Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011

hdecs@health.govt.nz

19 November 2020

Prof Jun Lu
WS 311B
34 St Paul Street
Auckland 1010

Dear Professor Lu,

Re:	**Ethics ref:**	**20/STH/153**
	Study title:	Mussel with fucoidan as a supplemented superfood – product development and clinical benefits

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.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee which require addressing by the Researcher are as follows.

1. Please note that the Chinese PIS consent has not been read or approved

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.

Non-standard conditions:

4. The compensation statement needs to reflect that this is a commercially-sponsored trial; this applies even if the item under study is not a pharmaceutical product. Participants who are injured as a result of study participation are therefore not eligible for ACC compensation. Please replace the ACC compensation statement with the commercial compensation statement.

Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDEC.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through Online Forms. Please clearly identify in the amendment form that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see section 128 and 129 of the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz)

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 19 November 2021.

Participant access to ACC

This clinical trial is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Section 32 of the Accident Compensation Act 2001 provides that participants injured as a result of treatment received as part of this trial will **not** 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,

Mrs. Helen Walker
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

Document	*Version*	*Date*
Evidence of scientific review: Peer review from Dr Yan Li	1	22 June 2020
CV for CI: CV for Prof Jun Lu	1	15 July 2020
Survey/questionnaire: Musculoskeletal Health Questionnaire	1	15 July 2020
Protocol: Study protocol	2	24 August 2020
Advertisement in English	2	24 August 2020
Advertisement in Mandarin	2	15 July 2020
PIS/CF: PIS/ICF	2	24 August 2020
Protocol: Study protocol	3	01 September 2020
Survey/questionnaire: Data collection form at baseline	1	24 August 2020
Application		01 September 2020
PIS/CF: Chinese version of PIS/CF - clean	3	27 October 2020
PIS/CF: Chinese version of PIS/CF - tracked	3	27 October 2020
Covering Letter: Cover letter addressing amendments	1	28 October 2020
Declined letter for previous application in respect of the same (or substantially similar) study	1	30 September 2020
PIS/CF: Updated PIS/CF after feedback from HDEC - clean version	3	27 October 2020
PIS/CF: PIS/CF after feedback from HDEC - tracked version	3 - tracked	27 October 2020
Protocol: Protocol after feedback from HDEC - clean version	Final - clean	15 October 2020
Protocol: Protocol after feedback from HDEC - tracked version	Final - tracked	15 October 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

Name	*Category*	*Appointed*	*Term Expires*
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