

Participant Information Sheet: Older Child Participant

Short Title	CHAANZ and NZ Heart Registries
Title	CHAANZ Congenital Heart Disease Registry & NZ Heart Disease Registry
Project Funding	Heart Research Institute NZ, HeartKids (Australia) Limited & Medical Research Future Fund (Australia)
Registry Manager	Professor Geoff Strange
Coordinating Principal Investigator	Professor David Celermajer
Principal Investigator	Dr Clare O'Donnell, Paediatric and Adult Congenital Cardiologist

Part 1 What does taking part in this study involve?

1. Introduction

- A registry is a type of research study where we collect information all about people with certain health conditions so that we can better understand those conditions and how to treat them.
- Registries work best when everyone with that health condition participates.
- The CHAANZ Congenital Heart Disease (CHD) Registry collects health information on people born with heart conditions in Australia and New Zealand.
- We are sharing information with the Australia New Zealand Registry only for those born with these conditions. These data are stored in Australia.
- In Auckland, we are including heart patients who were born with heart conditions, and patients who got them during childhood. These data are stored in Auckland.

2. Why have you given me this information?

- We are asking you to help us because you are looked after by our service for your heart conditions.
- Your parent or caregiver has also been given this information.
- This information will help you decide if you want to be involved.
- Ask your doctor or nurse as many questions as you need to understand this research.
- Talk to your family, and they will help you decide if you want to be involved.
- If you decide you do not want to take part, you do not have to and you can choose not to. You "Opt out", which means your information won't be included.
- You will receive the best possible care whether or not you take part.
- **You will be automatically included in the Registry, unless you decide to opt out.**

This Participant Information Sheet is available on paper if you want to keep it, or it can be downloaded from our website.

3. What is the purpose of this research?

- Congenital heart disease (CHD) is a heart problem people are born with. Acquired heart disease is when people develop them after they are born.
- Treatment for CHD is always improving, and it now also affects the lives of many teenagers and adults.
- The CHAANZ CHD Registry aims to better understand of the experiences and needs of people with CHD from childhood to adulthood, both here and all over Australia.

- In Aotearoa NZ, there are many children who develop heart conditions during childhood, and we are interested in these conditions too, such as Rheumatic Heart Disease, Kawasaki Disease and some types of cardiomyopathy.
- This research may help us develop better treatments, understand the needs of patients, and better plan our healthcare service to treat patients with heart conditions.

4. What does participation in this research involve?

- If you are happy to have your health information included in the Registry, you do not have to do anything. Participating in the Registry will not require you to have any additional procedures or tests.
- Information will be collected from your hospital medical record and entered into a secure database around 2 weeks after we give you this information, unless you tell us you don't want your information to be included.
- Additional information will be added each time you visit your doctor or at periodical intervals.
- We will collect information about your medical condition, such as test results, treatments you have had, how often you stay in hospital, and things that describe you, like your date of birth and ethnicity.
- We collect information that tells us who you are (name, medical number, date of birth, address) to connect all your information together, but only a few people involved in the research can see this information, and no-one outside of the research will know you are involved.

5. Do I have to take part in this research project?

- Participation in any research project is voluntary.
- If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the Registry at any stage.
- You will talk about this with your family and decide together if you want to be involved.
- If you do not want to participate in the Registry, your parents can tell us by:
 - Completing the "Opt-Out Form" on Page 6 of the parent information sheet
 - Telling your heart doctor or nurse specialist, or
 - Completing the opt-out form on our study website: <https://www.chaanz.org.au/participant-information-nz>.
- If we do not hear from you within two weeks from receiving this information, we will assume that you are happy for us to collect your information.
- We will ask you if you want to be involved again when you change from being treated at Starship to the Adult Hospital (around 16 or 17 years of age).

Your routine care, your relationship with your heart doctor or your care at Te Toka Tumai Auckland will not be affected in any way, whether you participate or not.

6. Further information and who can I contact?

You should first talk to your parents/family/whānau/Aiga if you have any questions or concerns. If you and your family want any further information concerning this project or have any problems which may be related to involvement in the project, your heart doctor or nurse specialist are good people to speak to. If you have any questions or concerns or at any stage, you can also contact:

- Study coordinator: ✉ CHAANZ@adhb.govt.nz
- Paediatric cardiology nurse specialist team: ✉ Paedcard.ns@adhb.govt.nz
- Adult congenital heart disease nurse specialist team: ✉ achdnurse@adhb.govt.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:
☎ 0800 555 050 | ✉ advocacy@advocacy.org.nz | <https://www.advocacy.org.nz/>
- If you require Māori cultural support, contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 307 4949 ext 29200. State title of the study (CHAANZ) and name of primary investigator (Dr Clare O'Donnell).

Ethics Approval and Complaints

This study has ethical approval in both Australia and Aotearoa New Zealand. This study has been approved in New Zealand by the Northern A Health and Disability Ethics Committee (HDEC). Any person with concerns or complaints about the conduct of this study should contact the HDEC by phone (0800 400 569 (Ministry of Health general enquiries) or email (hdec@health.govt.nz).

The conduct of this study at Starship Child Health, Te Toka Tumai Auckland has been authorised by the Research Review Committee, and Māori Research Review Committee. Any person with concerns or complaints about the conduct of this study may also contact the Research Office on 09 307 4949 or researchoffice@adhb.govt.nz and quote protocol number A+9540.