

16 December 2020

Dr. MARLA Ross
PO Box 1936
Shortland Street
Auckland Central
Auckland Central 4110

Dear Dr. Ross,

Re: Ethics ref:	20/CEN/264
Study title:	Autologous protein solution in the treatment of knee osteoarthritis: a randomised control trial

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 Central 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 16 December 2021.

Participant access to ACC

The Central 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
Chairperson
Central 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>
PIS/CF: Participant information sheet	2	15 December 2020
PIS/CF: Consent form	2	10 November 2020
Survey/questionnaire: KOOS score	1	10 November 2020
Survey/questionnaire: WOMAC	1	10 November 2020
Evidence of scientific review: Peer review	1	12 November 2020
Protocol: Protocol	1	12 November 2020
Survey/questionnaire: VAS scores	1	12 November 2020
CV for CI: CV	1	12 November 2020
Covering Letter: Cover letter	1	12 November 2020
Information regarding approval for nSTRIDE in NZ	1	11 November 2020
Information regarding approval for nSTRIDE in NZ	1	11 November 2020
Information regarding approval for nSTRIDE in NZ	1	11 November 2020
Information regarding approval for nSTRIDE in NZ	1	11 November 2020
Information regarding approval for nSTRIDE in NZ	1	11 November 2020
Application		12 November 2020
Covering Letter: Response to provisional approval	1	15 December 2020
Response to Request for Further Information		

Appendix B Statement of compliance and list of members

Statement of compliance

The Central 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 00008712) 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)	22/05/2018	22/05/2023
Ms Helen Davidson	Lay (ethical/moral reasoning)	06/12/2018	06/12/2021
Dr Peter Gallagher	Non-lay (health/disability service provision)	22/05/2020	22/05/2023
Mrs Sandy Gill	Lay (consumer/community perspectives)	22/05/2020	22/05/2023
Dr Patries Herst	Non-lay (intervention studies)	22/05/2020	22/05/2023
Ms Julie Jones	Non-lay (intervention studies)	22/05/2020	22/05/2022
Dr Cordelia Thomas	Lay (the law)	20/05/2017	20/05/2020
Dr Jill Wilkinson	Non-lay (observational studies)	22/05/2020	22/05/2023

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>