



<b>Study Title</b>	<b>Database of Lower Limb Disorders</b>
<b>Principal Investigators</b>	Prof Leo Pinczewski, Dr Michael O'Sullivan, A/Prof Justin Roe, Dr Matt Lyons, Dr Benjamin Gooden, Dr David Carmody, Dr Phil Huang, Dr Keran Sundaraj Dr Lucy Salmon
<b>Location</b>	North Sydney Orthopaedic and Sports Medicine Centre, The Mater Clinic, Sydney

### Part 1 What does my participation involve?

#### 1 Introduction

You are invited to participate in a database of lower limb disorders which systemically monitors the outcomes of lower limb surgery performed by the investigating surgeons listed above.

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

The purpose of this database is to systematically monitor the outcome of lower limb surgery that is performed by the investigating surgeons for the following purposes:

- Quality Assurance: this means systematically monitoring the types of treatment and the results of the treatment that our patients receive. This is to ensure that you and other patients having orthopaedic surgery are receiving the best and most current standard of care.
- Enable identification of people who might be eligible for participation in future clinical research/trials. In this case we will contact you and invite further participation which will be strictly voluntary.

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

If you agree to participate in this study, you will be asked to confirm your consent via the online form sent by our staff or by email or post as described in Part 3 below. Your participation in this study involves the completion of questionnaires regarding your lower limb symptoms and general health before, and at 6 and 12 months after surgery. We may also invite you to complete questionnaires over longer periods. These questionnaires may be completed online or using a paper copy via mail. You do NOT need to attend for any assessments or undergo further tests. At each stage participation is voluntary. Additionally, information relating to your name, demographics and details of the surgical procedure will be added to the database. In addition, the researchers would like to have access to your medical records to obtain relevant information such as your relevant clinical and operative details and contact information relevant to the study. This information is identifiable by your name. This information is only accessible by the surgeons and their research staff.

#### 4 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with NSOSMC.

#### 5 What are the possible risks and benefits of taking part?

There will be no clear benefit to you from your participation in this research. There are no foreseeable risks associated with participation.

### Part 2 How is the research project being conducted?

#### 6 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Data is stored on a secure medical server, accessible only by your surgeons and research staff.

Your surgeon is also participating in a project which is being run by the Australian Orthopaedic Association National Joint Replacement Registry (the Registry) which involves routine collection of patient reported outcome measures before and after surgery. As we do not want to ask you to complete the same information twice, we request your consent to share the information you provide with the Registry via a secure file transfer system. This will generate

valuable and important information on how well your operation has gone and how this varies compared to other participants across Australia. Using this information will help the Registry to work out what types of joint replacement work best.

Your information will only be used for the purpose of these research projects and it will only be disclosed with your permission, except as required by law. Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or New South Wales privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information. Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

### **7 Who is organising and funding the research?**

This research project is being conducted and funded by the investigating surgeons with the staff support from the Mater Hospital, and research support from The Friends of the Mater Foundation.

### **8 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). The ethical aspects of this research project have been approved by the HREC of St Vincent's Human Research Ethics Committee. This project 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.

### **9 Further information and who to contact**

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project you can contact the Coordinating Study Investigator, Dr Lucy Salmon on 02 9409 0500, [lsalmon@nsosmc.com.au](mailto:lsalmon@nsosmc.com.au), or your treating surgeon. 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 St Vincent's Hospital HREC on 02 8382 4960.

## **Part 3 Please confirm your participation in Database of Lower Limb Disorders**

Please confirm your consent to participation in this study. By providing consent you declare

- I have read this Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes and procedures of the research described in the project.
- I consent to take part in the research & the use of your personal and health information as described.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.
- I understand that I will be given a copy of this document to keep

#### **TO CONSENT VIA EMAIL:**

Copy and paste Part 3 above and send to [research@nsosmc.com.au](mailto:research@nsosmc.com.au) with your name

#### **TO CONSENT VIA OUR WEBPAGE**

Click on the link sent to you by email by our staff

#### **TO CONSENT VIA POST**

Send this page to Dr Lucy Salmon, NSOSMC Suite 2 The Mater Clinic, 3 Gillies St, Wollstonecraft NSW 2065.

Name of Participant (please print) \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_