

## The Australian and New Zealand Fontan Registry

### What is the Australian and New Zealand Fontan Registry?

The Australian and New Zealand Fontan Registry is a database collecting health information on children and adults living in Australia and New Zealand who have had a Fontan procedure. This registry is one of the largest of its kind, and it will become a unique tool to help researchers and doctors improve the health of Fontan patients.

### Why do we need a Fontan Registry?

The Fontan operation has been performed for more than 40 years, but we still do not know the long-term health outcomes of this operation. Some patients deteriorate and require heart transplantation. The registry will be the best way to investigate the reasons for heart health deterioration as well as help doctors and scientists determine prevention practices.

### What information is collected and when?

Your/your child's health information will automatically be entered into a secure database. This will happen approximately one month after you have received this information statement. Additional information will be added each year by your/your child's specialist. Information will be collected from you/your child's medical records.

The data collected will include the following:

- Demographic data (e.g., name, date of birth, address, cardiologist etc.)
- Outcome related data (e.g., death; transplant, take-down)
- Pre-Fontan hospital data (e.g., previous operations, morphology, catheter and echocardiogram reports)
- Fontan operation data (e.g., date, type of operation, concomitant procedures, complications, medications, operation report and discharge summary)
- Follow-up data:
  - Reviews (e.g., clinical review letters),
  - Investigations (e.g., echocardiogram reports, cardiopulmonary exercise testing, blood tests),
  - Treatment (e.g., reinterventions, medications),
  - Complications (e.g., thromboembolic events, arrhythmias), and
  - Other factors influencing outcomes (e.g., pregnancy data, substance use)

The personal information is required to link your/your child's hospital stay with any further follow-up visits. This information allows us to collect information regarding your/your child's health care needs from other hospital information systems so we can identify how well you/your child has recovered. **No other personal information is included.**

## **SUB-STUDIES:**

### **Medicare and Pharmaceutical Benefits Scheme (PBS) Access**

#### **Optional Consent**

You will be required to fill out a consent form authorising the study access to your/your child's complete Medicare and Pharmaceutical Benefits Scheme (PBS) data as outlined on the back of the consent form. This consent form is optional. You do not have to fill out this form if you do not want to. Medicare collects information on your/your child's medical visits and procedures, and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The consent form is securely sent to the Department of Human Services who holds this information confidentially.

#### **How will we keep your/your child's information confidential?**

Any information collected for the Fontan Registry that can identify you/your child 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 you/your child will be permanently stored in a secure, password protected, electronic database. Only the researchers involved with this project at the Royal Children's Hospital and the Ethics Committee can have access to this information. Once the information is entered in to the Registry, it will be given a unique identification number. Only the research team can re-identify your/your child's information if it is necessary to do so.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access and correct the information we collect and store about you/your child. Please contact us if you would like to access this information.

#### **For how long will the information be stored after the completion of the project and why has this period been chosen?**

This is an ongoing registry, and that information will be stored indefinitely.

#### **How will your/your child's information be used and reported?**

Reports may be presented at conferences or submitted for publication in medical journals. You/your child will not be identified in any reports or presentations.

If you are interested in the research findings of the registry, summaries and latest news will be available on the Fontan website: [www.fontanregistry.com](http://www.fontanregistry.com)

#### **What are the risks and benefits?**

There are no risks to having your/your child's health information stored in The Australian and New Zealand Fontan Registry. We anticipate that information in Registry will be used to further medical knowledge and

improve patient care. There are no immediate benefits for you/your child in being a part of the registry, but it is possible you/your child may be offered opportunities to participate in new research studies or new therapies in the future.

### **What if I do not want me/my child to be enrolled in The Australian and New Zealand Fontan Registry?**

A decision on whether or not you wish to be involved in The Australian and New Zealand Fontan Registry does not affect your/your child's treatment or care in any way.

We understand that people may not want this information used for research purposes or may just change their mind. If you feel this way and **do not** want your/your child's details included in the Australian and New Zealand Fontan Registry please contact us:

**Email:** [info@fontanregistry.com](mailto:info@fontanregistry.com)

**Phone:** (03) 9936 6714

**Mail: Australian and New Zealand Fontan Registry**

Murdoch Children's Research Institute  
PO Box 1100  
Flemington Road  
Parkville Victoria 3052

#### **Update your information**

You can update your information by using the contact details above or by visiting our website [www.fontanregistry.com](http://www.fontanregistry.com) by clicking on the **Participate** tab.

***You may remove some or all of the details from The Australian and New Zealand Fontan Registry at any time***

#### **Receiving invitations from the Australian and New Zealand Fontan Registry to participate in future research projects**

From time to time, we may send you information about new research projects that may be suitable for you/your child. If you **do not** want to receive this information, please contact us so we do not send you anything.

Any information we send you about new research projects in the future, does not commit you/your child to taking part in them.

#### **Maintaining the integrity of the Fontan Registry**

In order to make sure that our Registry data is always up-to-date, researchers will monitor information about your health status from Commonwealth health agencies under strict confidentiality conditions. This information may also be used for research purposes.

**Melbourne  
Children's**

A world leader  
in child and  
adolescent  
health



The information stored in the ANZ Fontan Registry will be kept indefinitely as long as the registry exists. If the registry ceases to exist the information kept on the registry will be destroyed in a secure manner.

### **Who do I contact if I have concerns or complaints about the Australian and New Zealand Fontan Registry?**

If you have you have any questions, concerns or complaints about the Fontan Registry, please contact:

Research Nurse, Patricia Moreno: (03) 9936 6714

If you wish to discuss the project with someone not directly involved, in particular about matters concerning policies on the conduct of research or your child's rights as a participant, or you wish to make an independent complaint, please contact the Director, Research Development & Ethics, The Royal Children's Hospital on (03) 9345 5044.

This project has been reviewed and approved by The Royal Children's Hospital Human Research Ethics committee.

