Application Approval

Dr Kelly Macgroarty
Brisbane Knee and Shoulder Clinic
Suite 2, Level 6
St Andrew's Specialist Suites
St Andrew's War Memorial Hospital

UnitingCare Health Human Research Ethics Committee
Ground Floor Moorlands House
The Wesley Hospital
451 Coronation Drive, Auchenflower QLD 4066
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Phone: 3232 7500
Email: ethics@uchealth.com.au

Our Ref: 1809

13 July 2018

Dear Dr Macgroarty,

Project Title: **Peroneus longus autograft ACL reconstruction**
Sponsor: **Nil**
Investigators: **Dr Kelly Macgroarty and Dr Jamie Brown**

I am pleased to advise that the UnitingCare Health Human Research Ethics Committee have reviewed the above named research proposal and granted ethical and governance approval on 12 June 2018

Approval of this project from Uniting*Care* Health HREC is valid from the approval date to 31 December 2019, subject to the guidelines on page 3 of this letter.

The approved documents include:

Document	Version	Date
Initial Application for Ethics Approval	V2	-
Patient Information Sheet	Not numbered	Not dated
Consent Form	Not Numbered	Not dated
Koos Knee Survey English Version	LK1.0	Not dated
Womac Osteoarthritis Index	Not numbered	Not dated
Ankle-Hindfoot Scale	Not numbered	Not dated
Lysholm Knee Questionnaire / Tegner Activity Scale	Not numbered	Not dated

As your project involves inpatients and/or the use of hospital facilities, the Director of Medical Services at St Andrew's War Memorial Hospital, has also given approval for your application. Please refer to point 3 of the Guidelines enclosed with this letter.

It is a strict condition of approval that any departure from the protocol detailed in the proposal submitted for approval be reported immediately to the UCH HREC. If there is any change to the status of the project, this should also be reported.

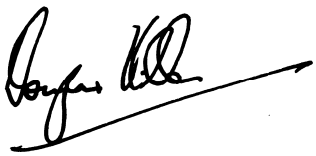
Approval for the project is given subject to your agreement to Uniting*Care* Health requirements for the monitoring of research (see overleaf), which have been based on the Australian Health Ethics Committee guidelines. Please note the requirement to submit a report annually or at the completion of the project, as appropriate.

The Investigator was not a member of the Uniting*Care* Health HREC at the time the above-mentioned study was reviewed and approved. The Uniting*Care* Health Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Human Experimentation and Supplementary Notes.

In all future correspondence please quote the UCH HREC number **1809.**

Please accept our very best wishes for the success of this study.

Yours sincerely



Douglas V Killer MBBS FRACP
Executive Officer
Uniting*Care* Health Human Research Ethics Committee

Uniting*Care* Health Human Research Ethics Committee Guidelines

Information for Researchers Gaining Scientific & Ethical Approval for Research Projects

Monitoring of Research

The Australian Health Ethics Committee now requires institutional ethics committees to monitor research projects to which they have given ethical approval. The principal reason for the monitoring of research projects is to ensure that their conduct does not jeopardize the rights and interests of those who have consented to take part as subjects in them. By monitoring the projects to which approval has been given, Ethics Committees will also be helping to ensure that researchers are practising responsible science and that the good reputation of the institution that is the setting for the research is maintained.

Uniting*Care* Health Requirements

Within Uniting*Care* Health, researchers who have approval from the Human Research Ethics Committee for their respective projects will undertake the following:

1 **A report on the approved project will be provided at least annually and a final report is to be submitted on completion of the study**. This does not preclude the Ethics Committee from asking for a report at more frequent intervals. Provision of relevant reports will be the responsibility of the applicant. In the case of multi-centre research, a report from the principal investigator may suffice. However, it is the applicant who is responsible for submitting the report to the Ethics Committee.

The report should provide details of the following:

- Status of the project (completed/in progress/abandoned/not commenced).
- Compliance with the conditions of ethical approval, including security of records and procedures for consent.
- Compliance with any special conditions stated by the Ethics Committee as a condition of ethical approval.

2 Applicants (or principal investigators) are responsible for notifying the Ethics Committee immediately of matters that might affect continued ethical acceptability of the project including:

- Serious adverse effects of the project on subjects and of steps taken to deal with these.
- Changes in the research protocol, together with an indication of ethical implications (if any).
- Any plan to extend the duration of the project past the approval period.
- The current principal investigator's inability to continue as coordinating principal investigator and will provide the name of the contact information for a replacement.
- Abstracts, presentations, publications as they occur
- Other unforeseen events.

Where the above requirements are not adhered to, the Ethics Committee may withdraw ethical approval for a project.

3 Any costs associated with the study performed at St Andrew's War Memorial Hospital are the responsibility of the Chief Investigator, and this includes Hospital costs. For an indication of hospital costs please contact the Director of Medical Services Office.

As a guide the following are examples of typical costs:

- Medical records including retrieval, off site costs and storage costs.
- Clinical and non clinical staff costs.
- Clinical and non clinical – consumables.