[insert site logo]
Participant Information Sheet/Consent Form

[Insert site name]

Title	The Australian Rotator Cuff (ARC) Observational Study
Short Title	ARC Observational Study
Project Sponsor	The University of New South Wales
Coordinating Principal Investigator	Professor Ian Harris
Location	*[Location]*

Part 1 What does my participation involve

1 Introduction

You are invited to take part in this research project, the Australian Rotator Cuff (ARC) Observational Study. An "observational" study follows the progress of a group of people without any additional treatment being given, apart from their usual care. This study will help us understand how people with rotator cuff tear/s in the shoulder recover following surgical and non-surgical treatments.

This Participant Information Sheet and Consent Form tells you about the research project. 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 local doctor.

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 the tests and research that are described
• Consent to the use of your personal and health information as described.

2 What is the purpose of this research?

You are being invited to participate in this study because you were considered suitable for the ARC randomised surgical trial but decided not to participate. We are therefore inviting you to participate in the observational study. The ARC Observational Study will help the researchers understand and explain the results of the ARC randomised surgical trial.

In this study you will NOT receive any study treatment but will proceed with the treatment agreed upon by you and your doctor, independent of the ARC research team. This may include arthroscopic rotator cuff repair or non-surgical care (e.g. physiotherapy). To be a part of this study, you are invited to give approval for measuring your progress using questionnaires and information from your health records over the same time period as those participating in the ARC randomised

study. We are looking to observe your progress over a 2 year time period and again at 5 and 10 years.

This study has been developed by an international group of experts and is run by Australian researchers, led by Professor Ian Harris.

This study is being conducted at your hospital by (*insert PI*)

3 What does participation in this research involve?

You are invited to take part in this research 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 scan. You have also indicated that you do not want to participate in the ARC Randomised Trial.

You and your doctor will discuss and jointly decide which type of care is most suited to you regarding your rotator cuff repair; either arthroscopic rotator cuff repair surgery or non-surgical care. If you agree to participate in this study, you will be asked to sign the Participant Consent Form and you will be given a copy of this to keep.

If you choose to sign the Participant Consent Form, then the ARC study researchers will contact you via email and/or over the telephone for 2 years to follow your progress. You will be contacted to complete a variety of health information in the form of questionnaires. Information from your health visits to your treating doctor(s) relating to the care of your rotator cuff tear/s, will also be collected.

Before surgery: After consent you will be asked to give details about yourself including your sex, age, date of birth, height, weight, and smoking status. You will also be asked to complete pre-surgery electronic (or telephone if required) questionnaires relating to your quality of life, pain and mobility and your activities of daily living. This should take less than thirty minutes to complete. The study team will receive a copy of the results of your MRI scan that your treating doctor will have organised as part of your routine care.

Follow up: Once you sign the consent form, you will be contacted at 1-2 weeks, 6-8 weeks and 3 months to confirm if you have had shoulder surgery and if you have had complications (if applicable). Follow up is then collected at 6 months, 12 months and 2 years. Follow up is similar to the pre-surgery assessments and will include electronic (or telephone if required) questionnaires relating to your quality of life, pain and mobility, and your activities of daily living. If you have had arthroscopic surgery, a copy of your operation report will be obtained. Information collected from your health records and/or your treating doctor will include any complications (if applicable). A copy of your 12 month MRI scan will be requested.

Additional costs & reimbursement: There are no costs associated with participating in this research project, nor will you be paid.

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 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 *[Institution]*.

5 What are the alternatives to participation?

You do not have to take part in this study to receive treatment at this hospital or treatment from your doctor. Your participation does not affect your treatment at all. If you do join this study it just means you will be monitored more closely and comprehensively during and after your treatment, than if you were not participating in the study.

6 What are the possible benefits of taking part?

This study aims to further medical knowledge and may improve future treatment of rotator cuff tear/s. However, there may be no clear benefit to you from your participation in this research.

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

There are no risks associated with your participation in this observational study as there is no intervention or treatment given by the researchers - you will only receive the usual care for your shoulder, as decided by you and your doctor. If your usual care includes surgery, your surgeon will discuss with you the risks associated with the surgery. The only thing you will need to do is be willing to give up your time. We estimate that in total over the course of the 2 years this may take up to 2-3 hours of your time.

Importantly, the information we collect from you will be anonymised at the end of the study and held securely. Your results will be combined with up to 190 other participants for purposes of analysis, so that when published or shared, your questionnaire responses and health record data will not be identified or identifiable.

8 What if I withdraw from this research project?

If you decide to withdraw from this research study, please notify a member of the research team before you withdraw. If you do withdraw your consent during the study, 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 study can be measured properly and to comply with law. You should be aware that data collected by the study team up to the time you withdraw will form part of the research study results. If you do not want them to do this, you must tell them before you join the research study.

Please note that it may not be possible to withdraw your information from the study results once these have been de-identified, analysed and publish at the end of the study. Rest assured any analysed data will have already had your identifying details removed.

9 What happens when the research project ends?

Once the study is completed, all the results will be checked for accuracy and analysed. All this analysis will be done on de-identified data (this is where any information that has the possibility of identifying you as a person is removed). The final study results and subsequent analysis will be published in medical journals and presented at conferences.

In any publication, information will be provided in such a way that you cannot be identified. The results of the study can be provided to you in the form of the final publication. If you would like to receive this, please ensure you let your 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?

10 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 ARC study researchers, monitors, representatives of regulatory authorities and the 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.

All information collected from you at the follow-up appointments that are conducted via email or over the telephone will be entered into a secure password-protected online database, managed by The University of New South Wales. 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.

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 research team accessing health records if they are relevant to your participation in this research study.

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 the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

11 Compensation

We do not foresee any possibility that you will be disadvantaged or injured as you are participating in a research study that is for the purpose of observation and data collection only and does not involve any additional treatment or lifestyle intervention. You do not give up any legal rights to compensation by participating in this study and are still able to lodge a complaint and claim, if you wish to do so.

12 Who is organising and funding the research?

This research study is being conducted by *Professor Ian Harris* and sponsored by *The University of New South Wales*.

13 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.

14 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 *[phone number]* or any of the following people:

Clinical contact person

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

15 Complaints contact person

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.