Participant Information Sheet

Perth Hip and Knee Clinic, Subiaco, Midland, Murdoch

Title: Perth Hip and Knee Research Registry

Coordinating Principal Investigators: Gavin Clark, Dermot Collopy,

Research Assistants: Bethany Tippett, Stef Pollock, Elise McNeill, Ashlee Connelly

Location: Perth Hip & Knee, Subiaco

Introduction

You are invited to take part in this research project as you have presented to the clinic for orthopaedic review of your knee or hip. This research project is gathering data in relation to hips and knees. The purpose of this registry is to gather data in relation to surgery, in order to identify patterns and trends and to help shape orthopaedic developments.

This Participant Information Sheet tells you about the research project. It explains the tests and treatments 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 take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.

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

What is the purpose of this research?

The purpose of this research is to create a registry of patients who have had hip or knee surgery. From gathering large amounts of data, patterns and trends can emerge. These patterns and trends can shape patient care and outcome, shaping education and care into further research. Requirements of this research registry are no more than that of standard medical care. This research has been initiated by the study doctors Gavin Clark and Dermot Collopy and is not funded. The research data is collected inside the organisation Perth Hip and Knee.

What does participation in this research involve?

Your participation in this registry is voluntary, and it is up to you to decide whether or not to take part This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

Your participation involves signing a consent form prior to seeing your orthopaedic doctor. This gives you time to read through this information booklet, and ask your doctor any questions in relation to the registry prior to signing. Normal standard of care follow up appointments are only required for this registry, there is no additional time requirements for you. You may be asked to complete some simple surveys, and have clinical measurements taken (height, weight, range of movements). Your involvement in this registry ends once you have been discharged from your orthopaedic doctor's care, though this registry has no definitive end date.

Involvement in this research registry involves nothing more than medical standard of care follow up. There is no lifestyle restriction, physical restrictions or medical restrictions involved. There are no foreseeable reasons in which we would expect you to be restricted from participating in this research registry.

There are no additional costs associated with participating in this research project, nor will you be paid. If admitted to hospital, or recommended by your doctor, you will have to pay for some medicines / procedures as they are not part of this research registry.

It is desirable that your usual doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

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.

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

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 Perth Hip and Knee. You are free to withdraw from the registry at any time and do not need to provide a reason for doing so.

What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include advances in orthopaedic care for future patients. There will be no clear benefit to you from your participation in this research.

What are the possible risks and disadvantages of taking part?

There are no foreseeable risks or disadvantages for participating in this research registry.
If you become upset or distressed as a result of your participation in the research, the study doctor will be able to refer you for appropriate counselling services. Any counselling or support will be provided by qualified staffs who are not members of the research project team. This counselling will be provided free of charge through either the public health system, or online support such as Beyond Blue.

What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

Can I have other treatments during this research project?

Whilst you are participating in this research project, you may be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

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. Identifiable data will only be able to access by those listed as investigators or research assistants as listed on the first page. If further research personnel are required to assist in this registry, an application will be made to the St. John of God Human Research and Ethics Committee for their approval. Data will be kept on the orthopaedic research program “Socrates”, and medical documents will be kept on the medical software administrative program “Genie”. If needing to send data to a third party for assistance in research, ie. Biostatistician, all data gathered will be de-identified, through using a code. Data will not be identifiable if sent out of the research location. 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.

Data will be stored as per the NHMRC Code (section 2.1.1) and held for a minimum of 5 years from the date of publication, or 5 years following the completion of the research registry. All data will be stored on computers, password protected, at Perth Hip and Knee Clinic. Information about you may be obtained from your health records held at this and other health services for the purpose of this research (i.e. hospital medical records). By signing the consent form you agree to the study 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 privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study 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 and for the future research described in Section 16 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.

Complaints and compensation

There are no expected complications arising as a result of your involvement in this research registry. If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

Who is organising and funding the research?

There is no funding or sponsorship involved in this research registry.

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. God of God Healthcare.

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.

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 (for example, any side effects), you can contact the principal study doctor on **(08) 6489 1700** or any of the following people:

Gavin Clark research team

Name	*Gavin Clark, Bethany Tippett, Stef Pollock, Ashlee Connolly*
Position	*Orthopaedic surgeon, research physiotherapist, physiotherapist, nurse*
Telephone	*08 6489 1777*
Email	*clark@hipnknee.com.au*

Dermot Collopy research team

Name	*Dermot Collopy, Elise McNeill*
Position	*Orthopaedic surgeon, research physiotherapist*
Telephone	*6489 1733*
Email	*research.collopy@hipnknee.com.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:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	*St. John of God Health Care Ethics Committee*
HREC Executive Officer	*Gorette De Jesus*
Telephone	*9382 6940*
Email	*Gorette.De.Jesus@sjog.org.au*

Consent Form

Title: Perth Hip and Knee Research Registry

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Research Assistants: Bethany Tippett, Stef Pollock, Elise McNeil, Ashlee Connolly

Location: Perth Hip & Knee, Subiaco, Midland, Murdoch

Declaration by Participant

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 give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Gavin Clark and Dermot Collopy concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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 study without affecting my future health care.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

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

Name of Participant _____

Signature _____ Date _____

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 participant has understood that explanation.

Name of Study Doctor/
Senior Researcher _____

Signature _____ Date _____

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.

Form for Withdrawal of Participation

Title: Perth Hip and Knee Research Registry

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Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Perth Hip & Knee Clinic.

Name of Participant _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher _____

Signature _____ Date _____