

Dr Diana Perriman
C/- Dr David Owen
4/37 Dominion Crescent
Forrest ACT 2603

ACT Reference	2020.ETH.00207
REGIS Reference	2020/ETH02083
Study Title	Randomised control trial of wrist arthrodesis with and without the carpometacarpal joint

This submission has been assessed under the usual guidelines for research ethics and site governance. Australian, State and Territory Government and relevant institution COVID-safety guidelines must be followed.

Dear Dr Perriman,

The ACT Health Human Research Ethics Committee considered the above referenced proposal at its meeting of 7 December 2020.

I am pleased to inform you that, following further correspondence, the Committee agreed the proposal satisfied the requirements for ethically acceptable research as per the National Statement on Ethical Conduct in Human Research and as such the application has been approved out of session.

Approval includes the following documents:

- Letter of response to HREC request for information, dated 9 December 2020
- HREA, date created 6 August 2020
- Study Protocol version 1, amended 9 December 2020
- Participant Information and Consent Form, version 1, dated 6 October 2020, amended 9 December 2020
- Patient Rated Wrist Evaluation Questionnaire, version undated
- Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire, copyright 2006
- Initial Patient Data Form (IDPF), version undated
- Patient Review Data Form (PRDF), version undated
- Surgeon Review Data Form (SRDF), version undated

The ACT Health Human Research Ethics Committee is constituted according to the National Statement on Ethical Conduct in Human Research 2007 and is certified for single review of multi-centre clinical trials. ACT Health HREC operates in compliance with applicable regulatory requirements and the principles of the International Conference on Harmonization Guidelines on Good Clinical Practice.

Please see attached Conditions of Approval.



ACT
Government

ACT Health

Research Ethics and Governance Office
Human Research Ethics Committee

This letter gives ethical approval for ACT Health/Canberra Health Services sites only. Please ensure appropriate site specific approvals are in place at other sites.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Paul Gatenby', with a long, sweeping flourish extending to the right.

Professor Paul Gatenby AM
MBBS PhD FRACP FRCPA
Chairman
ACT Health Human Research Ethics Committee

9 December 2020

Conditions of Approval

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REGIS Reference	2020/ETH02083
Study Title	Randomised control trial of wrist arthrodesis with and without the carpometacarpal joint
Coordinating Principal Investigator	Dr Diana Perriman
Principal Investigator	Dr David Owen
Date of Approval	9 December 2020

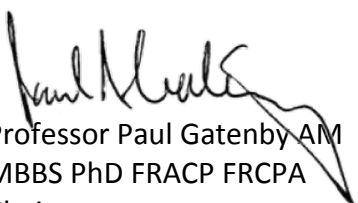
This submission has been assessed under the usual guidelines for research ethics and site governance. Australian, State and Territory Government and relevant institution COVID-safety guidelines must be followed.

This project was considered by the ACT Health Human Research Ethics Committee and approved for a period of 5 years from 9 December 2020 to 9 December 2025

First Annual Review due: 15 November 2021

Conditions of Approval:

- At regular periods, and not less than annually, Principal Investigators are to provide reports on matters including:
 - unforeseen events that could affect the continued ethical acceptability of the project
 - proposed changes in the protocol
 - updates of the investigator brochures
 - continued compliance with approved consent procedures and updates of consent documentation
 - Data Safety Monitoring Board Reports (where applicable)
 - security of records
 - updated insurance coverage
 - compliance with other approved procedures.
- All published reports are to carry an acknowledgement stating:
 - Approved by ACT Health Human Research Ethics Committee on 9 December 2020



Professor Paul Gatenby AM
MBBS PhD FRACP FRCPA
Chairman
ACT Health Human Research Ethics Committee
9 December 2020