

What is the purpose of this research?

The information from the Australian Spine Registry will provide an important resource for surgeons who perform spine surgery, our hospitals and our community. The Australian Spine Registry will tell us about:

- the frequency of spine surgery in our community;
- the usefulness, safety and results of different surgical approaches and different implantable devices;
- the factors that predict favourable and unfavourable surgical outcomes in both the short and longer term;
- the variety of care provided for people undergoing spine surgery in our community, and how it compares to best practice internationally.

What Information is Collected?

We will collect:

- your name, age, address and contact details;
- the name of your surgeon and the hospital where you have your surgery;
- information relating to your surgery including any complications that may have been experienced;
- some information about any other illnesses you may have, or medications you may be taking, which could influence your care;
- the outcome of your surgery after 6, 12 and 24 months.

Questions or Concerns?

If you would like more information about this project, please contact:

Mx XXXXX XXXXX

Orthopaedic Spine
Surgeon Principal Investigator

 **03 9xxx xxxx**

Dr Esther Apos

Project Coordinator
Monash University

 **03 9903 xxxx**

 **1800 XXX XXX (Free call)**

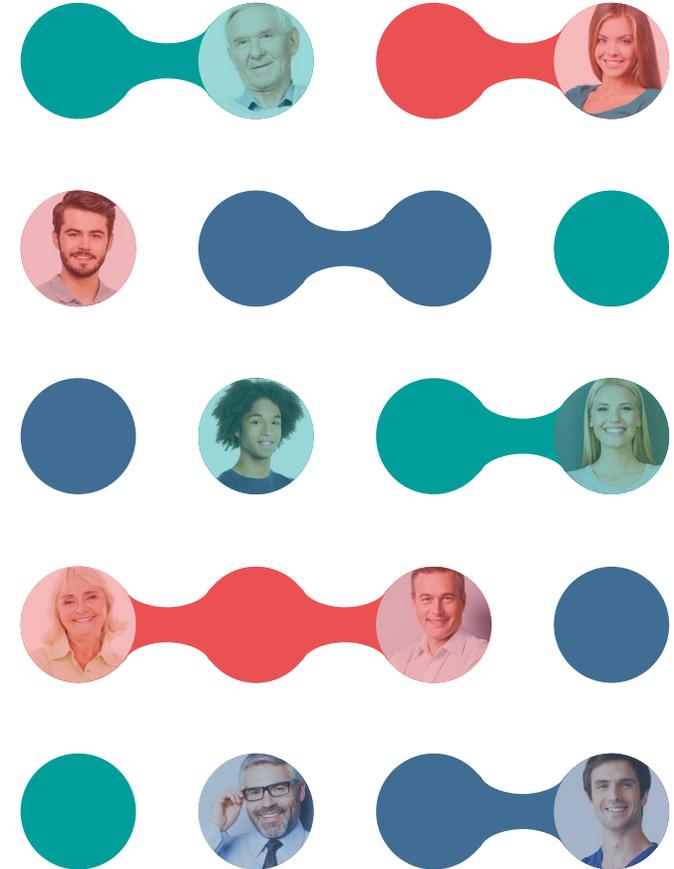
or visit:

 **www.spineregistry.org.au**

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact the Manager, Melbourne Health Human Research Ethic Committee on (03) 9342 8530.



Information for Patients and Families



An initiative of the Spine Society
of Australia in conjunction with

 **MONASH University**
Medicine, Nursing and Health Sciences



Introduction

We are developing and piloting an Australian Spine Registry to improve the quality of care provided to individuals undergoing spine surgery. We would like to collect data on care provided to all patients who undergo spinal surgery at XXX Hospital.

This information brochure is intended for you, the patient, and explains what is involved. This will help you make a decision as to whether or not to take part in the registry.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, a friend or your local health worker.

This is an opt-out registry. That means that your details will automatically be included on the registry unless you let us know that you do not want to participate. You can opt-out at any time by contacting us on **Free call 1800 XXX XXX** or by emailing XXXXXXX@monash.edu.

Your care will not be affected if you decide to opt-out.

What does participation in this research project involve?

If you are happy to participate, you do not need to do anything. Your surgeon and their staff will collect most of the information either directly from you when you have appointments or from your medical record.

At 6, 12 and 24 months post-surgery, two short questionnaires about your recovery will be sent to you by email or regular mail from the Australian Spine Registry. These should only take about 5 minutes to complete. You may also receive a phone call.

We collect your details to help us keep in contact with you. If you do not want us to keep these details or do not want to participate in the registry, please tell your surgeon or let us know by telephoning **Free Call 1800 XXX XXX**.

This registry is being piloted across a number of hospitals in Australia. We expect to have approximately 1000 registrations per year, with approximately 200 from XXX Hospital.

What are the possible benefits?

The Registry allows your surgeon to obtain extra information about your progress after surgery by reviewing your questionnaires.

You may also, benefit indirectly from findings obtained from the registry and you will be helping those who undergo spine surgery in the future. Specifically, a major benefit from the registry will be the ability to monitor quality of care to maximize the benefit to individuals undergoing spine surgery in the future.

What are the possible risks?

Registry staff directly involved in collection of data will have access to your medical record. Privacy of patient information is taken very seriously. Patient information is safeguarded by the State and Commonwealth privacy laws and registry staff must comply with these strict privacy principles.

Monash University has expertise safeguarding private information as they supervise and run numerous registries. All data are stored on a computer server within a high-security health research environment. Registry staff will not release your identifiable information to any person or organization outside the registry. No report or publication will contain any identifying information about you.

Is this research project approved?

This project is an initiative of the Spine Society of Australia. Project administration and data/information security is coordinated and administered by the Department of Epidemiology and Preventative Medicine Registries Unit, Monash University.

This research project has been approved by the Human Research Ethics Committee of Melbourne Health (HREC Project Number HREC/16/MH/93).

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) (updated May 2015) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Who has access to your information?

Your surgeon will have access to the information concerning their participating patients to assist ongoing care and provide feedback on progress. Monash University registry staff have access to enough information to allow functioning of the registry.

Registry staff will not release any of your identifiable information to any person or organization outside the registry such as government agencies, insurance companies or court officials. Any reports or publications provided to anyone other than your treating surgeon will not contain your identifiable data.

Any future research undertaken using this registry data will require approval by a Human Research Ethics Committee. In consenting to having this information collected, you will be agreeing to the use of this information for research which aims to investigate quality of care issues relating to spine surgery.

Do I have to take part in this research project?

You do not have to take part in this research project. Participation in any research is voluntary. If you decide to take part and later change your mind, you are free to withdraw from the registry at any stage. Your decision whether to take part or not, or to take part and then withdraw, will not affect your relationship with your surgeon or XXX Hospital.

Can I access research information kept about me?

Under Commonwealth and State privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact your surgeon or the project coordinator named at the end of this document if you would like to access your information and your results.