Participant

**Australia and New Zealand Pulmonary Hypertension Patient Registry**

**Principle Investigator: Associate Professor Robert Weintraub**

**HREC number 2019.024**

Thank you for taking the time to read this **Participant Information Statement and Consent Form**. We would like to invite you to participate in a research project that is explained below. This document is 6 pages long. Please make sure you have all the pages. These pages tell you about the research project. It explains to you clearly and openly all the steps and procedures of the project. The information is to help you decide whether or not you would like to be included in the registry. Please read this Information Statement carefully.

Before you decide if you want to take part or not, you can ask us any questions about the project. You may want to talk about the project with your family, friends or health care worker.

**Important things you need to know**

* It is your choice whether or not you are included in the registry. You do not have to agree if you do not want to. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.
* If you decide you do not want to take part, it will not affect the treatment and care that you receives at the hospital.

If you would like to be included in the registry, please sign the consent form at the end of this information statement. By signing the consent form you are telling us that you:

* understand what you have read
* had a chance to ask questions and received satisfactory answers
* consent to you taking part in the project

We will give you a copy of this information and consent form to keep.

1. **What is the research project about?**

We are inviting you to take part in this registry, which will help us learn more about the health of children and adults with Pulmonary Arterial Hypertension (PAH). This is a complex health problem, where there is abnormally high pressure in the blood vessels between the heart and the lungs.

The custodian of the Australia and New Zealand Pulmonary Hypertension Patient Registry is the Pulmonary Hypertension Society of Australia and New Zealand. We hope the registry helps us to learn more about the health of children and adults with PAH by collecting basic information about your health. We will use this information to better understand the incidence of PAH (how often PAH happens each year in Australia and New Zealand), clinical features, and outcomes among children with different types of PAH. This information may help guide better management of patients with PAH in the future.

1. **Who is funding this research project?**

The project will be funded by the Pulmonary Hypertension Society of Australia and New Zealand (PHSANZ).

1. **Why am I asked to take part?**

We are inviting you to be part of this study because you have been diagnosed with PAH (Pulmonary Arterial Hypertension).

1. **What do I need to do to do in this research project?**

If you decide you would like to be part of this project, your doctor or member of the research team will explain the project and then ask you to sign the consent form, after reading and understanding this information.

After you have signed the form, information regarding your information will be entered into the database and updated, roughly every 3 – 6 months. Information is collected from the latest clinic visit and may include: basic information (age, gender, and race), disease severity, test results (ultrasounds of the heart, x-rays/scans, heart monitoring, exercise tests, 6 Minute Walk test, etc), medical treatment and any other medical conditions at that time. All of the information collected will be from records from your usual care. No extra hospital visits or tests are needed and there is no change to your usual treatment.

You may change to a different pulmonary hypertension team when reaching 18 years of age and you will be re-consented for the registry as an adult.

All information will be entered by the Pulmonary Hypertension research team at the hospital where you are managed. If you agree to be a part of this study, then the “identifiable” information such as your name will only be visible to research team at your treating hospital and the paediatric- and adult database manager of the PHSANZ registry.

1. **Can I withdraw from the project?**

You can stop taking part in the project at any time. You just need to tell us so. You do not need to tell us the reason why. If you leave the project we will use any information already collected unless you tell us not to.

1. **What are the possible benefits for me and other people in the future?**

You will not receive any direct benefit from being part of this project. The registry should allow for better management of patients with PAH in the future.

1. **What are the possible risks, side-effects, discomforts and/or inconveniences?**

There are no expected risks, side-effects or discomforts associated by taking part in this study. No extra tests or visits are needed as information is part of standard clinical care.

1. **What will be done to make sure my information is confidential?**

Any information obtained in connection with this research project that can identify you will remain confidential. We will use your information only for this research project.

Health information and some information which may identify you will be permanently stored in a secure, password protected, electronic national registry database. We can disclose the information about you, only with your permission, except as required by law.

Consent forms will be stored securely in a locked cupboard in the research office at your hospital

Users consisting of a research team at each hospital will be assigned a username and password and will only be able to see their patients.

If the registry is discontinued all stored information will be destroyed.

The following people may access identifiable information collected as part of this research project:

* + The research team / medical team involved with this project at your current treating hospital
  + The paediatric- and adult database manager of the PHSANZ
  + The Human Research Ethics Committee at the hospital you receives treatment

1. **Will we be informed of the results when the research project is finished**

The outcomes of this project will be presented at appropriate conferences and in professional journals. Any information presented will be in summarized format and in no way you could be identified. Therefore, we will only present information about the whole study group, not individuals.

If you would like more information about the project or if you need to speak to a member of the research team in an emergency please contact:

|  |  |
| --- | --- |
| **Name:** | Associate Professor Robert Weintraub |
| **Contact telephone:** | 03 9345 5718 |

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| --- |
| If you have any concerns and/or complaints about the project, the way it is being conducted or your rights as a research participant, and would like to speak to someone independent of the project, please contact: Director, Research Ethics & Governance, The Royal Children’s Hospital Melbourne on telephone: (03) 9345 5044. |

**CONSENT FORM**

**Australia and New Zealand Pulmonary Hypertension Patient Registry**

**HREC number 2019.024**

* I acknowledge that I have read the Participant Information Sheet, which explains why I have been asked to participate.
* I believe I understand the purpose, extent and possible risks of my involvement in this project.
* I voluntarily consent to take part in this research project.
* Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.
* I understand that this project has been approved by a Hospital Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research.
* I acknowledge receipt of a signed copy of this Consent Form and the Participant Information Sheet.

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| --- | --- | --- | --- | --- |
| Participant Name |  | Participant signature |  | Date |
|  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Witness Name |  | Witness Signature |  | Date |

Declaration by researcher: I have explained the project to the participant who has signed above, and believe that they understand the purpose, extent and possible risks of their involvement in this project.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Research Team Member Name |  | Research Team Member Signature |  | Date |

***Note: All parties signing the Consent Form must date their own signature.***

**REVOCATION OF CONSENT**

**Australia and New Zealand Pulmonary Hypertension Patient Registry**

I hereby wish to **WITHDRAW** my consent to participate in the Registry described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with The Royal Children’s Hospital

Signature Date

Please PRINT Name

The section for Revocation of Consent should be forwarded to:

Associate Professor Robert Weintraub

Cardiology Department

The Royal Children’s Hospital

50 Flemington Road

Parkville

VIC 3052