Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 21/CEN/178

30 September 2021

Dr Sharad Paul

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New Zealand

Tēnā koe Dr Paul

APPROVAL OF APPLICATION

Study title: Randomized, Within-Patient, Clinical Trial Comparing a Mineral Sunscreen containing Bioactive agents against Standard Moisturiser and Sunscreen use in Reducing Sun-damage and Pre-cancerous lesions

I am pleased to advise that your application was **approved** by the Central Health and Disability Ethics Committee (the Committee) on 4 September 2021 . This decision was made through the 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 Central Health and Disability Ethics Committee is required.

Standard conditions:

- Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
- Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a registry approved by the World Health Organization (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au or https://clinicaltrials.gov/).
- Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Ethics RM. 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 *SOPs* for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 4 September 2022.

Participant access to compensation

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.

Further information and assistance

Please contact the HDECs Secretariat at hdecs@health.govt.nz or visit our website at www.ethics.health.govt.nz for more information.

Nāku noa, nā

Mrs Helen Walker

Chair

Central Health and Disability Ethics Committee

Appendix A: Documents submitted

Document Type	File Name	Date	Version
"Declined" letter for previous application	HDEC Letter 21CEN137 Declined Application.pdf	21/06/2021	Declined letter for previous application in respect of the same (or substantially similar) study (1)
Covering Letter	Cover letter	21/06/2021	Covering Letter (2)
CV for Coordinating Investigator	CV-Sharad HDEC2021.docx	21/06/2021	CV for CI (2)
PIS/CF	Revised consent form after HDEC feedback	21/06/2021	PIS/CF (2)
PIS/CF	Revised consent form after HDEC feedback	21/06/2021	PIS/CF (2)
Protocol	Revised after HDEC feedback, and also changed at ANZCTR registry	21/06/2021	Protocol (2)
Evidence of Scientific Review	Peer review that had been obtained from independent overseas expert in the field	21/06/2021	Evidence of scientific review (2)
Other	Sunscreen Questionnaire BEST study.pdf	21/06/2021	Survey/questionnaire (2)
MDF Doc	Form Submission	01/07/2021	NZ/1/8C5A17
Other	HDEC Letter - 21CEN178 - Valid expedited application.pdf	01/07/2021	HDEC Documents
Other	HDEC Letter 21CEN178 Provisionally Approved Application.pdf	19/07/2021	HDEC Documents