

03 December 2020

Ms Monique Baigent
55 Parkhill Road Howick
Auckland 2014

Dear Ms Baigent,

Re:	Ethics ref:	20/STH/203
	Study title:	What is the reliability and diagnostic accuracy of individual and combinations of commonly used clinical tests for the diagnosis of chronic acromioclavicular joint pain?

I am pleased to advise that this application has been approved by the Southern Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Southern Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au) or <https://clinicaltrials.gov/>.
3. Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 3 December 2021.

Participant access to ACC

The Southern Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Helen Walker', written in a cursive style.

Mrs. Helen Walker
Acting Chairperson
Southern Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

<i>Document</i>	<i>Version</i>	<i>Date</i>
CV for CI	1	01 November 2020
Evidence of scientific review: Independent lecturer review by AUT the before proposal submission (Richard Ellis)	2	01 November 2020
Survey/questionnaire: Oxford shoulder score questionnaire	1	01 November 2020
Survey/questionnaire: SPADI questionnaire	1	01 November 2020
Survey/questionnaire: CSI questionnaire	1	01 November 2020
Survey/questionnaire: Standardised baseline assessment	1	01 November 2020
Survey/questionnaire: Patient waiting room handout	1	01 November 2020
Discussed additions for equity of Maori participants collated with the CMDHB Maori health team	5	01 November 2020
Mātauranga Māori Committee proposal AUT	3	01 November 2020
CMDHB Maori support letter	1	01 November 2020
PIS/CF: Participant consent form	3	01 November 2020
PIS/CF: Reliability study participant information sheet	4	01 November 2020
PIS/CF: Diagnostic accuracy study participant information sheet	4	01 November 2020
Protocol	24	04 November 2020
Application		04 November 2020
Declined letter for previous application in respect of the same (or substantially similar) study: Current version 28/11	5	28 November 2020
Declined letter for previous application in respect of the same (or substantially similar) study: current version 28/11/2020	5	28 November 2020
Covering Letter: Cover letter in response to feedback	2	28 November 2020
PIS/CF: amended consent form	4	28 November 2020
PIS/CF: amended version reliability study information sheet	5	28 November 2020
PIS/CF: amended version diagnostic accuracy study information sheet	5	28 November 2020
Protocol: Data management plan	1	28 November 2020
Response to Request for Further Information		

Appendix B Statement of compliance and list of members

Statement of compliance

The Southern Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008713) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Mrs Helen Walker	Lay (consumer/community perspectives)	19/08/2020	19/08/2021
Dr Pauline Boyles	Lay (consumer/community perspectives)	05/07/2019	05/07/2022
Dr Paul Chin	Non-lay (intervention studies)	27/10/2018	27/10/2021
Mr Dominic Fitchett	Lay (the law)	05/07/2019	05/07/2022
Dr Sarah Gunningham	Lay (other)	05/07/2016	05/07/2022
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	28/06/2019	28/06/2020
Professor Jean Hay-Smith	Non-lay (health/disability service provision)	31/10/2018	31/10/2021
Dr Devonie Waaka	Non-lay (intervention studies)	18/07/2016	18/07/2019

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

<http://www.ethics.health.govt.nz>