- Matua / Parents or guardians are able to give consent on their child's behalf.
- If your **child is unable to fully understand**, their assent can be obtained, unless your child is unable to do this (in addition to the parent / guardian consent).
- If your **child is able to fully understand**, then they have the right to consent to participate in the Register too (in addition to the parent / guardian consent).
- Tamariki / Children under the age of 5 years will be contacted again after their 5th birthday for final confirmation of details. Please notify the register if your personal details change.

You may also want to talk about the Register with other people, such as family, whānau, friends, or healthcare providers. Please feel free to do this.

What about privacy and confidentiality?

We respect your privacy. The information you provide to the Register is strictly confidential and data will be stored with upmost security and care.

- The Register requires that your personal information is identifiable to some NZ CP Register staff. This is to allow for planning of prevention strategies in your region.
- Your information will not be sent to any third parties, except with your consent or where required by law.
- Only your de-identified data will be included in the Australian CP Register.
- No material that could personally identify you will be used in any reports on the Register.

NZ CP Register details

- The Register is being led by Professor Susan Stott, Paediatric Orthopaedic Surgeon, Starship Children's Health, Auckland, in conjunction with a team of health professionals and stakeholders from across New Zealand
- The Register is being sponsored by Auckland District Health Board, NZ, with contributions from Cerebral Palsy Society of NZ and Allergan Ltd, Australia.
- This proposal has received ethical approval from the NZ Health and Disability Ethics Committee, ethics reference number (13/NTA/130).
- It is highly unlikely you could be injured participating in this proposal; if you were you would be able to apply for compensation from ACC.

- The Register is planned to continue indefinitely. Should funding for the NZ Cerebral Palsy Register cease, all data held by the Register will be maintained securely by the ACPR.

If you agree to participate, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep. This document is 5 pages long, including the Consent Form. Please make sure you have all the pages.

Who do I contact for more information or if I have concerns?

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

*Alexandra Sorhage
Research Officer, Paediatric Orthopaedics, Starship Children's Health
Tel: 09 307 4949 Ext 21898
Email: asorhage@adhb.govt.nz*

*Dr Anna Mackey,
Honorary Research Associate, Paediatric Orthopaedics, Starship Children's Health
Email: a.mackey@auckland.ac.nz*

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

*Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz*

If you require Māori cultural support please talk to your whānau in the first instance.
*Alternatively you may contact He Kamaka Waiora (Māori Health Team)
Phone: (09) 486 8324 ext 2324*

If you have any questions or complaints about the study you may contact the: *Auckland & Waitematā District Health Boards Maori Research Committee or Maori Research Advisor
Phone 09 4868920 ext 3204*

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

*Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz*

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I, _____ (Name of Person giving consent)

hereby give consent to the inclusion of

(Participants full name)

on the New Zealand Cerebral Palsy Register, being myself / or the matua / parent / person responsible (please circle appropriate response).

Declaration:

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet. I have had the opportunity to ask questions and I am satisfied with the answers I have received. I freely agree to participate in the Register.

I have a copy of the Participant Information Sheet and Consent Form to keep.

I agree to the recording and permanent storage of information relating to me / my child / the person, on the NZ Cerebral Palsy Register. Yes No

I agree to allow the NZ CP Register access to my medical records and / or contacting my health care provider/s only for the purpose of obtaining information relevant to this Register. **List providers in Attachment A over page if known** Yes No

I agree to my NZCPR information being made available to my regional NZCPR representative, for purposes of local service planning and clinical surveillance programmes. Yes No

I agree to transfer of my de-identified information (un-named) to the Australian Cerebral Palsy Register on a yearly basis Yes No

I am happy to be contacted by the Register with invitations to participate in relevant research studies. Yes No

Signature:

Relationship to child/person:

Date:



ATTACHMENT A:

Health professionals nominated to be contacted to assist in completing and verifying information for the Register.

Health professionals (name; place of work; phone number)

1. _____
2. _____
3. _____

Name of participant on Register: _____

Signature: _____ **Date:** _____

ATTACHMENT B:

Investigator declaration

I certify that I have given a verbal explanation of the project to the person / parent / and or person responsible and believe that he / she understands what is involved and has freely given consent to participate.

Signature: _____

Name: _____

Title: _____

Date: _____