

Participant Information Sheet: Parent, legal guardian or medical decision-maker

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 participation involve?

1. Introduction

The CHAANZ Congenital Heart Disease (CHD) Registry, is a database collecting health information on children and adults living in Australia and New Zealand who have had a diagnosis of a CHD. The Registry has been designed to better understand the health-related experiences and needs of people with CHD from childhood to adulthood. In Aotearoa New Zealand, our Registry process is designed to collect health information on all the children and young people seen in Auckland with problems with the structure of their heart – congenital (problems present from birth) or those that develop in childhood (we call these 'acquired'). We will then share the information we have on our congenital heart (CHD) patients with the Australia New Zealand Registry.

This Participant Information Sheet has been given to you because you are a parent, caregiver or medical decision-maker of a patient cared for by our service. We want to tell you about the Registry and explain what is involved. If you do not want their health information included, there is information below explaining what to do. Knowing what is involved will help you decide if you want them take part. Your heart doctor and nurses are best placed to convey and discuss this with you if you have questions.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether to take part, you might want to talk about it with a relative, friend or local health worker.

Participation in this research is **voluntary**. If you decide you do not want them to take part, you do not have to and you can choose to "Opt out". Your child or family member will receive the best possible care whether or not they take part. **They 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.

2. What is the purpose of this research?

Congenital heart disease (CHD) is a heart problem people are born with. It is the most common congenital disorder in newborns and although it is often associated with babies and children, CHD now also affects the lives of many teenagers and adults. Because of surgical and medical advancements, many people with more complicated CHD are living longer. Some people are also first diagnosed with their CHD when they are adults.

The CHAANZ CHD Registry is a database collecting health information. The aim of the Registry is to gain a better understanding of the experiences and needs of people with CHD from childhood to adulthood. Information from the Registry will be used to monitor the clinical care that is provided, including treatment, complications and both short- and longer-term outcomes. This information will be used to help identify trends and whether gaps exist in service provision. It will be imperative to people with CHD, the healthcare professionals responsible for caring for them and health policy makers, to ultimately deliver better, more sustainable models of care. As it builds and collects information on the lifespan impact of CHD for many thousands of people, the Registry will become a unique tool to help researchers and doctors to improve the health and quality of care for people with CHD through all phases of life.

The Registry will be collecting data on people who have been diagnosed with CHD and those who are being managed at Congenital Heart Units at participating hospitals in Australia and New Zealand. In New Zealand we recognise that our clinic population also has many children with rheumatic heart disease and other types of acquired heart disease (conditions developed after birth) such as Kawasaki disease and some types of cardiomyopathy. Some children we see have both CHD and another diagnosis. This is why in New Zealand we are asking patients and families to join us in collecting information on all of the patients we see who have been diagnosed with a problem with the way their heart structure works (CHD and acquired heart disease). We will share with the Registry all of the CHD diagnoses that are part of the CHAANZ Australia/New Zealand study.

This research project is being coordinated by the Congenital Heart Alliance of Australia and New Zealand (CHAANZ). It has been funded by HeartKids (Australia) Limited, with support from The Kinghorn Foundation and The Pinnacle Charitable Foundation, and a Medical Research Future Fund from the Australian Government Department of Health. The Heart Research Institute (HRI) has provided a grant to fund the establishment of the CHAANZ Registry in Aotearoa New Zealand.

We have also consulted with Heart Kids New Zealand, who are in support of this project.

3. What does participation in this research involve?

If you are happy to have your child or family member's health information included in the Registry, you do not have to do anything. Information will be collected from their hospital medical record and entered into a secure database. If you were born with your condition (congenital), your information will be sent to a database in Australia. If you developed your condition after birth (acquired), your information will be saved on a database within Starship Hospital. This will happen approximately two weeks after you have received this information sheet (unless you opt-out). Additional information will be added each time they visit their doctor or at periodical intervals.

The study doctor and research staff will electronically review their medical records and collect the following information about their health and wellbeing, if available:

- Demographic information (e.g. name, date of birth, address, cardiologist, next of kin etc.);
- Medical history (e.g. diagnosis, heart operations, other health conditions, complications, medications);
- Investigations (e.g., echocardiogram reports, catheter tests, blood tests);
- Routine visits and monitoring (e.g., changes in their condition, medications, new heart operations, complications, hospital admissions);
- Other factors influencing outcomes (e.g., pregnancy, substance use, transplant or death);
- Information about their general state of health.

Participating in the Registry will not require the patient to have any additional procedures or tests.

Personal information is required to link participants' information with any further follow-up visits. This information allows us to collect information regarding their health care needs from other hospital systems and, if relevant, from administrative health datasets; this is likely only relevant if you moved between NZ and Australia.

There are no costs associated with participating in the Registry, nor will participants be paid for participation.

4. Does my child or family member have to take part in this research project?

Participation in any research project is voluntary. If you do not wish for them to take part, they do not have to be involved. If you decide for them to take part and later change your mind, you are free to withdraw from the Registry at any stage. When a child is transitioned from being cared for by Child Health (Starship) to Adult Health, they will be again presented with this information and given the opportunity to decide for themselves if they wish to still be included; this will happen around 16-18 years of age.

If you would prefer they do not to participate in the Registry, you will need to tell us by completing the "Opt-Out Form" on Page 6, by telling your heart doctor or nurse specialist, or by 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 child or family member's information.

Your decision to take part or not to take part, or withdraw, will not affect their routine care, your relationship with your heart doctor or their care at Te Toka Tumai Auckland in any way.

5. What are the possible benefits of taking part?

There are no immediate benefits for the patient from participating in the Registry. However, we hope that information learned from the Registry will help doctors have a better understanding of CHD, be used to further medical knowledge and improve patient care and will benefit people diagnosed with these conditions in the future.

6. What are the possible risks of taking part?

There are few risks to having health information stored in the Registry. The identified risks mostly relate to a potential loss of privacy; whilst we perceive this as an unlikely risk, it cannot be eliminated entirely. Researchers directly involved with collection of data will have access to participants' medical records. To ensure that participants' private information is safeguarded, Registry staff must comply with very strict privacy principles. We may use computer programmes to link data now or in the future; for example, if patients move between New Zealand and Australia, or between different regions of Australia, or if there are different places where health information is stored. Otherwise, researchers will not release identifiable information to any person or organisation outside the Registry. No report will contain identifying information about individuals.

Although many efforts will be made to protect all participants' privacy, absolute confidentiality of their information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that they cannot be identified. The risk of people accessing and misusing health information (we can't think of any possible examples with this study) is currently very small, but may increase in the future as people find new ways of tracing information.

The health information is being sent overseas to the main CHAANZ server based in Australia. We acknowledge that data protection rules in Australia may differ from those in New Zealand. This study

has however also been through detailed review by health authorities in Australia and New Zealand to check the processes involved. There is a risk that overseas researchers may work with information in a way that is not culturally appropriate for New Zealanders/tangata whenua Aotearoa. We believe it is very important for New Zealand data to be included in large studies like this. New Zealand representatives will continue to be part of study governance and research teams, and are aware of the importance of protecting the taonga of our local data and the larger dataset.

By taking part in this study our intention is to give voice to an inclusive description of CHD outcomes. These may be different by country, locality, gender or ethnicity. We hope that this will achieve better understanding of the impact of CHD for different communities through the lifespan. We recognise though, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of certain groups.

7. What if I withdraw my child or family member from this research project?

If you decide to withdraw your child or family member from this research project, you will need to notify a member of the research team and you will need to complete the “Opt-Out Form” on Page 6, or by completing the opt-out form on our study website: <https://www.chaanz.org.au/participant-information-nz>.

If you decide to leave the study, you can tell us to make your data “silent”; that means it cannot be deleted, but we will no longer see your data, it will not form part of future analyses, and we will not collect further information about you.

Part 2 How is the research project being conducted?

8. What will happen to information about my child or family member?

Any information collected for the Registry that can identify patients will remain confidential. We will use this information only for research purposes. We can disclose this information only with your permission, except as required by law.

Health information and personal information which may identify your child or family member will be permanently stored in a secure, password protected, electronic database located in Australia in you have a congenital heart condition, or in Auckland if you have an acquired heart condition. Only the researchers involved with this project at Te Toka Tumai Auckland, the Registry management team and the Ethics Committees can have access to this information. Once the information is entered into the Registry, it will be given a unique identification number. Only the research team can re-identify this information if it is necessary to do so. In accordance with relevant Australian and/or New Zealand privacy and other relevant laws, you have the right to request access to the information about your child or family member that is collected and stored by the research team. You also have the right to request that any information that is not accurate be corrected. Please inform the research team member named at the end of this document if you would like to access this information.

As this is an ongoing Registry, data will be kept indefinitely in a secure environment as long as the Registry exists. If the Registry ceases to exist, the information stored in the Registry will be destroyed in a secure manner.

The data collected in this project may also be used in future research studies. The results of this study and de-identified data may be shared in the future with national and international collaborators. Any data that is used for related or future research will first be reviewed and approved by an appropriately constituted Ethics Committee. If you do not wish for your child or family member’s data

to be used in future research, please contact a member of the research team with the contact details provided below to notify them of your decision.

The data in the Registry may form part of an Honours, Masters by Research or a Doctoral thesis. Prospective students must be associated with a contributing centre and the site Principal Investigator must be involved in the student's supervision (either as lead or as auxiliary supervisor).

Reports may be presented at conferences or published in medical journals. Patients will not be identified in any reports or publications. If you are interested in the research findings from the Registry, summaries and the latest news will be available on the CHAANZ website.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* and the New Zealand National Ethics Advisory Committee – Kāhui Matatika o te Motu (NEAC). These published ethical guidelines have been developed to protect the interests of people who agree to participate in human research studies.

10. Further information and who can I contact?

The person you may need to contact will depend on the nature of your query. If you 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 (hdecs@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.

Opt-Out Form

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Registry Manager	Professor Geoff Strange
Coordinating Principal Investigator	Professor David Celermajer
Principal Investigator	Dr Clare O'Donnell, Paediatric and Adult Congenital Cardiologist

Please ONLY sign this form if you DO NOT want to participate in the Registry

This form is only to be completed if you do not want your information to be collected for the Registry

Declaration by Parent, Caregiver or Medical Decision-Maker of the Participant

1. I do not wish for them to participate in the Registry and I understand that my decision will not affect their future health care.
2. I have read the attached Participant Information Sheet.
3. I understand the purposes, procedures and risks of the research described in the project.
4. I have had an opportunity to ask questions and I am satisfied with the answers I have received.

Name of Participant (patient) (PLEASE PRINT) _____

Name of Parent, Caregiver or Medical Decision-Maker (& state relationship):

(PLEASE PRINT) _____

Signature _____ Date _____

Please return signed form to one of the following:

- You heart doctor or cardiology outpatients reception
- Study coordinator: ✉ CHAANZ@adhb.govt.nz
- Paediatric cardiology nurse specialist ✉ Paedcard.ns@adhb.govt.nz
- Adult congenital heart disease nurse specialist team: achdnurse@adhb.govt.nz

Or alternatively, complete the opt-out form on the study website (address and QR code): <https://www.chaanz.org.au/participant-information-nz>

