Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2023 FULL 18780

10 January 2024

Dr Annie Wong

11 Riddiford Street, Newtown
Wellington
6021
New Zealand

Tēnā koe Dr Wong

APPROVAL OF APPLICATION

Study title: FAST study: Feasibility ASessment of circulating Tumour DNA (ctDNA) in the diagnosis of advanced lung cancer

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 full 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 ensure the family member nominated to receive relevant genetic results is made aware they have been nominated as soon as possible, to ensure they are comfortable with the responsibility.
2. Please correct the typo in section 11 of the data management plan ('Disaibility').

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:

- Please ensure the family member nominated to receive relevant genetic results is made aware they have been nominated as soon as possible, to ensure they are comfortable with the responsibility.
- Please correct the typo in section 11 of the data management plan ('Disaibility').

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 10 January 2025.

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 hdecs@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 Dominic Fitchett

Chair

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 Type	File Name	Date	Version
CV for Coordinating Investigator	Annie Wong HRC CV 2023		
PIS/CF	FAST_clinician_PICF_final		
PIS/CF	FAST-PICF_trackedchanges		
Other	MPS_certificate2023		
Other	HDEC Response to comments		
Surveys/questionnaires	FAST_clinician_survey_Final		
Surveys/questionnaires	FASTSemi_structured_interviews		
Surveys/questionnaires	Patient Survey ctDNA_final		
Protocol	clinicaltrialprotocoltemplatedocx_FAST_tracked		
Protocol	Data management plan tumour samples_FAST_tracked		
Scientific Peer Review	hdec-peer-review AT 2023		
Data and Tissue Management Plan	Data management plan tumour samples_FAST_cleaned	27/07/2023	1
Non-Review Document	Letter_outcome	04/09/2023	
PIS/CF	FAST-PICF_cleaned	14/09/2023	1
Protocol	clinicaltrialprotocoltemplatedocx_FAST_v1_cleaned	19/10/2023	
Response to PA Document	Ethics_reply_Dec23	20/12/2023	
Response to PA Document	clinicaltrialprotocoltemplatedocx_FAST_v1_cleaned_20231204	20/12/2023	1
Response to PA Document	FAST-PICF_cleaned20231204	20/12/2023	1
Response to PA Document	Data management plan tumour samples_FAST_cleaned20231204	20/12/2023	1

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

Mr Dominic Fitchett (Lay (the law)), Dr Devonie Waaka (Non-lay (intervention studies)), Ms Amy Henry (Non-lay (observational studies)), Associate Professor Nicola Swain (Non-lay (intervention studies)), Ms Dianne Glenn (Lay (consumer/community perspectives)), Ms Neta Tomokino (Lay (consumer/community perspectives)), Dr Maree Kirk (Lay (consumer/community perspectives)), Mrs Carla Strubbia (Non-lay (intervention studies)).

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