

Ethics reference: 2022 EXP 12827

11 October 2022

Dr Margaret Sage

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Wellington
6011
New Zealand

Tēnā koe Dr Sage

APPROVAL OF APPLICATION

Study title: HPV Technology Validation study for processing self-collected swab samples

I am pleased to advise that your application was **approved** by the Southern Health and Disability Ethics Committee (the Committee) with non-standard conditions. This decision was made through the EXP 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:

- 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.

Non-standard conditions:

- As per the provisional approval letter, please include contact details for Māori cultural support in the PISCF alongside the added HDEC and HDC advocacy contact details. Currently a name has been provided on page 1, but no method of contact.

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

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through the [Ethics Review Manager](#). 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 paragraphs 125 and 126 of the [Standard Operating Procedures for Health and Disability Ethics Committees \(SOPs\)](#).

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 11th October 2023.

Participant access to compensation

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 trialed. 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 hdec@health.govt.nz or visit our website at www.ethics.health.govt.nz for more information, as well as our [General FAQ](#) and [Ethics RM user manual](#).

Nāku noa, nā



Mr Anthony Fallon

Chair

Southern Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Scientific Peer Review	Meeting Notes 2 Feb 2022 Governance group HPV self-testing validation protocol FINAL		
Scientific Peer Review	Peer review Richard Massey 24 Feb 2022		
Evidence of Consultation	AdcockA		
Other	20043_VCS.How to take your own HPV.WEB.ART		
Protocol	Validation protocol HPV Self-collects_FINAL for Ethics 26 May2022		
PIS/CF	Participant Information Sheet and Consent form HPV test validation FINAL 26 May 2022		
Tissue Management Plan	Data and Tissue management plan		
Data Management Plan	Data and Tissue management plan		
CV for Coordinating Investigator	MSageCV 2022		
Other	SCL Request form FINAL		
Response to PA Document	Validation protocol HPV Self-collects_UPDATED for Ethics 4 August 2022		
Response to PA Document	Participant Information Sheet and Consent form HPV test validation V3		
Response to PA Document	Data and Tissue management plan for HDEC - V2		
Response to PA Document	APHG Privacy Statement		
Response to PA Document	Māori consultation Wendy Dallas-Katoa 22 Aug 2022	22/08/2022	1
Response to PA Document	Covering letter August 2022	22/08/2022	1

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