



## Participant Information and Consent Form

### Incidence and risk factors for graft failure following anterior cruciate ligament reconstruction

Principal Researcher: Associate Professor Julian Feller, OrthoSport Victoria

#### 1. Introduction

You are invited to take part in this research project. Your details have been obtained from your file at Associate Professor Julian Feller's office. The research project aims to determine the incidence of graft failure after anterior cruciate ligament reconstruction and the associated risk factors.

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

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 health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to complete the online survey you are telling us that you:

- understand what you have read;
- consent to take part in the research project;

consent to the use of your personal and health information as described.

You may download a copy of this Participant Information and Consent Form to keep.

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

Anterior cruciate ligament rupture is a common injury that can result in significant limitations for an individual and increase the risk of developing knee osteoarthritis. It is frequently treated by reconstructive surgery using a piece of tendon to make a new ligament. Although the results of such surgery are generally satisfactory, there remains a risk of reinjury and rupture or failure of the reconstructed ligament. This can be particularly significant in a young and active patient. The factors that increase the risk of reinjury remain poorly understood. This study aims to determine the incidence of graft rupture and failure, and the associated risk factors in a large group of patients.

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

You will be asked to complete an online survey about your previous knee operation. The questions will cover some basic information about you and how your knee functions, whether you have had a further injury to your knee and the setting of any further injury. The survey will take approximately 10 minutes to complete. We may also need to contact you via telephone after completing the survey if any of your responses need further clarification. Once you have completed the online survey your medical record at Associate Professor Julian Feller's office will be reviewed to obtain additional information about your surgery. You will not be paid for your participation in this research.

**4. What are the possible benefits?**

The results of this study will provide valuable information regarding the medium term outcomes of ACL reconstruction and reasons for failure. This data will be useful in advising future patients undergoing ACL reconstruction.

**5. What are the possible risks?**

There are no specific risks associated with this project. The only inconvenience is the time taken to complete the online survey.

**6. 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 a later stage. If you decide to withdraw at a later stage, please notify a member of the research team. However, if you withdraw after 4 weeks we will still use your data in our analysis. Your decision whether to take part or not, or to take part and then withdraw, will not affect your relationship with the researchers.

**7. How will I be informed of the final results of this research project?**

Participants will be given access to the publication or presentation of this study if requested.

**8. What will happen to information about me?**

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 permitted by law. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. The data from this study will be kept for future comparisons.

**9. Can I access research information kept about me?**

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers named at the end of this document if you would like to access your information. In addition, in accordance with regulatory guidelines, the information collected in this research project will be kept for at least 7 years.

**10. Is this research project approved?**

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of Epworth HealthCare. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* 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.

**11. Consent**

By completing the online survey, you indicate that you have read this document and understand the purposes, procedures and risks of this research project as described within it, and that you freely agree to participate in this research project, as described.

**12. Who can I contact?**

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

**For further information:**

If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project (for example, feelings of distress), you can contact the principal researcher on (03) 90385200.

**For complaints:**

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:

HREC Secretary: Ms Kay Foley, Epworth HealthCare: (03) 9426 8896