Brisbane Knee and Shoulder Clinic

St Andrew’s Specialist Suites

St Andrew’s War Memorial Hospital

457 Wickham Terrace Brisbane 4000

**Peroneus longus autograft clinical trial information sheet**

To potential participants.

Dr Macgroarty is currently recruiting patients to a clinical trial of a new technique for anterior cruciate ligament (ACL) reconstruction. At present an ACL operation usually involves taking one of the tendons from around the knee and using it to make a new ACL. As the knee has already been injured when the ACL tore taking a tendon leads to additional injury. In an effort to minimise trauma to the knee and improve recovery Dr Macgroarty has begun using a new technique where a tendon from the side of the ankle is taken instead. Prior studies of this technique have been conducted and have shown very good results with regard to both knee and ankle function after operation.

*What will be asked of participants?*

After the operation participants will be invited for follow-up appointments where they will be examined. Participants will also be asked to fill out a series of questionnaires which will help us assess how well they are doing. Follow-ups are scheduled for 2 weeks, 6 months, 1 year and 2 years after surgery. The follow-up is similar to a standard ACL operation and you will not incur any extra costs as a result of the study.

*How will this affect my surgery?*

Your surgery will be conducted as planned regardless of whether you choose to participate in the study. In the case that you do not elect to participate Dr Macgroarty will use one the standard ACL reconstruction techniques. The new technique does not involve any extra surgical time and the recovery after the operation is very similar.

*How will the operation affect my rehabilitation?*

The rehabilitation protocol after the operation is the same as after a standard ACL reconstruction.

*What effects might the new operation have?*

Potential benefits are:

* less trauma to your knee possibly allowing a quicker recovery and less pain
* no loss of hamstring strength as a result of taking the hamstring tendons
* less scarring around the knee (you will however have a scar on the outside of your ankle)

Potential risks are:

* ankle pain where the tendon has been taken
* reduced strength when moving the foot outwards (also called eversion of the foot)

As this is a new technique unforeseen risks may be identified as the study progresses. In the event of this we will inform study participants.

*Who is eligible for the study?*

The study is open to patients with an isolated ACL injury that is planned for reconstruction and who are at least 16 years old.

If any of the following apply to you however you will not be able to take part in the trial:

This is a reoperation of a previously performed ACL reconstruction (also called a revision)

Other stabilising procedures than the ACL reconstruction are required

A meniscal repair is required

You have had previous foot or ankle surgery

You have longstanding ankle instability

You are under 16 years of age

You cannot read and understand English

You are unable to give consent for the procedure yourself

*Do I have to participate in the trial?*

Participation in the trial is entirely voluntary. Saying no will not affect any other aspect of your care and you can still have your ACL surgery with us as planned.

If you decide to take part you are able to change your mind at any time up until your surgery. You are also welcome to withdraw from the study at any time without it having an impact on your care.

*Will my personal data be secure?*

All personal data will be held on a secure server and deleted when the study is complete (2 years). You will be assigned a unique study ID. You will not be identifiable through any publications resulting from this study.

*How many people are we recruiting?*

At present we are seeking to recruit 30 people.

If you require any further information you can contact us here:

Tel: 1300 746 853 Fax: 07 3832 1900 Email: office@kneeandshoulderclinic.com.au