



## **We would like to use your information for Adult Spinal Surgery Outcomes 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, requiring surgical intervention. Our files indicate that your medical records may provide useful data for this Adult Spinal Surgery Outcomes Registry.

The registry is a way of collecting information about people with spinal conditions who require surgery. Our aim is to progress our knowledge of the surgical treatment of spinal conditions, rather than to provide medical treatment for spinal conditions. This means that the study will not directly benefit you. Possible benefits may lead to a better understanding of adult spinal conditions and effectiveness of treatments, leading to an improved standard of treatment for adults with these conditions.

**We will use your information** for this Adult Spinal Surgery Outcomes 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, Medicare number to your unique ID code. However, this list will be kept on a password-protected computer at your treating doctor's office or 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
- Radiology results, blood test results
- Clinical details regarding your surgery technique, implants and biologic use
- Complications associated with your surgical treatment
- Questionnaires that are part of your routine clinical care

We will get your information from:

- Your medical records at the treating surgeon's office or treating hospital
- 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 surgical treatment of adult spinal conditions. We hope that it will help us to understand:

- what surgical treatments work best for people with a adult spinal condition?
- what are the long-term outcomes for people with a adult spinal condition who have surgery?
- how can health services provide better care for people with a adult 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:

- Spine and Scoliosis Research Associates Australia (SSRAA)

As mentioned previously, your study-related information that will be entered into the research database maintained by Spine and Scoliosis Research Associates Australia Ltd. This database is password encrypted and housed on a secure server within Australia. You, and your surgery will be assigned an ID code in order to allow assessment of procedures individually, in the event that some people may have more than one spinal surgery over their lifetime. Your personal information will be accessible only by SSRAA staff who will monitor the data for accuracy and completeness, in addition to your treating surgeon’s office, or treating hospital.

## 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, 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 Ramsay Health 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 a period of 25 years.

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  
at research.coordinator@spineandscoliosis.org

**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](mailto:research.coordinator@spineandscoliosis.org)

Thank you very much for your time.

Kind regards

**Prof Aaron J. Buckland**

Orthopaedic Surgeon – Melbourne Orthopaedic Group & Royal Children's Hospital, Melbourne  
Chairman & Director – Spine and Scoliosis Research Associates Australia Ltd

## Opt Out Form

**HREC project number:** 9011

**Name of registry** Adult Spinal Surgery Outcomes Registry

I **do not** consent for you to pass on my information to the Adult Spinal Surgery Outcomes Registry run by Spine and Scoliosis Research Associates Australia Ltd.

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Participant's Name

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Participant's Signature

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Date