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**Participant Information Sheet/Consent Form**

*St. John of God Murdoch Hospital*

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| **Title** | Outcomes following randomised patellar resurfacing versus retention in anatomically designed total knee arthroplasty.  |
| **Coordinating Principal Investigator** | Piers J. Yates |
| **Associate Investigator(s)** | Dr Heidi WilsonProf Gareth ProsserA/Prof Christopher Jones |
| **Location**   | Orthopaedics WA,St. John of God Murdoch Hospital |

**1 Introduction**

You have been invited to take part in this research project. This is because you are undergoing knee replacement surgery and you are suitable for a particular type of implant called a SAIPHTM knee system. This research project is investigating whether or not replacing the underside of your kneecap affects your results after surgery specific to this SAIPHTM knee implant.

This Participant Information Sheet/Consent Form tells you about the research project. It explains what is involved. Knowing what is involved will help you decide if you want to take part in the research.

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, friend or your local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to taking part in the research project

• Consent to participating in everything described

• Consent to the use of your health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

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

Replacing the underside of the kneecap during total knee replacement is known as patella resurfacing. Currently, there isn’t a clear scientific argument in support of resurfacing, nor is there one against resurfacing. Standard practice, therefore, currently depends on surgeon preference. All knee implants are not created equal, and the results from studies on one type of implant don’t necessarily translate to all implants. This research aims to guide whether patella resurfacing should always or never be used with SAIPHTM knees, or whether it should occur on a case by case basis.

This research is being conducted by Orthopaedics WA and the Murdoch Centre for Orthopaedic Research at St John of God Murdoch Hospital.

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

If you agree to participate, certain things will remain the same as they would should you decline participation, as they are part of the normal standard of care for people undergoing total knee replacement. These include a preoperative consultation in which your surgeon will ask you questions about your symptoms and history, an examination including the range of movement in your knee and imaging in the form of plain xrays and a scan called an EOS scan which assesses your alignment. After your surgery, you will be reviewed at 6 weeks and 12 months, and have a repeat examination and repeat xrays at these time points.

The additional participation requirements forming this study is the completion of questionnaires at each of these reviews. There are 3 questionnaires that you will be asked to complete before your surgery, and 4 questionnaires that you will be asked to complete 6 weeks and 12 months after your surgery.

You will not be told whether you receive patella resurfacing or not, as this information alone can sometimes influence results in a phenomenon known in research as the “placebo effect”.

There will be no other change to your usual care, and no extra tests or procedures.

You will be in the study for one year and all the study visits will be at the time of your normal clinic visits with your surgeon. There are no additional costs associated with participating in this research project, nor will you be paid. You may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit. If you have a local doctor, and have provided us of their details we may inform them of your participation in this research project.

**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 without any change to your treatment, your relationship with those treating you, or your relationship with Orthopaedics WA.

If you do to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

**5 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. You may choose to have the same procedure done, but not be involved in our research project. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project.

**6 What are the possible benefits of taking part?**

There will be no clear benefit to you from your participation in this research.

**7 What are the possible risks and disadvantages of taking part?**

Your surgeon will review you as a person and decide on the best type of implant to suit you, prior to consideration of participation in this study. The study involves randomly assigning participants to either receive patella resurfacing, or not. If you are being asked to take part, your surgeon has carefully considered your case and deemed it safe for you to either receive resurfacing, or not to. There is not a foreseeable risk of being assigned to either group, and you are received standard care.

Your treatment and follow up is the same regardless of your participation in this study. We will be asking you to complete additional questionnaires and as such will require a small time commitment. There are no restrictions on medications or treatments while you are in this study.

**8 What if I want to withdraw from this research project?**

If you decide you no longer want to be in this research study, please notify a member of the research team. This will not affect your other care in any way. If you do withdraw during the research project, the study doctor and relevant study staff will not collect any additional information from you, although information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. Information collected by the research team up to the time you withdraw will form part of the research project results. If you wish to withdraw all of your information please let the research team know.

**9 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. The study records will be kept at the Murdoch Centre for Orthopaedic Research, St John of God Murdoch Hospital, Western Australia, in a locked archive for at least 7years from the time the study is closed, and may be destroyed at any time thereafter. Your rights under any applicable data protection laws are not affected. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

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.

**10 Who is organising and funding the research?**

This research has been initiated by the Principal Investigator, Prof Piers Yates, and is being funded by the Orthopaedic Research Foundation of WA.

**11 Who has reviewed the research project?**

The St John of God Health Care Human Research Ethics Committee has given ethical approval for the conduct of this study. If you have any concerns or complaints regarding this study, you can contact the Executive Officer of the Committee (telephone number (08) 9382 6940) on a confidential basis. Your concerns will be drawn to the attention of the Committee that is monitoring the study.

**12 What if I have questions about this study?**

 **For clinical enquiries, please contact:**

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| --- | --- |
| Name | Heidi Wilson |
| Position | Orthopaedic Registrar |
| Telephone | 0450 501 290 |
| Email | Heidi.wilson@health.wa.gov.au |

For matters relating to research at the site at which you participating, the details of the local site complaints person are:

**Complaints contact person and reviewing HREC Executive Officer details**

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| Name |  St John of God Healthcare HREC |
| Position |  Executive Officer |
| Telephone | 08) 9382 6940 |
| Email | ethics@sjog.org.au |

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**Consent Form**

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**Declaration**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I believe that participation in this study is not contrary to my best interests.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the research project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

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|  |
|  | Name of Participant (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the person responsible has understood that explanation.

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|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.