

<b>Project Title</b>	<i>The Melbourne ACL Rehabilitation Project 2.0</i>
<b>Project Sponsor</b>	<i>La Trobe Sports &amp; Exercise Medicine Research Centre</i>
<b>Coordinating Principal Investigator/ Principal Investigator</b>	<i>Professor Kay Crossley</i>
	<i>Dr Adam Culvenor</i>
<b>Associate Investigator(s)</b>	<i>Brooke Patterson Randall Cooper Mick Hughes</i>

## Part 1. What does my participation involve?

### 1 Introduction

You are invited to take part in this research project. The research project is collecting information about an evidence-based treatment program for rehabilitation for anterior cruciate ligament (ACL) injury. The treatment program is called The Melbourne ACL Rehabilitation Guide 2.0, which you will be already completing with your physiotherapist as part of your routine clinical care after ACL injury.

The Melbourne ACL Rehabilitation Guide 2.0 is a six-phase, goal-based rehabilitation program for people who have had/are planning to have an ACL reconstruction. More information about the program can be found here <https://www.premax.co/au/all/acl-rehab-protocol>

This Participant Information Statement tells you about the research project. It explains what is involved. Knowing what is involved will help you decide if you want to allow us to collect information about your participation in the Melbourne ACL Rehabilitation Guide 2.0. 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, your physiotherapist 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 DO NOT want to take part in the research project, you will be asked to tick a box below indicating this.

***If you do not tick the box, it is implied that you consent to taking part, and 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
- Consent to the use of data collected during this research project in future research projects that are related to the current project topic. You also understand that you may or may not be informed of the use of data in future research projects
- Consent to be contacted about future research projects

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

The aim of this study is to collect information about the Melbourne ACL Rehabilitation Guide 2.0. This is needed to ensure that rehabilitation programs for people who have an ACL reconstruction are effective at improving outcomes and reducing the risk of re-injury. The information we collect about the Melbourne ACL Rehabilitation Guide 2.0 will allow us to continue to refine and improve the program for Australians who undergo an ACL reconstruction.

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

Participation in the research involves answering some questions about yourself and your knee injury online when you complete each of the 6 phases of the Melbourne ACL Rehabilitation Guide 2.0. 1, 2 and 3 years after completing your ACL rehabilitation, you will automatically receive an email asking you the same questionnaires.

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Participation in the Melbourne ACL Rehabilitation Guide 2.0 is separate to the research, and you can still do the program if you choose not to participate in the research.

The information we will ask you will include your age, your email address, how much pain you have, when you have had surgery, whether you have any other health conditions and how much your knee injury affects your lifestyle and confidence. It will take you 15 minutes to complete the online questions at each time point. Your physiotherapist will ask you to perform some physical tests at different stages of the program (these are part of a standard assessment after ACL injury). This information will also be recorded and entered online.

The information will be collected online, and will be stored online in a secure database onsite at La Trobe University, using secure password-protected methods. Only the researchers will have access to this information. You can choose to withdraw your information. You can also choose to be sent information about your individual results, and the overall results of the research can be sent to you or your treating physiotherapist, by contacting the investigators at La Trobe University. The information collected in the project will enable us to continue to improve the Melbourne ACL Rehabilitation Guide 2.0.

### **4     What do I have to do?**

You have already chosen to participate in the Melbourne ACL Rehabilitation Guide 2.0. If you also choose to take part in the research, you will be required to answer some questions online at the start of the program, and at completion of each of the 6 phases of the program. Participating in this research project will not affect your routine care in anyway.

### **5     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 La Trobe University.

### **6     What are the alternatives to participation?**

You do not have to take part in this research project to do the Melbourne ACL Rehabilitation Guide 2.0. You can still complete the Melbourne ACL Rehabilitation Guide 2.0, even if you do not take part. Your physiotherapist can discuss this option with you before you decide whether or not to take part in this research project.

### **7     What are the possible benefits of taking part?**

There will be no clear benefit to you from your participation in this research, however providing us with the information about your condition online will enable us to continue to refine and improve the Melbourne ACL Rehabilitation Guide 2.0.

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

You have already chosen to take part in the Melbourne ACL Rehabilitation Guide 2.0 as part of your routine clinical care. The research project only involves the collection of your information online, and will not affect your participation in the Melbourne ACL Rehabilitation Guide 2.0 in any way. The risks and side effects of taking part in this research are very small, but should be acknowledged. Given the online nature of the data collection, there is a very small risk that your personal (name, email address, date of birth) and health-related (medical history, impact of knee injury on your lifestyle) information could become public. The researchers have employed all security measures to minimise the likelihood of this occurring, and only they will have access to the data collected.

### **9     Can I have other treatments during this research project?**

There are no limitations to the treatment you receive while taking part in this project. As part of the online questions you will be asked about past and current treatment you are receiving.

### **10    What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team. If you do withdraw your consent during the research project, the physiotherapist 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 up to the time you withdraw will form part of the research project results.

## **11 What happens when the research project ends?**

When the research project ends, your information will be stored for 7 years in a secure online repository at La Trobe University.

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

### **12 What will happen to information about me?**

By completing the questionnaires, you consent to the relevant research staff collecting and using personal information about you for the research project. We will collect information about you in ways that will reveal who you are.

Any information obtained in connection with this research project that can identify you will remain confidential. All information is stored in a secure online facility and is only accessible to the members of the research team. 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. We will store information about you in ways that will reveal who you are. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. We will publish information about you in ways that cannot be identified in any type of publication from this study. Any data you provide will be dealt with on a strictly confidential basis.

We will keep your information for 7 years after the project is completed. After this time we will destroy all of your data. The storage, transfer and destruction of your data will be undertaken in accordance with the Research Data Management Policy <https://policies.latrobe.edu.au/document/view.php?id=106/>

The personal information you provide will be handled in accordance with applicable privacy laws, any health information collected will be handled in accordance with the Health Records Act 2001 (Vic). Subject to any exceptions in relevant laws, you have the right to access and correct your personal information by contacting the research team.

### **13 Will I hear about the results of the study?**

You are able to obtain a copy of your individual results and the overall study results (online annual report) by contacting the research team.

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

This research project is being conducted at La Trobe University by Professor Kay Crossley, Dr Adam Culvenor, Brooke Patterson, Randall Cooper and Mick Hughes.

### **15 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 La Trobe University. 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.

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

For matters relating to the Melbourne ACL Rehabilitation Guide 2.0, but not the research, you should speak to your treating physiotherapist. If you want any further information concerning this research project, please contact:

Name/Organisation	Position	Telephone	Email
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## Participant Information Statement

Dr Adam Culvenor La Trobe University	Research Fellow	1 3 9479 3902	<a href="mailto:culvenor@latrobe.edu.au">culvenor@latrobe.edu.au</a>
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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, please contact:

Ethics Reference Number	Position	Telephone	Email
HEC-19025	or Research Ethics Officer	1 3 9479 1443	<a href="mailto:nanethics@latrobe.edu.au">nanethics@latrobe.edu.au</a>