



Participant Information Sheet/Consent Form

Interventional Study - Adult providing own consent

Title	Optimising outcomes after anterior cruciate ligament reconstruction: SUPER KNEE randomised controlled trial
Short Title	The SUPER KNEE trial
Ethics Reference Number	HEC19447
Project Sponsor	La Trobe University
Coordinating Principal Investigator/ Principal Investigator	Prof. Kay Crossley (La Trobe University)
Associate Investigators	Dr Adam Culvenor (La Trobe University) Dr Christian Barton (La Trobe University) Prof. Ewa Roos (Southern Denmark University) Prof. Steven McPhail (Queensland University of Technology) Ass. Prof. Edwin Oei (Erasmus Medical Centre) Dr Andrea Bruder (La Trobe University) Mr Thomas West (La Trobe University)
Location	La Trobe University

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project because you have had an anterior cruciate ligament (ACL) reconstruction within the last 9-36 months. The research project aims to compare the effectiveness of two different exercise and activity monitoring programs to optimise your knee symptoms, function and activity level and maximise your quality of life.

This Participant Information Sheet/Consent Form 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.

Your participation is voluntary

Participation in this research is completely voluntary and there will be no cost to you. 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 to take part and later change your mind, you are free to withdraw 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 or the hospital/orthopaedic surgeon who performed your ACL surgery.

If you decide you want to take part in the research project, you will be given a copy of this Participant Information Sheet and 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.

Your withdrawal from the study

You are under no obligation to continue with the research study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons and you do not need to provide a reason.

You can withdraw from the study at any time by completing and signing the 'Participant Withdrawal of Consent Form'. This form is provided at the end of this document and is to be completed by you and supplied to the research team if you choose to withdraw at a later date.

If you withdraw from the study, you will be able to choose whether the study will destroy or retain the information it has collected about you. Information about you that has already been analysed (i.e., once you have been allocated to either exercise program), may not be able to be destroyed to ensure accurate and unbiased study reporting. Personal details collected, such as your name and contact details, can be destroyed at any time upon study withdrawal.

2 What is the purpose of this research?

As you may be aware, many people who have had an ACL reconstruction do not recover to a level that they are satisfied with. Therefore, it is important to investigate treatments that can improve outcomes. The purpose of this study is to investigate whether two different exercise and activity monitoring programs can improve knee symptoms, function, physical activity and quality of life, and prevent knee arthritis. We will recruit 184 adults who have not completely recovered at 9-36 months after ACL reconstruction in Australia.

This study is being coordinated by researchers at La Trobe University. It is supported by international researchers and has been funded by an Australian National Health and Medical Research Council Project Grant. All assessments and treatment will be at **no cost** to you.

3 Who can participate?

You can participate in the study if you meet all the following:

- Have had ACL reconstruction surgery 9-36 months previously
- Be aged 18-40 years at the time of your ACL reconstruction
- Have not completely recovered from your ACL reconstruction, assessed by a questionnaire (provided by the researchers)
- Willing to complete exercises 2-3 times per week

You are not eligible and cannot participate in this study if you meet any of the following:

- Have had another knee injury/surgery or knee injection in the past 3 months
- Have had physiotherapy treatment for your knee in the past 6 weeks
- Have another injury or health condition that affects your ability to perform functional tasks and exercises
- Have contraindications for MRI (e.g. pacemaker, a history of metallic foreign body in the eye, previous surgery for cerebral aneurysm, other implanted metal material other than your ACL graft or claustrophobia)
- Currently pregnant or breastfeeding
- Planning on relocating interstate or overseas in the next 18 months or unable to commit to the various study assessments over the next 18 months (as detailed below)
- Unable to understand written and/or spoken English

4 What does participation in this research involve?

If you agree to participate in this study, you will be asked to sign the participant consent form before any study assessments are performed. This study will be conducted over 18 months in total (see flowchart on next page).

A comprehensive knee assessment by a physiotherapist

For the first assessment at the start of the study, you will attend La Trobe University. At this testing session you should allow approximately 2 hours, where you will undergo a physical examination by a physiotherapist. You will be asked to wear shorts and a small piece of stocking (provided) over both of your knees during some tests so that the examiner is unable to tell which knee is your operated one. The tests conducted in the physical examination will include a measure of knee movement and joint swelling, activities including squatting and hopping, and measures of muscle strength (quadriceps and hamstrings). Muscle strength will be assessed using a special chair and you will be asked to push up and down a few times against an ankle pad as hard as you can. We will also measure and record your height, weight and waist circumference. We will video your performance during clinical tests (e.g. single-leg squat and jump). These videos will not include your face, so you cannot be identified from the footage. If any of your face (or other identifying feature) is inadvertently videoed, this will be masked (by electronically blurring the area) prior to data analysis.

You will also be asked to complete a series of questionnaires related to pain, physical function, confidence with physical movements and physical activity, as well as details about your knee injury/pain (e.g. injury mechanism, location of pain; history of pain). These may be completed in person at the testing session or online via link provided by email.

If you are interested, you may also undergo a 3D biomechanics assessment at the La Trobe University gait laboratory. This is optional and takes an additional 30-60mins. Small reflective skin markers will be attached to your skin (with tape on arms, pelvis, legs) and tracked with infrared cameras when you walk, run and perform hopping tasks.

A knee MRI

You will also attend Lake Imaging Specialist and Research Centre, North Melbourne (within 1-week of your assessment at La Trobe University) where you will have a magnetic resonance imaging (MRI) scan of your reconstructed and possibly your other knee (if uninjured). For the MRI scan you will be asked to lie on a narrow table that can slide inside a large tunnel-like tube with a scanner. The scanner creates a magnetic field around you, then pulses radio waves at the knee. This does not contain any radiation. It is very important that you keep very still during the scanning. All imaging will be provided at **no cost** to you and will take approximately 25-45 mins to complete.

Random assignment to one of two different treatments

At the end of the first assessment at La Trobe University you will be randomly assigned (50:50 chance, like a coin toss) by a computer system to receive one of the exercise and activity monitoring programs provided by physiotherapists to increase lower-limb muscle strength, power, endurance and agility. This means neither you or the researchers will be able to choose which group you are assigned to. We do not know which treatment is best. To find out we need to compare the different treatments. There is equal chance that you will receive either treatment. All treatment will be at **no cost** to you.

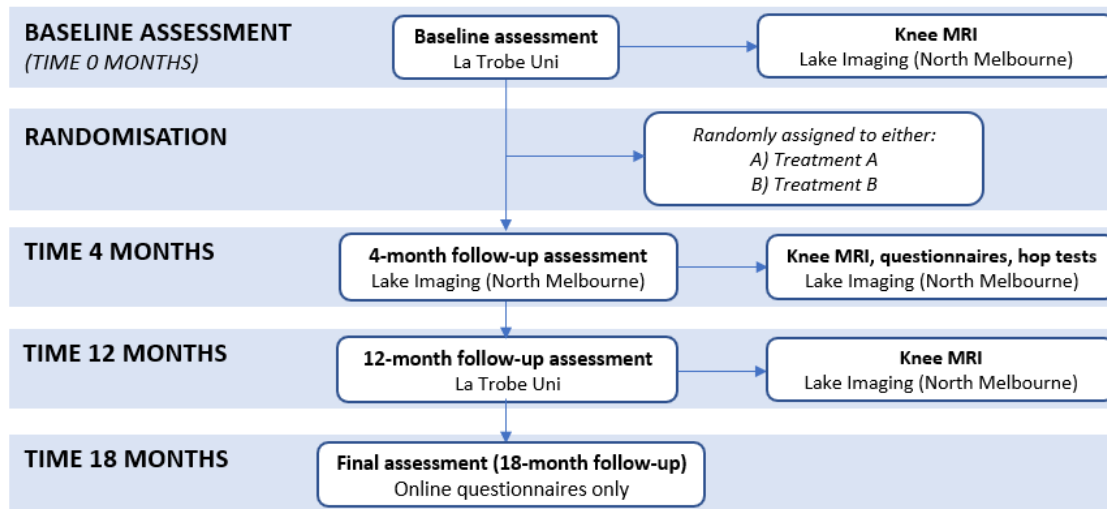


Figure 1. Flowchart of study assessments

If you are randomised to receive **Treatment A**, you will receive a “best-practice guide” booklet and a face-to-face appointment with a physiotherapist to explain the exercises and education in the booklet. Your physical activity and sports participation will be monitored with fortnightly (for first 4 months) and monthly (after first 4 months) online questionnaires. You will also be provided with an activity monitor (Garmin™ watch) to count your steps.

If you are randomised to receive **Treatment B**, you will receive 2 x per week face-to-face appointments for 4 months with a physiotherapist to perform muscle strength and agility/balance exercises. We have trained physiotherapists at clinics throughout Melbourne and Victoria to be convenient for you to attend. We will offer reimbursement for travel costs to attend each local physiotherapy appointment. You will have the option to access a gym (located conveniently for you and at no cost) at the 4-month assessment to continue to perform strengthening exercises up to 12-months after baseline. We will monitor your physical activity in the same way, and you will also get a physical activity monitor (Garmin™ watch) to measure your daily step count.

Follow-up assessments

At 4-months after baseline assessment, the same assessments will be repeated (questionnaires, hop tests and MRI) at Lake Imaging Specialist and Research Centre, North Melbourne and La Trobe University. At 12-months after baseline assessment, all assessments will be repeated: questionnaires, physical examination at La Trobe University, and MRI at Lake Imaging Specialist and Research Centre, North Melbourne. At completion of the study (18-months after baseline), the same online questionnaires will be repeated only.

There are no additional costs associated with participating in this research project. All medical care required as part of the research project will be provided free of charge. Your travel costs to attend the assessments will be reimbursed up to \$100.

5 What else do I have to do?

In addition to the assessments conducted at baseline, 4-, 12- and 18-months, you will be asked to record the exercises you have completed in a log book. You will also be asked to record any other healthcare treatments you receive during the study. This will be recorded in the fortnightly/monthly online questionnaire. You will otherwise be able to carry on with your normal lifestyle. It is also important for us to know about your surgical details (e.g. technique, cartilage/meniscus treatment), so we will request to access your surgical notes.

At the end of the first 4 months, or after 12 months, we may also ask if you are willing to have a separate interview with one of the study researchers. The purpose of this interview is to seek

feedback on the study interventions, satisfaction with the process received and whether there are any suggestions for improvement. The interview will take approximately 30 minutes, but you can cease the interview at any time. To ensure responses are correctly interpreted, responses to questions will be audio recorded and transcribed. Audio recording transcriptions will be completed by 'Transcription Australia' on their secure, encrypted Australian-based software. Although voice in your audio recording could lead to your identification, this file will not be used during analysis. Instead a re-identifiable transcription, which you will have the opportunity to check for accuracy, will be used for analysis. Re-identifiable means that we will use a code number and not your name on data collected to ensure your anonymity. Following the completion of analysis of this transcription, the audio file associated with your interview will be deleted. After analysis, overall findings and conclusions from all interviews will also be sent to you, to allow an opportunity to make any further comments. We will seek around 40 participants to be interviewed (n=30 at 4 months, and n=30 at 12 months). It is your decision or not whether you wish to be interviewed.

6 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment for your knee. Other options are available; these include attending physiotherapy (in a private practice or via the public hospital system). The research team will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your surgeon, local doctor or physiotherapist.

7 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 improved symptoms, function, quality of life, physical and sports activity, and confidence in your knee. You may also gain valuable insight into your physical functioning of your knee joint.

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

The testing procedures and exercise-therapy treatments may cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with the study coordinator.

Possible Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
<i>Muscle soreness</i>	Commonly, after testing; or after a change in exercises	Muscle may be tender to touch, may notice pain when using muscles (e.g. going up/down stairs)	May last 2-3 days
<i>Increase in knee pain or swelling</i>	Rarely after testing; Rarely after exercise-therapy if instructions followed	Mild Moderate Severe	2-3 days 3-7 days > 1 week
<i>Re-injury (e.g. rupture of ACL graft), or injury to opposite knee (or ankle/hip)</i>	Extremely rare during testing or exercise (research team are only aware of 1 incident in 20+ years in this field)	Mild to severe	Depends on injury – maybe months

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell the researchers immediately if you get any new or unusual symptoms. Most side effects go away shortly after treatment ends. If a severe side effect or reaction occurs, the study coordinator may need to stop your treatment. The study coordinator will discuss the best way of managing any side effects with you.

Muscle and joint soreness

The physical tests and exercises represent usual examination and intervention by a physiotherapist. You may experience a small amount of discomfort in the joints or muscles. Please report to the researcher any discomfort or pain experienced during the testing or exercises. If the pain or discomfort is deemed to be excessive by yourself or the investigators, the testing/treatment will cease.

Re-injury

There is a very slight risk of falling during the hopping tasks. During the physical tests and exercises, there is also an extremely low risk of re-injuring your ACL reconstructed knee. During the first 5 years after ACL reconstruction, approximately 5% of people will re-rupture their ACL graft, with almost all of these occurring during sport. To minimise the risk of graft rupture, an experienced physiotherapist will conduct all testing, and you can choose to not perform tests if you are not confident to do so. The exercises have been designed using the best available research, and you will be provided with criteria to appropriately progress the difficulty of exercises to minimise re-injury risk. In particular, before attempting sport, we strongly recommend approval from your surgeon and possibly a return to sport assessment by a health professional.

Magnetic Resonance Imaging (MRI)

When you lie in the MRI machine, the MRI team will make sure you are in a comfortable position so you can keep still. The scanner is very noisy and they can give you some earphones to reduce the noise. Some people may experience symptoms of claustrophobia from lying in a confined space. If you do experience discomfort at any time during the scan, you will be able to alert staff by pressing on a call button provided to you.

There are no proven long-term risks related to MRI scans. MRI is considered safe when performed at a centre with appropriate procedures. However, the magnetic attraction for some metal objects can pose a safety risk, so it is important that metal objects are not taken into the scanner room.

The MRI team will examine you to make sure there is no reason for you not to have the scan. You must tell them if you have metal implanted in your body, such as a pacemaker or metal pins.

The scans we are taking are for research purposes. They are not intended to be used like scans taken for a full clinical examination. The scans will not be used to help diagnose, treat or manage a particular condition. A specialist will look at your MRI scans for features relevant to the research project. This may be done by specialists we work with overseas – all identifying information (name, date of birth etc) will be removed from your MRI scans prior to analysis so that you will not be able to be identified. On rare occasions, the specialist may find an unusual feature that could have a significant risk to your health. If this happens, we will contact you and/or your health practitioner to talk about the findings. We cannot guarantee that we will find any/all unusual features. The MRI team will provide you with a copy of your MRI scans.

9 Can I have other treatments during this research project?

While you are participating in this research project, you should not participate in alternative or additional exercise-therapy (or physiotherapy). It is important to tell the study co-ordinator about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. We prefer that you do not commence any new treatment during the research project. However, should you decide to do so, we require you to describe any treatments (including medications) in your "study log book".

10 What happens when the research project ends?

At the completion of the research project, there will be no additional treatment provided by our research team. If you wish to continue with your exercise-therapy treatment, you can continue to use the resources provided to you. Any additional treatment (e.g. physiotherapy) that you might require at the completion of the research project will be at your own cost. If requested, we will provide you with your individual results and whole study results. We, or other researchers, may also use coded information (so that you cannot be identified) collected for this research study in future related studies. If you consent (tick the box on the consent form) to be contacted for future related research, we will store your contact details (name, address, phone number, email) on the secure La Trobe University research drive, only accessible to members of the research team, and may contact you about future related research projects.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

By signing the consent form you agree to the 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 and securely stored. It will be disclosed only with your permission, or in compliance with the law.

The research staff will also collect information on the health services you have used for the 6 months before, and 18 months after, baseline assessment. To collect this information, identifiable data (e.g. name, age, address) will be submitted to the Department of Human Services so that information about your health service usage can be obtained from a range of health datasets (e.g. Medicare Benefits Schedule (MBS), Pharmaceutical Benefits Scheme (PBS)) and linked to your study data. The health service data will be provided to the research team, by the Department of Human Services, in a format where your identifiable data (e.g. name, address) has been removed and the anonymous data will be held and analysed within a Department of Human Services approved, secure data storage environment. This information will be used solely for this project.

You will be asked to sign a consent form authorising the study to access your complete MBS and PBS data as outlined in the consent form. Medicare collects information on your doctor visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to the Department of Human Services who holds MBS and PBS data confidentially.

Storage, retention and destruction

The anonymity of your participation is assured with our procedure, in which a code number and not your name will identify you. Data will be kept securely at La Trobe University in a locked filing cabinet and password protected research computer. Re-identifiable (i.e. coded) information will also be kept to link your health service utilisation. Identifiable data will be stored for 15 years, after which time it will be securely destroyed (electronic records deleted, and paper-files shredded). All data and results will be handled in a strictly confidential manner, under guidelines set out by the National Health and Medical Research Council. The principal investigator (Professor Kay Crossley) is responsible for maintaining this confidentiality.

Information about you may be obtained from your health records held at health services for the purpose of this research. 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.

In accordance with relevant Australian and/or Victorian 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 member named below if you would like to access your information.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums and may be used by research higher degree students to obtain a research degree. In any publication, presentation or data files shared with other researchers, information will be provided in such a way that you cannot be identified, except with your permission. Any personal information that could identify you will be removed or changed before files are shared with other researchers.

12 What happens if I am injured as a result of participating in this research project?

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible. You will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. Waiting lists may apply and you may not see the surgeon who performed your original ACL reconstruction. In the first instance your study physiotherapist and/or research team will evaluate your condition and then discuss treatment with both you and your regular health practitioner. In the event of loss or injury, any question about compensation must initially be directed to the research team who will advise the university insurer of the matter.

13 Who is organising and funding the research?

This research project is being conducted by Professor Kay Crossley and a team of national and international researchers. It has been funded by an Australian National Health and Medical Research Council Project Grant. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

14 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 and the Alfred Hospital Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15 Further information and who to contact

The person you may need to contact will depend on the nature of your query. For all enquiries, you can contact the Clinical Trial Manager, during business hours:

Dr Adam Culvenor, Research Fellow in Physiotherapy, La Trobe University
Tel: 03 9479 5116; E-mail: a.culvenor@latrobe.edu.au

If you have any medical problems which may be related to your involvement in the project (for example, any side effects), the number to call Dr Adam Culvenor after hours is: 0401390974.

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: La Trobe University Human Research Ethics Committee
Complaints Contact: Senior Human Ethics Officer, Ethics and Integrity, Research Office
Telephone: 03 9479 1443 E-mail: humanethics@latrobe.edu.au

* Please quote the application reference number HEC19447.



Consent Form - Adult providing own consent

Title	Optimising outcomes after anterior cruciate ligament reconstruction: SUPER KNEE randomised controlled trial
Short Title	The SUPER KNEE trial
Ethics Reference Number	HEC19447
Project Sponsor	La Trobe University
Coordinating Principal Investigator/ Principal Investigator	Professor Kay Crossley
Associate Investigator(s)	Dr Adam Culvenor Dr Christian Barton Professor Ewa Roos Professor Steven McPhail Associate Professor Edwin Oei Dr Andrea Bruder Mr Thomas West
Location	La Trobe University

Consent Agreement

I have read the Participant Information Sheet and I understand the purposes, procedures and risks of the research described in the project.

Information about you may be obtained from your health records held at health services for the purpose of this research. I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to La Trobe University concerning my knee injury and treatment for the purposes of this project. I understand that such information will remain confidential.

I understand that data files may be shared with other researchers, and that information will be provided in such a way that I cannot be identified, except with my permission.

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.

At the end of the first 4 months, or after 12 months, you will be asked if you are willing to have a separate recorded interview with one of the study researchers for the purposes of seeking feedback.

- I agree to participate in a recorded interview
 I do not agree to participate in a recorded interview

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. I agree that data gathered for the study may be published provided my name or other identifying information is not used.

- I wish to receive results of the study I do not wish to receive results of the study
 I consent to be contacted for future related research
 I do not consent to be contacted for future related research

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

Name of Participant (please print) _____
 Signature _____ Date _____

Declaration by 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 Researcher[†] (please print) _____

Signature _____ Date _____

† A 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 - *Adult providing own consent*

Title Optimising outcomes after anterior cruciate ligament reconstruction: SUPER KNEE randomised controlled trial

Short Title The SUPER KNEE trial

Ethics Reference Number HEC19447

Project Sponsor La Trobe University

**Coordinating Principal Investigator/
Principal Investigator** Professor Kay Crossley

Associate Investigator(s) Dr Adam Culvenor
Dr Christian Barton
Professor Ewa Roos
Professor Steven McPhail
Associate Professor Edwin Oei
Dr Andrea Bruder
Mr Thomas West

Location La Trobe University

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 access to Health Services or Government benefits, my relationship with those treating me or my relationship with La Trobe University or the health system where I had my knee surgery. I understand that no further information about me will be collected for the study from the withdrawal date. I understand that information about me that has already been analysed and/or included in a publication by the study, may not be able to be destroyed. I request that the study handles the information they have collected about me in the following way (choose one option):

- DESTROY all my information collected so it can no longer be used for research
- RETAIN all my information collected so it can be used for research

Name of Participant (please print) _____

Signature _____ Date _____

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

Date:
Time:

Declaration by 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 Researcher† (please print) _____

Signature _____ Date _____

† A member of the research team must provide the explanation of and information concerning withdrawal from the research project.

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