INFORMATION FOR PARTICIPANTS

We invite you to participate in the National Congenital Heart Disease Survey, also known as the Registry, coordinated by the Congenital Heart Alliance of Australia and New Zealand (CHAANZ). You can consent to participate yourself provided you are 18 years of age or older. If you are not 18 years of age yet, you can still participate with the consent of a parent or guardian. Before you do, it is important that you understand what is involved and what will be done with the information you provide. This information document contains answers to some of the questions you might have. At the end there is a section for you to confirm that you agree to participate. If you have any questions after reading this form, please contact your local general practitioner or heart specialist before signing the form.

What is a registry and why would you want to participate in one?

A Registry is a centralised data set. The National Congenital Heart Disease Survey is considered a vital first step to achieving a nationwide Congenital Heart Disease Registry. The Registry aim is to collect data from all people in Australia living with a previously diagnosed Congenital Heart Disease, also known as CHD, regardless of their current health status. Some people may not be aware that their condition is known as a Congenital Heart Disease condition. If you believe you may fit the congenital heart disease criteria, even if you have never had a heart operation, we ask that you still consider participating in this registry as you might fit the criteria for CHD. This first stage is considered vital to achieving the overall goal of an Australia and New Zealand Congenital Heart Disease Registry because it will help in collecting important information about children, adolescents and adults with CHD and their parents or carers.

Whose data is being collected in this registry?

This Registry is for people living with a previous diagnosis of CHD. Some examples of CHD that are included in the Registry are:

- Atrial Septal Defect (ASD)
- Ventricular Septal Defect (VSD)
- Patent Ductus Arteriosus
- Coarctation of the Aorta
- Aortic Valve Disease
- Pulmonary Valve Disease
- Mitral Valve Disease
- Atrio-ventricular septal defects (AVSD)
- Tetralogy of Fallot
- Transposition of the Great Vessels
- Pulmonary Atresia
- Single Ventricle pathology
- Cyanotic Congenital Disease

What information is being collected and why?

The Registry will contain basic information about you such as: name, date of birth, sex, post-code, state, phone number, email address, your ethnicity, country of birth and language spoken. Information that can identify you (identifiable information) will be stored in a secure and confidential manner in order to prevent you from being identified by anyone other than those directly involved with the Registry.

The Registry will also contain information about your heart condition, such as the name of your heart condition, if you have ever had a heart operation, the type and quality of care you have received, how your heart condition and treatment has influenced different aspects of your life, such as school, work, your relationships and your emotional wellbeing, and any financial costs. Being a part of the Registry will help us gather new information on what it is like to live with CHD and how CHD care could be improved. Ultimately, the information in the Registry will provide us with a better understanding of the experiences and needs of people with CHD from childhood to adulthood.

Who should fill in this form?

If you are the participant, you can consent online and agree to participate, provided you are aged 18 years or older. If you are under 18 years of age but can understand this information, you may consent, but we will also require your parent or guardian to consent with you. Whatever your age, please discuss registration with your family and don't hesitate to contact your local general practitioner or heart specialist if you have any questions. If you are the parent or guardian of a child who is not old enough to understand this form, and want your child's data included in the Registry, please consent via the 'Carer' option on the previous screen by selecting 'disagree' below first.

What do I have to do and where will my data go?

If you agree to take part in this project, you should read this information and consent form carefully. Once you have given consent, you will be invited to answer a list of questions online. You can do this at your own pace and in your own time, from anywhere you feel comfortable. The information you provide will be stored securely on a server. No unauthorised people will be able to gain access to any information. Only specific people within the Registry are given authority to access identifiable data.

Who will be able to access the data within the Registry?

Only specific people within the Registry are given authority to access identifiable data. Your data will be stored in a re-identifiable or coded form.

Selected data (in coded form) about all participants will be made available for research purposes or for health policy development purposes. This information will not identify you in any way.

The research purposes may involve publishing information on the incidence of CHD in Australia, on access to services in Australia, and on people's perceptions of CHD care. Examples of policy development purposes may include presentation of data to local or federal government to support policy changes or funding arrangements to hospitals. It is not know for certain what all purposes may be at this time, however each purpose will be governed by the overseeing ethics committee for this project.

How long will my data be kept?

The data in the Registry will be maintained indefinitely. If the Registry closes down or ceases to function, then all records held within the Registry will be stored in a secure setting by the national curator for a period of 7 years or less and then destroyed by the electronic destruction methods in place at that time.

How will my privacy be protected?

The Registry is a stored electronic record of a participant's personal and clinical experiences. This file will be subject to the regulations on data protection, at both state and national levels, and we will only transfer under national laws[1,2]. Any information we collect in the Registry that can identify you will be treated as confidential. We will not disclose identifiable information without your permission, except as required by law. All confidential information will be encrypted and stored securely, in accordance with state and national privacy laws.

If we publish any research or other documents based on data from the Registry, this research will never identify you by name.

Third parties wishing to have access to data in the Registry (such as researchers for publication purposes, or companies planning clinical trials or conducting research on new treatments) will only have access to information identifiable by a code. They will not be able to identify you using this coded information. Before any third party is granted access even to this coded information, they must have the approval of a Human Research Ethics Committee. The Registry will not be made available to employers, government departments, insurance companies or educational institution; however there may be occasions where coded information is prepared as described above and presented to third parties for policy change initiatives. Your information will remain confidential except in the case of a legal requirement to pass on personal information to authorised third parties. This requirement is standard and applies to information collected both in research and non-research

situations. Such requests to access information are rare; however we have an obligation to inform you of this possibility.

How can I update my data if it changes?

You can assist us by updating your data as and when it changes by logging into the website. Aspects which may change more frequently could be your contact details for example.

Who will have access to my medical records?

Nobody within this Registry will have access to your medical records. The only information that will be available in this Registry is information that you have provided and consented to its use by the Registry coordinators. In the event that the scope of this Registry extends, we will contact you and request additional consent to be able to access medical records. This consent would only be sought freely from you and you would be able to decline further participation if that was your decision.

How will I be identified in the Registry?

Your personal details (e.g. name, address,) have to be stored in the Registry so that we can contact you if required in the future. This information will be stored securely and your records will be assigned a unique code. If we transfer your data to any third party, including any other disease registry, we will not transfer any personal details, and your records will only be identifiable by the code. Only the coordinators of the Registry or a person explicitly appointed by the coordinators will be able to 'de-code' the data to get access to your personal details.

How will I benefit from participating?

The Registry is intended as a public service for the benefit of people living with a previous diagnosis of CHD. You will not receive any payment or any other financial benefit as a result of submitting your data to the Registry. The results of research facilitated by the Registry may have commercial potential one day, but this is not known at this time. However, you will not receive financial benefits from future commercial development. Nevertheless, there may be other benefits to participating, such as:

The data collected might provide benefits to other people with your heart condition, for example by discovering how many people in Australia have the same condition, or by providing information for researchers developing the best standards of care for people with your condition.

We will publish some general statistical information from the Registry on our website located at www.CHAANZ.org.au.

Do I have to participate in The Registry and can I withdraw if I change my mind?

Your participation in this project is completely voluntary. The Federal Privacy Act and associated principles and guidelines[1,2] grants you the right to rectify your data or withdraw from further participation in the Registry at any time. Should you wish to withdraw from the Registry you will be free to do so without having to provide any explanation. This will not have any effect on your care now or in the future. Once you withdraw your existing information will be deleted. To request withdrawal, please click on the ‘unsubscribe’ link. Your information will then be deleted and an email confirmation of this will be sent to you, if you have provided an email address to us. Once you withdraw you will not receive any further contact from the Registry organisers.

Who should I contact if I have any questions?

Your health and wellbeing is of utmost importance to us. Should you feel upset, worried or distressed at any time during your participation in this project, we strongly encourage you to contact your local general practitioner (GP) or heart specialist who will be able to provide assistance or referral to an appropriate support service.

This study has been approved by the Human Research Ethics Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the

Executive Officer on 02 9515 6766 and quote Protocol number X16-0217.

FOOTNOTES

[1]The Federal Privacy Act 1988 is Australia's national law for the protection of personal information when handled by Federal and ACT Government Agencies and many private sector organisations. Within the Act, eleven Information Privacy Principles have been developed to govern things such as the collection, storage, use and disclosure of personal information. The Principles also provide individuals with certain rights to access their personal information and correct any errors.

[2]National Health & Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (2007); The primary purpose "… is the protection of the welfare and the rights of participants in research…" and the secondary purpose "… is to facilitate research that is or will be of benefit to the researcher's community or to humankind..".

INFORMED CONSENT

If you are aged 18 years or older, you can fill in and sign the consent form below electronically. If you are under 18 years of age then you may also sign the consent form, and additionally your parent or guardian will need to provide their consent for your participation.