

## APR Participant Information Sheet Parent/Guardian or Young person

### Royal North Shore Hospital

<b>Title</b>	Australasian Paediatric Endocrine Group Patient Registry (APR)
<b>Protocol Number</b>	2021/ETH01172
<b>Coordinating Principal Investigator</b>	A/Prof Andrew Biggin, Sydney Children's Hospital Network
<b>Local APR Contact</b>	Dr Kim Ramjan; P: 9463 2166; E: kim.ramjan@health.nsw.gov.au
<b>Location</b>	Royal North Shore Hospital; Northern Sydney Local Health District
<b>Research Governance Office/Complaints</b>	Research Governance Office, NSLHD. <b>Study Reference:</b> 2021/STE03449 P: 9926 4590 E: NSLHD-Research@health.nsw.gov.au

### 1 Introduction

This is an invitation for you to contribute information to the **Australasian Paediatric Endocrine Group Patient Registry (APR)**. The APR is a national database containing information from children and young people with endocrine conditions from across Australia and New Zealand.

**This Participant Information Sheet is for mature young people and the parent or guardian of the child (all ages).** This sheet explains what information about you or the child in your care is collected, and what will happen to this information. Knowing what is involved will help you decide if you want to allow your doctor to share the information with the registry.

### 2 What is the purpose of this research?

The APR has been designed as a data repository for all paediatric patients with endocrine conditions in Australia and New Zealand. The creation of the APR has been funded by a grant from the Australasian Paediatric Endocrine Group (APEG), a professional body of Paediatric Endocrinologists from Australia and New Zealand. Data from the registry will be made available to researchers for ethically approved projects, and will be used to optimise patient care in the future. Data may also be shared with international registries in the future to facilitate global monitoring of endocrine conditions.

### 3 What does participation in this research involve?

Please read this information carefully and ask any questions you may have. If you decide you want to allow you/your child's information to be included in the registry, you will be asked to sign the parental consent form. Young people are encouraged to countersign the consent form in the space provided.

By signing the consent form, you are telling us that you:

- Understand what you have read
- Consent to the child taking part in the research project
- Consent to the use of the child's personal and health information as described.

Your endocrine doctor will enter information collected during your visits, including you/your child's endocrine and other diagnoses, demographic information, their date of birth, measurements such as height and weight, the results of any blood or other diagnostic tests, relevant variants identified during genetic testing, and other clinical notes related to you/your child's condition.

**If you give permission for your doctor to use your/your child's name, hospital number and contact details in the registry, they will be able to search your records and enter details about you or your child during the consultation. It will also mean they can use your hospital number at later appointments to search for and update your registry record. This will ensure the registry stays accurate and up to date.**

The only people who will have access to this identifying information will be:

- Approved clinical and research staff **at your hospital**
- The Coordinating Principal Investigator, and the Database Administrator at the Children's Hospital at Westmead.

Approved staff at your hospital may use your contact details to search for your/your child's records, and to add additional information during or after your appointments. The Coordinating Principal Investigator and Database Administrator will have access to your identifiable data for database maintenance purposes only.

Your data will be de-identified before it is sent to researchers, and they will be required to keep the data confidential and refrain from attempting to re-identify you.

#### **4 Future studies**

On the consent form, you will also be asked if you are willing to be contacted by your hospital doctor, or electronically by the APR with invitations to participate in other research in the future. This might involve you and/or your child completing surveys at home, or it might involve extra clinic visits. **These projects will always be optional** – even if you agree to be contacted, you will not have to say yes or fill out any surveys unless you want to. You can also change your mind later and ask not to be contacted anymore. Just give your local APR contact a call and they can help you manage your preferences.

#### **5 Do I or my child have be part of the registry?**

While the aim of a registry is to have as complete a dataset as possible, it is important to remember that **participation in any research project is voluntary**. You/your child do not have to take part to receive treatment at this hospital. You/your child will be treated with the same care regardless of whether you/they take part. If you decide that you/they can take part now, and later change your mind, you are free to withdraw from the project at any stage. You/your child will also be contacted to confirm or deny consent to keep their data in the registry once you or they turn 18.

#### **6 What are the possible benefits of taking part?**

Registries often do not benefit the people contributing data directly. However, they provide an important source of information which can be used for research that benefits similar people in the future. If you want to know more about the research that comes out of the registry, visit <https://apeg.org.au/subcommittees/registry/>.

#### **7 How will the privacy of my/my child's information be protected?**

The APR is a registry of health information. You/your child's health information in the registry is protected by the *Health Records and Information Privacy Act (2002, NSW)*, as well as the laws and regulations specific to the state or territory in which you live. These laws restrict what can be done with this data, and who it can be shared with.

We are doing everything we can to ensure the data in the registry is kept confidential and secure in accordance with our obligations under this legislation. This is how we will ensure your data is secure:

- Access to your identifying information is restricted to those who need it:
  - Investigators at your hospital (who already have access to your medical records and are bound by your hospital's confidentiality and privacy regulations), and
  - The Coordinating Principal Investigator (A/Prof Andrew Biggin) and his nominated Database Administrator at the Sydney Children's Hospital Network, who will have access for data management procedures only.
- Individual user management – all staff will need to apply for access to view and enter data, and will be given a secure individual login so their contributions can be tracked.
- Data is encrypted, and is stored securely on servers at the University of Sydney designed for highly sensitive data.
- Researchers are required to apply to for access to de-identified data and, if approved, must sign an agreement specifying the terms of use.

It is anticipated that the results of projects conducted using APR data will be published and presented in a variety of forums. If you or your child have a very rare condition (eg. a genetic diagnosis known to affect fewer than 10-100 people), it is possible that clinicians familiar with your case will recognise your information in published reports. Unless you have previously agreed to share this information publicly, it is very unlikely that your identity would be recognised by anyone outside the team providing you medical care. Under all circumstances, information which would directly identify you (such as your name, date of birth, or images) will never be presented or published without your express written permission.

If, after reading this information sheet you are still concerned about your personal information, you can opt to send *de-identified data only* to the APR on the consent form. Identifying information such as your/your child's name, address, and hospital identification number will be replaced by a code, which will be used by your hospital doctor to locate your records. **If you choose this option, your doctor will not be able to view or update your registry record during your visit.** Your information will be uploaded later and made available for approved research projects.

## 8 What if I want to take my/my child's data out of the registry later on?

You can change your preferences at any time. If you/your child later decide to remove your/their data from the registry, please ask one of the clinical staff for an APR registry opt out form. Once a child becomes a legal adult, only they can ask to remove their data. New adults will be sent an invitation to re-affirm consent around their 18<sup>th</sup> birthday.

## 9 What happens when the research project ends?

The intention is for this registry to continue for as long as ongoing nation-wide investigations are required, which may be indefinitely. In the event a decision is made to close the APR, the coordinating principal investigator will retain a copy of the dataset for a minimum of 15 years after the youngest participant has turned 18. Medical records will be retained at your hospital for the duration prescribed by their data retention policies. Consult your hospital for more information.

## 10 Can I see my/my child's data? What about research results?

In accordance with relevant Australian and New Zealand national, state and territory privacy and other relevant laws, you have the right to request access to your/your child's medical records. You also have the right to request that any information with which you disagree be corrected. Please ask your treating doctor if you would like to access this information. If you would like to know which information is kept in the registry, you can find a copy of the data dictionary on the APR website. This website will also be updated whenever research using the data is presented or published. Please get in touch if you would like to view a copy of this research.

## 11 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This registry and all associated research will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

In Australia, the ethical aspects of this research project have been approved by the HREC of The Sydney Children’s Hospital Network under the National Mutual Acceptance scheme. This approval has also been recognised by the Northern Sydney Local Health District HREC.

This project has also received site specific approval from the NSLHD Research Governance Office.

## 12 Further information and who to contact

For more information about the APR, visit the website at <https://apeg.org.au/subcommittees/registry/> where you will find details about the governance of the registry, links to participant materials (including opt out forms), and updates about research arising from the registry. If you have any questions, you can get in touch with your local APR contact (listed on page 1) or submit an enquiry through the website. You can also ask your treating doctor to walk you through the APR forms to see what data can be entered and/or omitted, at your preference.

If you have any questions or concerns about the project that you would like answered anonymously, you can contact the SCHN Ethics office at SCHN-ethics@health.nsw.gov.au or call (02) 9845 1253.

### Reviewing HREC approving this research and HREC Executive Officer details

<b>Reviewing HREC</b>	Sydney Children’s Hospital Network HREC	<b>Executive Officer</b>	Asra Gholami
<b>Phone</b>	(02) 9845 3066	<b>Email</b>	Asra.gholami@health.nsw.gov.au

### Local HREC/Governance Office contact

<b>Name</b>	Research Governance Manager	<b>Email</b>	NSLHD-Research@health.nsw.gov.au
<b>Phone</b>	02 9926 4590	<b>Reference</b>	2021/STE03449

**This information sheet is for you to keep.**