



Participant Information Statement for Opt-Out Consent

St Vincent's Hospital (Melbourne)

The St. Vincent's Melbourne Arthroplasty Outcomes Registry Patient Information Sheet

Principle Investigators: Assoc. Professor Michelle Dowsey, Professor Peter Choong
Protocol Number: HREC-A 100/14

1. Introduction

You have consented to undergo a knee or hip replacement at St. Vincent's Hospital (Melbourne) and will be included in the St. Vincent's Melbourne Arthroplasty Outcomes (SMART) research Registry unless you request to 'opt-out'. Participation in this research registry is voluntary and if you don't wish to take part, you don't have to. **Please read this entire document carefully.**

The Department of Orthopaedics and University of Melbourne Department of Surgery, St. Vincent's Hospital (Melbourne), are conducting a population-based registry that aims to improve the quality of care provided to patients undergoing hip or knee replacement. In order to improve the quality of care for joint replacement surgery, we need to know what factors contribute to both a successful outcome and complications. To achieve this, The SMART Registry has been set up to collect information in order to monitor the treatment provided to patients, to track any complications and to better understand the outcome of patients undergoing hip and knee replacement surgery. This information will help us to inform patients and clinicians about the effectiveness and appropriateness of joint replacement surgery.

We ask that you participate in the SMART Registry simply by allowing us to document information relevant to you, your procedure and its outcomes

2. What information is needed?

The information we intend to collect includes your full name, date of birth, contact information, the reason for your surgery, and basic information that is directly related to your health status, before, during and after your joint replacement. This information is recorded in the Registry as we need to be able to link back with your medical records to follow-up on your health status after your surgery. The information collected does not exceed that which is already stored in your medical record. You may also be asked to complete a brief survey on your health state prior to your surgery and 12 months after surgery. This will be sent to you with a reply paid envelope to complete and return. You do not have to complete the survey to participate in the registry.

3. How is information collected?

You are not required to do anything to participate in the registry. If you do not contact us to withdraw from the Registry, a St. Vincent's SMART Registry staff member will access your medical records to collect information about you, your surgery and follow-up. This information will be entered onto a secure database that is only accessible by a St. Vincent's staff member directly involved in entering data on the Registry. This information will also be linked with hospital administration data and supplied to the Australian Institute of Health and Wellbeing (AIHW) in a secure and confidential manner to link your data with health datasets such as hospital or Medicare (e.g., Medicare Benefits Schedule and Pharmaceutical Benefits Schedule) for the purposes of checking your access of other health services and following up your health outcomes.

4. How is this information stored?

Registry data will be stored and maintained securely by the Department of Orthopaedics on a database at St. Vincent's Hospital (Melbourne). The database is only installed on computers in the Orthopaedic Department and access is restricted to SMART Registry Investigators and staff members directly involved with entering data on the database. A de-identified copy of your Registry data and linked health records will be stored on a secure remote platform, SURE (The Secure Unified Research Environment). Only approved Investigators can access this data. Please note the Registry will retain the collected information for an indefinite period to track the long-term outcomes of joint replacement surgery.

5. How will the information be used?

We will produce general reports on joint replacement outcomes for public, government, clinical and academic audiences. These reports will help to inform the community about the effectiveness and appropriateness of joint

replacement surgery. **No publication or report will ever contain any identifying information about you.** Researchers may use unidentified group data for future research projects that have been approved by a Human Research Ethics Committee. By consenting to having your information stored in the Registry, you agree that the information collected may be used for further research relating to the standard of care provided for patients undergoing joint replacement surgery.

6. Confidentiality and Privacy

All information obtained for the purpose of the Registry that can identify you will be treated as confidential and stored securely. Identifying information is protected by privacy legislation and would only be disclosed with your permission. All data will be safeguarded by State and Commonwealth laws. We will ensure that our security measures conform to national standards to prevent unauthorized access. Access is limited to approved Registry Staff. Requests for registry data by other researchers will be approved by a Human Research Ethics Committee and all identifying information will be removed prior to data transfer.

7. What are the potential risks and benefits of taking part?

Registry staff who will have access to your medical records at St. Vincent's Hospital, must comply with very strict privacy principles. Having your information stored in the Registry will not affect any future health care or your relationship with your treating surgeons and clinical staff. Surgeons and clinical staff involved in your care will not be informed that your information has been recorded on the Registry.

8. Is it compulsory to Participate?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to allow your information to be recorded in the Registry but later change your mind, you are free to 'opt-out' from the Registry at any stage by contacting us directly. This will not affect your relationship with those treating you or your relationship with St Vincent's Hospital (Melbourne).

If you do not want to your information included in the Registry, please contact the SMART Registry Coordinator by phone, email or mailing address below. If you do contact us to 'opt-out' of the Registry, we may ask from some identifying information, so we can accurately remove details from our records.

Telephone:	03 9231 3028
Email:	SMARTRegistry@svha.org.au
Postal Address:	St. Vincent's Hospital, Department of Orthopaedics, PO Box 2900, Fitzroy, Victoria, 3065

9. Who can I contact for more information?

For further information about the Registry, contact Assoc. Prof. Michelle Dowsey (Principle Investigator and Registry Custodian) on 03 9231 3955 or a SMART Registry Coordinator on 03 9231 3028 or email your inquiry to SMARTRegistry@svha.org.au

10. Complaints and research participant rights

If you have any complaints regarding any aspect of this project or the way in which it is being conducted, you may contact, the Patient Liaison Officer at St. Vincent's Hospital (Melbourne), on 03 9231 3108. You will need to tell the Patient Liaison Officer the name of the person who is noted above as principal investigator. If you have any questions about your rights as a research participant, then you may contact the Executive Officer Research at St Vincent's Hospital (Melbourne) on Telephone: 03 9231 3930

11. Who is organising and funding the registry?

The Registry is housed at St. Vincent's Hospital and is sponsored by funding received through the Department of Orthopaedics and University of Melbourne Department of Surgery, St. Vincent's Hospital and funding received by the National Health & Medical Council of Australia. No member of the SMART Registry team will receive a personal financial benefit from your involvement in this registry (other than their ordinary wages).

12. Who has reviewed the 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 Hospital (Melbourne). 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.