



We would like to use your information for a Paediatric Spine Condition Registry

Thank you for taking the time to read this information sheet. We are inviting you to take part in a research project about spinal conditions, including scoliosis. Our files indicate that your medical records may provide useful data for this Paediatric Spine Condition Registry.

The registry is a way of collecting information about people with spinal conditions such as scoliosis. Our aim is to progress our knowledge of paediatric spinal conditions, rather than to provide medical treatment for paediatric spinal conditions. This means that the study will not directly benefit your child. Possible benefits may lead to a better understanding of paediatric spinal conditions and effectiveness of treatments, leading to an improved standard of treatment for children and adults with these conditions.

We will use your information for this Paediatric Spine Condition Registry **unless you tell us not to.**

The rest of this letter gives you more information about the registry. It also tells you how you can opt out of the registry if you want to.

What information will we give the registry?

We would like to give the registry your re-identifiable routine clinical care information. Your study-related information that will be entered into the research database will be assigned an ID code in order to protect your identity. A list will be kept that links your identifiable information, such as your initials and date of birth, to your unique ID code. However, this list will be kept on a password-protected computer at your treating hospital and access will be restricted to the study team. The information that will be given to the registry includes:

- Health information such as your past medical history and demographic information such as your age and sex
- Clinical assessments including trunk measurements
- Clinical photographs
- Pulmonary function test results
- Radiographs
- Questionnaires that are part of your routine clinical care

We will get your information from:

- Your medical records
- questionnaires you complete during clinic visits

Why does the registry need this information?

The aim of the registry is to find out more information about paediatric spinal conditions such as scoliosis. We hope that it will help us to understand:

- what treatments work best for people with a paediatric spinal condition?
- what are the long-term outcomes for people with a paediatric spinal condition who have surgery?
- what are the long-term outcomes for people with a paediatric spinal condition who have do not surgery?
- how can health services provide better care for people with a paediatric spinal condition?

The registry will use this information to understand the above questions and improve the future care of patients with a spinal condition.

Who will have access to your information?

The following people and organisations – also called ‘third parties’ – will have access to the registry

- The Royal Children’s Hospital, Cabrini Health or Epworth Hospital (depending on where you are treated)
- Murdoch Children’s Research Institute, as part of ‘Melbourne Children’s’
- Spine and Scoliosis Research Associates Australia (SSRAA)

As mentioned previously, your study-related information that will be entered into the research database will be assigned an ID code in order to protect your identity. A list will be kept that links your identifiable information, such as your initials and date of birth, to your unique ID code. However, this list will be kept on a password-protected computer at your treating hospital and access will be restricted to the study team. SSRAA staff that are not part of your treating hospital’s study team will only be able to access de-identified information and will not be able to link you back to your identifying information.

How will the registry store your information?

Your information will be stored on the Spine and Scoliosis Research Associates Australia Ltd (SSRAA) database on a password protected server housed at 33 The Avenue, Windsor, Vic 3181 Australia. Because the information will be stored in Australia, it will be protected by Australian privacy laws.

What are the risks?

The main risk to you is a potential breach of privacy. However, as we have explained, we will protect your privacy by assigning your information an ID code, for re-identification purposes, that can only be accessible by the study team. We need to be able to re-identify you as we will be following your care over a number of years, including whether further treatments for the same condition are required into adulthood. We will collect information at different time points.

Ethics

The registry has been approved by The Royal Children's Hospital Human Research Ethics Committee.

What happens next?

a. If you agree to share your information

If you are happy for us to share your information you do not have to do anything. We will simply input your information to the registry.

The registry will store your information for an unlimited period.

You will not be able to remove your information from the registry if you choose to withdraw, however we will stop collecting any further information about you if you decide you no longer want to be part of the registry.

b. If you do not agree to share your information

If you do not want us to share your information with the registry, please contact us **within four weeks** of the date of this information sheet. That is, the [date]

You can get in touch with us several ways:

Email: Send the SSRAA Research Coordinator an email using research.coordinator@spineandscoliosis.org

Phone: 03 9573 9691

Do you have any questions?

Please get in touch if you have any questions about this letter. You can contact the SSRAA Research Coordinator on 03 9573 9691. You can also email them on research.coordinator@spineandscoliosis.org.

Thank you very much for your time.

Kind regards

A handwritten signature in dark ink, appearing to read 'A. Buckland', is positioned above the printed name and title.

Prof Aaron Buckland
Orthopaedic Surgeon - The Royal Children's Hospital, Melbourne
Chairman & Director – Spine and Scoliosis Research Associates Australia Ltd

Opt Out Form

HREC project number: 71942

Name of registry Paediatric Spine Condition Registry

I **do not** consent for you to pass on my information to the Paediatric Spine Condition Registry run by Spine and Scoliosis Research Associates Australia

Participant's Name

Participant's Signature

Date

You can contact the Director of Research Ethics & Governance at The Royal Children's Hospital Melbourne if you:

- have any concerns or complaints about the project
- are worried about your rights as a research participant
- would like to speak to someone independent of the project.

The Director can be contacted by telephone on (03) 9345 5044.