[Insert Site Logo]

Participant Information Sheet

[Insert site name]

Title	The ARC (Australian Rotator Cuff) Trial: a randomised controlled trial of surgical repair of rotator cuff tears of the shoulder
Short Title	The ARC trial
Project Sponsor	The University of New South Wales (UNSW)
Coordinating Principal Investigator	Professor Ian Harris
Principal Investigator(s)	*[site Principal Investigator(s)]*
Location	*[Location]*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project because you have been diagnosed with what is called a "degenerative" tear in some tendons in your shoulder, otherwise known as a "rotator cuff tear". The research project is testing whether surgery to repair the tear is an effective treatment to improve shoulder pain and function and quality of life in people with rotator cuff tears.

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 Sheet to keep.

2 What is the purpose of this research?

Shoulder pain is common, and tears of the rotator cuff tendons in the shoulder are also common. Although most rotator cuff tears are not treated with surgery, some are repaired (stitched together), usually through arthroscopic (keyhole) surgery. It is not clear that surgical repair of rotator cuff tears in the shoulder leads to better results than not repairing the tear (no surgery).

Researchers, doctors and patients all agree that high quality scientific evidence is needed to determine if repairing the rotator cuff is better than not repairing it. Previous research in this area has not shown that surgery is clearly better than non-surgical treatment, but the kind of high quality research that is needed to answer this question is a study that compares repairing the rotator cuff to not repairing the rotator cuff, but keeps the researchers and the patients 'blinded', which means that they will not know if they had the repair or not until the end of the study. This kind of study has not been done for this specific condition. The ARC Rotator Cuff Trial is this kind of study.

This type of research study will provide the highest quality evidence that will contribute to the future treatment and management of rotator cuff tears. This study has been developed by an international group of experts and is run by Australian researchers, led by Professor Ian Harris.

3 What does participation in this research involve?

You are invited to participate in this study because you are aged between 45-75 years old, you have been suffering from shoulder problems for the last six months and you have been diagnosed as having a reparable rotator cuff tear, which was confirmed by an MRI imaging scan.

In this study, participants will be RANDOMLY ALLOCATED to receive EITHER: A) arthroscopic shoulder surgery WITH repair of the rotator cuff tear (called the intervention group) OR B) arthroscopic shoulder surgery WITHOUT a repair of the rotator cuff tear (called the control group).

What this means is ALL participants will receive arthroscopic shoulder surgery. During this shoulder surgery all participants will be able to receive surgical procedures such as cleaning out the soft tissues and any bone that might be causing problems, and/or surgery to *other tendons* (such as the biceps tendon). These procedures if necessary, will be done first. After these procedures are completed, the decision to repair or not repair the rotator cuff will occur via what is called "randomisation".

To ensure the two groups (intervention and control) are similar to start with, **a computer** allocates each study participant into a group randomly (randomisation), so the chances of being in either group are 50/50, like the flip of a coin. **Neither the doctor nor the study participant can decide which treatment the participant receives.** This allows for an even mix of people in each group and improves the quality of the study.

As mentioned before, neither you nor the research team will know which treatment you receive. The only person involved in your care that will know the type of surgery you will receive is the operating surgeon and they will only find out during the operation, not beforehand. **The operating surgeon will not be involved in your follow up care after surgery.** This is crucial to ensure trial staff and you (the participant) do not know which treatment you received, as it important to get true results that are not influenced by past beliefs and experiences (otherwise known as bias) of participants, researchers, nurses, and doctors.

Although none of your treating staff will be aware of your treatment (except the surgeon) there is a process for the doctor to find out which surgery you had in-case of any medical emergency or safety concern (this is managed centrally through the study coordinating centre staff).

Following the surgery, the main part of this study will follow your progress for a period of 2 years with contact from research staff at different time points, as listed below. You will also be contacted at 5 years and 10 years to check your progress. Most of this contact will be either via email or

telephone, to limit any inconvenience to you. Up to 190 participants will participate in this research study in hospital sites across Australia.

If after reading this information sheet and answering any questions you may have, you are keen to take part, we will first ask you to come in to the hospital or attend a video appointment with the researchers to sign the consent form, so that we have permission to allocate you to a study group and collect the following information below from you, during the study.

Prior to surgery: You will be asked to sign the study's Participant Consent form. Prior to surgery you will then be asked to complete a variety of questionnaires relating to your quality of life, pain and mobility, your activities of daily living, and other aspects of your health. This will take less than 30 minutes to complete. We will receive a copy of the results of your MRI imaging scan that your treating doctor will have organised as part of your routine care

Treatment: Your surgeon will schedule you to be admitted to hospital for your arthroscopy. During your arthroscopic shoulder surgery (while you are under anaesthesia) you will be randomised to either undergo repair of the rotator cuff (intervention group) or no repair (control group). As mentioned prior, other procedures performed during the arthroscopy will not be altered and will occur *prior to* the decision about rotator cuff repair. Standard treatment protocols for the arthroscopy according to the hospital and/or treating surgeon will apply and will not be modified for the study.

For all participants, the type of anaesthetic used for the arthroscopy will depend on your anaesthetist's normal practice and may involve general anaesthetic or a regional nerve block.

Post-operative care will be the same for all participants and is offered according to standard practice. This includes length of time spent in theatre, post-surgical pain relief and physiotherapy.

Follow up: After your surgery and for your follow up care you will be cared for by an experienced shoulder surgeon who works with your operating surgeon but will not know what study group you belong to.

Following your surgery, a four-phase physiotherapy program will be implemented according to usual practice post a rotator cuff repair. The number of physiotherapy visits you will attend during the 20 weeks post your surgery, will depend on your physical progress post-surgery. You will be contacted by a study researcher over the phone or by email at 1-2 weeks, 6-8 weeks, 3 months, 6 months,12 months and 24 months post-surgery. Collection of information at these time points may coincide with your usual care visits to your follow up surgeon. You will also be contacted at 5 years and 10 years to check your progress.

Information collected by the study researcher during these follow ups will be similar to the information collected prior to surgery and will include completing a variety of questionnaires relating to your quality of life, pain and mobility, and your activities of daily living. A copy of your operation report will be collected for the research study. In addition, the following information will be collected from the surgeon treating you post-surgery: physical measurements on your shoulder strength, any recorded complications post your surgery and a copy of your MRI scan 12 months post-surgery.

Continual review and monitoring will take place regarding the progress and safety of the research project and this will enable early detection of any problems participants may experience, as participant safety is of utmost importance to all trial staff.

Additional costs

You will not be paid for your participation in this research. Procedures will be funded as per usual care with the exception that participants treated in the private sector will not be billed for any out of pocket surgical and anaesthetic fees and will not be billed for rotator cuff repair, regardless of whether or not the repair was performed. Patients treated in the public sector will not have to pay

for treatment received in public hospitals. All patients treated in the private sector will NOT be out of pocket in regard to any health insurance hospital policy "excess". Private patients will either be reimbursed for payment of their insurance policy hospital "excess" (associated with the study surgery). Alternatively, a number of health insurance funds have agreed to waive the hospital "excess" for the study surgery. If you are a private patient, to keep you blinded, the private hospital and your treating surgeon will delay billing the Private Health Insurer for your medical and hospital care until after six months following your surgery.

It is possible, that some expenses will be incurred. These may include transport and parking, a pathology test, additional consultations, medications or private physiotherapy. In the case where you and your doctor decide you require further surgery, this will be funded in the usual way, either via your private health insurance, Medicare or with your own funds.

Reimbursement: You will not be paid to participate in this research.

If you decide to participate in this research project, the study doctor will inform your local doctor.

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.

If you do decide to take part, you will be given a Consent Form to sign and you will be given a copy of this sheet 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 *[Institution]*.

5 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment. You can discuss your treatment options with your doctor.

6 What are the possible benefits of taking part?

This study aims to further medical knowledge and may improve future treatment of rotator cuff tears, it may not directly benefit you.

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

The risks of taking part in this research study are similar to the usual risks associated with having surgery. The expected risks with traditional arthroscopic repair of rotator cuff tear/s will be discussed with you by your surgeon as part of the usual consent process prior to your surgery. The group that does not have the rotator cuff repair will have similar risks to the traditional surgery but will not include the complications directly associated with repair of the rotator cuff.

In the event of side effects that require treatment, these will be managed according to normal practice and will be paid for as per usual practice (e.g. Medicare or private health insurance).

8 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.

9 Can I have other treatments during this research project?

it is important that you **do not** have any X-rays or scans on your shoulder after surgery, at least for the first 6 months. It is not usual practice to perform scans within 6 months of surgery and avoiding these tests will keep you "blinded about what treatment you received'.

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 before you withdraw.

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 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.

11 What happens when the research project ends?

Further treatment (including surgery) will not be available from the study team after the study finishes. If you require further treatment once the study is complete you can receive this treatment from your study doctor and this decision will be made in consultation with you and your treating doctor, about the most appropriate treatment for you at the time.

A copy of the published results of the study can be made available to you by the study team once the study results are formally published in a medical journal. If you would like to receive this, please ensure you let the study coordinator know before you complete the study and they will ensure a copy is emailed or mailed out to you.

Part 2 How is the research project being conducted?

12 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 and will be disclosed only with your permission, or except as required by law.*** Only the study researchers, monitors, representatives of regulatory authorities and ethics committee may have direct access to it. Access may be requested to check the accuracy of the information collected and to ensure that the trial is being carried out according to local requirements and/or regulatory guidelines.

Information about you may be obtained from your health records held at this and other 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. Information about your participation in this research study may be recorded in your health records.

All your information collected from you for the study follow-up will be entered into a secure password-protected online database, managed by the Ingham Institute and UNSW. Once you sign the consent form, you will be assigned a unique study code. All information collected from and about you, will be stored under your study code within this research database. The study team will need to enter your email into the study database to be able to send you the questionnaires to complete online. Your email will be linked to your study code in the study database. If you do not wish to provide your email, the study questionnaires may be completed over the telephone with a study team member.

If you give us your permission by signing the Consent Form, we plan to discuss your progress and results with the doctors and researchers participating in the study. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. ***In any publication, all information will be provided in such a way that you cannot be identified*** (de-identified). After this study has been completed, it is possible that the de-identified data will be used for future research.

The study data will be kept for 15 years and will be destroyed after it is no longer needed for the study. 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.

13 Compensation

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible who will assist you in arranging appropriate medical treatment. You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation will be available if your injury or complication is caused by the drugs or procedures, or by the negligence of any of the parties involved in the study.

You do not give up any legal rights to compensation by participating in this study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

Surgeons are covered by their own medical indemnity cover that will be called upon if any legal claim is made by a participant during the course of this research study.

14 Who is organising and funding the research?

This research project is funded by the Whitlam Orthopaedic Research Centre sponsored by The University of New South Wales and is conducted by Professor Ian Harris. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

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 *[Name of institution]*.

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

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 study team on *[phone number]* or any of the following people listed below. In the case of an emergency contact your local hospital or 24 hour clinic.

Clinical contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

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

Reviewing HREC approving this research and HREC Executive Officer details

This study has been approved by the South Western Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research and Ethics Office, Locked Bag 7103, LIVERPOOL BC NSW 1871 on 02 8738 8304 / fax 02 8738 8310 / email SWSLHD-ethics@health.nsw.gov.au, website: http://www.swslhd.nsw.gov.au/ethics/default.html and quote [*2020/STEXXXXX*].

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.