Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2022 FULL 11858

12 May 2022

Dr Frank Weilert

Waikato Hospital, 183 Pembroke Street, Hamilton 3204.
Hamilton
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New Zealand

Tēnā koe Dr Weilert

PROVISIONAL APPROVAL OF APPLICATION

Study title: Feasible, safety and utility of Endoscopic ultrasound-guided PPG measurement (EUS-PPGM) in patients undergoing liver resection and major intra-abdominal surgeries.

This application was reviewed by the Southern Health and Disability Ethics Committee (the Committee) and **provisionally approved** pending receipt of further information. This decision was made through the FULL pathway.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee clarified that the accessing of the portal vein would carry no increased risk of bleeding than in routine Fine Needle Aspirations (FNA). Please include this information in the information sheets.
2. The Committee clarified that the study in Adelaide was a sister study that was separate, but that data would be shared for the sake of combining for publication.
3. The Committee clarified that the participants would not be recruited by the study team and the surgeon would only contact the patient and provide the PIS once they had been forwarded to the study. The consenting would be on-site prior to the operation and study team would be informing participants as necessary to understand the procedure.
4. The Researcher clarified that the scientific peer reviewer was not an investigator and had been listed in the protocol in error.

Summary of outstanding ethical issues

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

1. Please remove the provider of the scientific peer review from the protocol as per the request of the Committee.
2. The Committee would like the researcher to provide their medical indemnity for review.
3. Please ensure the study is registered in a World Health Organization (WHO) -approved clinical trial registry prior to commencing recruitment activities.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. The Committee noted that there was an abundance of technical language and images that would need to be amended and reviewed for lay language and the overly technical or specialist aspects removed for clarity.
2. Please state that the study doctors have experience with the EUS-PPGM procedure and state the approximate number of procedures undertaken at the study site.
3. Please specify that the result of the EUS-PPG could impact on the decision to proceed with their scheduled surgery.
4. Please clarify whether participants would still undergo trans-jugular (TJ) measurement if they do not take part in the study (p8).
5. Please remove “If you agree” as the future use of coded data is not optional (page 10).
6. Please ensure the information about the study being stopped matches that in the protocol (page 11).
7. Please delete the Yes/No box from the General Practitioner (GP) notification clause in the consent form as this should not be optional.
8. Please review for typos and grammatical errors (i.e. on p5 “our very experience endoscopist”, mixing tenses, etc).
9. Please explain conditions and terms used in the risk section on page 6.

Further information requested

The further information requested in order for the Southern Health and Disability Ethics Committee to make a final decision is as follows.

The Committee requested the following changes to the Protocol:

1. Section 10 of the data management plan (DMP) states 'we will only be collecting data for a small group of patients receiving their medical care through

specialised cancer pathway'; the protocol discusses liver cancer and colorectal cancer but does not limit study inclusion to adults receiving specialist cancer care. Please specify in the eligibility criteria that study entry is restricted to adults with a confirmed cancer diagnosis and liver lesions.
2. Please amend to include informed consent procedure and timing; screening/ eligibility procedures (including whether these are collected as a study procedure or whether standard of care samples results will be used); and all time points for scheduled in-person or remote participant contact.
3. Please address safety monitoring and study stopping criteria adequately.
4. Please clarify the sample size and amend as required.

The Committee requested the following changes to the Data Management Plan (DMP):

1. Please identify appropriate data governance policies / standard operating procedures required at the locality (Waikato District Health Board) and reference these.

Responding to requests for further information

Please track or highlight changes made to new versions of existing study documentation. Both tracked and clean versions of updated documents should be provided when responding to a provisional approval.

In addition to making requested changes to study documentation, a cover letter should be used to respond to all outstanding ethical concerns. This includes addressing concerns raised about questions in the application as the application form cannot be edited when responding to provisional approval.

Timeline for providing further information

You have 90 days to provide this further information. Your application will be considered to have been withdrawn if this information is not received on or before 90 days from the date of this letter . A new application would be required in this case.

A reminder notification will be sent through ERM after 60 days have elapsed if the response has not been received.

Timeline for giving a final decision

The review clock within which a final decision must be made on this study is suspended as of the date of this letter. This clock, on which 22 days remain, will restart on the date on which **all** of the further information requested above is received by the Committee.

How to respond to provisional approval

Your application form will now be unlocked and you may make any changes to questions. These will be saved as a new version when you re-submit the form.

Please upload new or revised documents into the 'Response to PA' section at the end. For more information please see the Ethics RM manual.

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 manual.

Nāku noa, nā

Yours sincerely,

Mr Anthony Fallon

Chair

Southern Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix B: statement of compliance and list of member

Appendix A: Documents submitted

Document Type	File Name	Date	Version
CV for Coordinating Investigator	CV Apr 2021 Weilert	01/04/2021	
Protocol	Protocol EUS-PPGM	31/03/2022	1
PIS/CF	Participant Information Sheet and Consent form	31/03/2022	1
Data Management Plan	DATA MANAGEMENT PLAN	31/03/2022	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

Ms Amy Henry, Mr Anthony Fallon, Dr Devonie Waaka, Mr Dominic Fitchett, Associate Professor Nicola Swain

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).

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