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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 11 March 2025 |
| **Zoom details:** | 96507589841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 10:00 - 10:30am |  | Committee Welcome |  |  |
| 10:30 - 11:00am | 2024 EXP 22105 | Rhythms of recovery in mood disorders | Professor  Richard Porter | Maree / Nicola |
| 11:00 - 11:30am | 2025 FULL 22226 | V118\_24: A study to compare adjuvanted Influenza vaccine with non-adjuvanted Influenza vaccine in adults aged 65 years and over | Dr Paul Hamilton | Catherine / Albany |
| 11:30am - 12:00pm | 2025 FULL 22178 | Oral ketamine for bipolar depression | Associate Professor  Ben Beaglehole | Amy / Neta |
| 12:00 - 12:30pm | 2025 FULL 22120 | FLAGSHIP FIH NZL | Dr Andrew Holden | Dianne / Patries |
| 12:30 - 1:30pm |  | **BREAK (60 mins)** |  |  |
| 1:30 - 2:00pm | 2025 EXP 22190 | Testing a new artificial intelligence tool to improve gallbladder surgery analysis | Professor Tim Eglinton | Catherine / Amy |
| 2:00 - 2:30pm | 2025 FULL 22189 | A Clinical Study to Assess the Safety and Effectiveness of Tovinontrine in Patients With Chronic Heart Failure | Dr James Pemberton | Maree / Albany |
| 2:30 - 3:00pm | 2025 EXP 21655 | Multimodal Computer Vision Enhanced Analysis of Bile Duct Cytology in Pancreatic and Bile Duct Cancer | Professor Tim  Eglinton | Dianne / Nicola |
| 3:00 - 3:30pm | 2025 FULL 21555 | ACT-GLOBAL - A multi-faCtorial, mulTi-arm, multi-staGe, randomised, gLOBal Adaptive pLatform trial for stroke | Dr Teddy Wu | Patries / Neta |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mr Dominic Fitchett | Lay (the Law) (Chair) | 05/07/2019 | 05/07/2022 | Apologies |
| Dr Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Dr Nicola Swain | Non-lay (Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Dianne Glenn | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Neta Tomokino | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Dr Geoff Noller | Non-lay | 03/03/2025 | 02/03/2029 | Present |
| Ms Catherine Garvey | Lay (the Law) (Chair) | 11/08/2021 | 11/08/2024 | Present |
| Dr Patries Herst | Non-lay (Intervention studies) | 03/03/2025 | 02/03/2030 | Present |
| Mx Albany Lucas | Non-lay (Observational studies) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 10:00am and welcomed Committee members, noting that apologies had been received from Mr Dominic Fitchett.   
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Catherine Garvey, Dr Patries Herst and Mx Albany Lucas confirmed their eligibility and were co-opted as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 04 February 2025 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2024 EXP 22105** |
|  | Title: | Predicting bipolar disorder course from the 24-hour rest-activity rhythm |
|  | Principal Investigator: | Professor Richard Porter |
|  | Sponsor: | Te Whatu Ora, Canterbury |
|  | Clock Start Date: | 27 February 2025 |

Professor Richard Porter, Professor Greg Murray and Dr Matthew Tennant were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

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

1. The Committee advised a withdrawal form is not required in New Zealand as participants may withdraw at any time verbally.

Summary of outstanding ethical issues

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

1. The Committee noted there was no consent form. The Researcher clarified two sheets were submitted, a brief one for people in the midst of an episode and a longer sheet that contains a more detailed description of the study. This is due to the change in presentation of the participants over time. The Researcher clarified there is a separate consent form supplementary to both sheets and this was submitted separately. The Committee noted this was not included and requested it is uploaded.
2. The Committee queried whether the study would recruit inpatients only, or also from the community. The Researcher stated they would recruit some eligible participants who are community-based patients. The Researcher stated some of the inpatients may be under a compulsory treatment order and the study would not affect that. The Committee advised it is important to have an independent treating clinician record that the participant is able to provide informed consent, separate from the clinician responsible for the community treatment order assessments.
3. The Committee requested the Researcher include a paragraph in section 8.3 of the data management plan to address AI/machine learning uses of anonymised information. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15)*
4. The Committee noted the Pacific consultation recommended a Pacific advisory person is included in the study team and queried whether this has been organised

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please ensure consistency as the sheet switches between ‘you’ and ‘they’.
2. Please explain what data is stored in the watch and that it does not transmit data; you might also refer to the information sheet about the watch that should be provided to participants.
3. Please explain what machine learning is in simple language (eg data from the watch will be used to build an algorithm) and include more information on what it does with the data in an appropriate section. .
4. Please inform participants who the interviewer is (e.g. a student, psychiatrist or trained researcher).

**Decision**

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the data management plan (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15)*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Maree Kirk and Dr Nicola Swain.

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| **2** | **Ethics ref:** | **2025 FULL 22226** |
|  | Title: | A Phase 3/3b, Randomized, Observer-blind, Multicenter Clinical Study to Evaluate the Efficacy, Safety and Immunogenicity of an MF59-Adjuvanted Subunit Inactivated Influenza Vaccine Compared to a Non-adjuvanted Influenza Vaccine in Adults ≥65 Years of Age |
|  | Principal Investigator: | Dr Paul Hamilton |
|  | Sponsor: | Seqirus UK Limited |
|  | Clock Start Date: | 27 February 2025 |

Dr Paul Hamilton and Ms Charlene Botha were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

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

1. The Committee noted the equipoise standard was not addressed in the application and queried how the options are equally poised. The Researcher explained the MF59 adjuvant is something used successfully and this study is looking to see if the same benefits can be gained from adding it to the investigational vaccine. The Researcher stated every participant will receive a vaccine and it is yet to be determined if adding the adjuvant provides an extra efficacy benefit.
2. The Researcher confirmed the study would only analyse viral cells and not human tissue cells.

Summary of outstanding ethical issues

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

1. The Committee queried the process for GPs advertising the study to potential participants. The Researcher explained they were collaborating with some local practices where GPs will do database searches for particular patient populations. The GP would make first contact and ask them for interest about the study. If the patient is interested the study team will reach out to provide more information. The Researched confirmed the GPs would obtain permission from the patient to share their details and that they are eligible for the study. The Researcher confirmed GPs would be reimbursed for the database search but not for recruitment numbers. The Committee recommended this is disclosed upfront and GPs are aware of their obligations around these interactions with respect to guidelines issued by the Medical Council of New Zealand.
2. The Committee advised the study is required to collect New Zealand specific ethnicity data at a site-level. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.20)*
3. The Committee noted advertisements contained language promising benefits from this study than is permissible and which are overstated eg free health monitoring, access to care needed and expert treatment. The Committee requested these are amended. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.10)*
4. The Committee requested information on how the flu affects Māori as it was not provided in the application form. The Researcher agreed to supply this in the response to provisional approval.
5. The Committee advised C5-C10 of the application form ought to have included consideration of the head being tapu as a significant cultural issue. As this study involves touching of the face and neck please include an acknowledgement of this in the information sheet when discussing the physical exam required.
6. The Committee noted separate information sheets for different vaccines may not be required. If the adjuvant is the only significant difference to side effects this may be noted in one single sheet.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please include a short lay title.
2. Please state how many participants will be recruited in New Zealand.
3. Please undertake a revision to use plain lay-friendly language eg amend the sentences regarding ‘scores of previous studies’, ‘unintentional significant harm’. Please simplify technical terms such as observer blind and myalgia.
4. Please simplify the information about the different vaccines. It is sufficient to say that there are two vaccines that are similar and one will have an adjuvant and one will not. The study will look at whether the adjuvant makes a difference.
5. Please include that future access and use of deidentified information will be released to projects with ethical approval.
6. Please simplify repetitive information on page 8.
7. Please state whether participants are required to undress for the physical exam, whether they can bring a support person and whether gender matching is available (ie the person performing the exam is the same gender as the participant).
8. Please move the bold paragraph about allergy exclusion to earlier in the sheet.
9. Please state reimbursement for reasonable travel costs instead of compensation on page 12.
10. Please amend the information on page 15 about personal data. Please review the HDEC template and align the information (eg whether personal data is identified or coded). Please review the reference to anonymous data and whether it is truly anonymised or deidentified.
11. Please state whether wifi is required for the e-diary.
12. Please state whether the e-diary is monitored in real time.
13. Please state how long samples will be kept for.
14. Please include a ‘yes / no’ tickbox next to requesting a summary of results.
15. Please remove the ‘yes / no’ tickbox next to GP notification as this should be mandatory. Please remove any tickboxes unless they are truly optional (ie the participant can answer no and still participate).

**Decision**

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study advertisements. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.10).*
4. Please ensure New Zealand ethnicity data is collected at a site-level (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.20).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Catherine Garvey and Mx Albany Lucas.

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| **3** | **Ethics ref:** | **2025 FULL 22178** |
|  | Title: | Feasibility of oral ketamine for bipolar depression: a 20-week open-label study |
|  | Principal Investigator: | Associate Professor Ben Beaglehole |
|  | Sponsor: | The University of Otago |
|  | Clock Start Date: | 27 February 2025 |

Associate Professor Ben Beaglehole was present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

Mx Albany Lucas declared a potential conflict of interest. The Committee determined this was minor and Mx Lucas was allowed to participate in the discussion.

Summary of resolved ethical issues

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

1. The Committee advised a media release is considered advertising and requested this is uploaded for review.
2. The Researcher confirmed the trial has been registered.

Summary of outstanding ethical issues

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

1. The Committee queried how concerns about a participant having an acute episode during consenting would be addressed. The Researcher stated if the person does not wish to participate the study would write back to their referrer that they have withdrawn. If a participant becomes acutely unwell on the study, there are psychiatrists on the team who would review them and write back to their referrer. The Committee requested the Researcher update the protocol to include more information on this.
2. The Committee requested the Researcher supply the qualitative evaluation interview guide.
3. The Committee requested the Researcher update the protocol to include more information on the dosing regime and potential side effects. Please include reference to the previous study investigating ketamine as a treatment for major depressive disorder if the dosing regime will be replicated. The Committee suggested a schedule of visits table would be useful. Please ensure all applicable requirements from Standard 9.8 are met. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8).*
4. The Committee requested the Researcher determine if SCOTT review is required.
5. The Researcher clarified the study involves an eight-week treatment period and a three-month follow-up period. The Committee expressed concern at the limitations on relying upon GP support and what care is provided to participants during an acute episode or if participants score on the QOL surveys, indicating risk or distress. The Committee requested a plan is included in the protocol. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*
6. The Committee expressed concern at the risk of a participant trying to access ketamine from the black market. The Researcher stated participants are drug screened and an interview checks for substance use disorders and participants are not accepted unless they have a supporting letter from a referring GP or specialist. The Committee requested additional information about duty of care is included in the protocol and whether this may be extended and what resources may be available. The Committee strongly recommended a 12 month follow-up.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please include information about the dosing regimen (e.g. dose given, maximum dose, justification for whether a participant will have one or two doses per week etc).
2. Please include more information about the actigraphy, what it is used for, what data is collected by the watch and whether it is stored or transmitted to another party.
3. Please state what koha is available for participation.
4. Please include a discussion of the risk of how participants feel when the trial stops and the potential for misuse of ketamine long-term.
5. Please ensure the sheet reflects that ketamine for bipolar disorder is investigational and not an established treatment. For example please revise sentences such as “During the first 8 weeks of our study, we will provide treatment for your bipolar disorder” and “we are offering you treatment for your bipolar depression”.

**Decision**

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above.

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| **4** | **Ethics ref:** | **2025 FULL 22120** |
|  | Title: | False Lumen Treatment for Prevention of Aortic Growth using Shape Memory Polymer – First-in-Human Study |
|  | Principal Investigator: | Dr Andrew Holden |
|  | Sponsor: | Shape Memory Medical Inc. |
|  | Clock Start Date: | 27 February 2025 |

Dr Andrew Holden, Ms Helen Knight and Ms Cindy Corne were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

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

1. The Committee queried if participants could refuse a Sponsor representative being present. The Researcher clarified if the participant was having an explant the representative would be an observer and it was optional to have them present. At the implant the representative would be offering technical advice and would be required to be present.
2. The Committee appreciated the use of diagrams in the information sheet.
3. The Researcher clarified testing for notifiable diseases would not be performed.

Summary of outstanding ethical issues

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

1. The Committee queried why pregnancy was an exclusion and why a participant who receives the surgery and then later becomes pregnant would be excluded. The Committee noted this is inconsistent with Standard 9.12 of the National Ethical Standardsand requested this is reconsidered. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.12).*

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please state the ethical aspects of the study have been approved by the HDEC (not the entire study).
2. Please consider whether you can quantify the risk of adverse events and whether the possibility of device migration should be included.
3. Please consider extra support for a disabled participant and whether costs can be covered for them bringing a support person.

**Decision**

This application was *approved* by consensus, subject to the following non-standard conditions:

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* please reconsider pregnancy as an exclusion *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.12).*

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| **5** | **Ethics ref:** | **2025 EXP 22190** |
|  | Title: | Computer-vision based artificial intelligence systems for real-time identification of significant intraoperative events |
|  | Principal Investigator: | Professor Tim Eglinton |
|  | Sponsor: | The University of Otago |
|  | Clock Start Date: | 27 February 2025 |

Professor Tim Eglington, Dr Jayvee Buchanan were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of outstanding ethical issues

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

1. The Committee queried if the surgeons performing the procedure would be study participants. The Researcher acknowledged that they will be as they are separate from the study and the module will run in the background of the operating theatre. The surgeon will not be aware of the outputs of the algorithm in real time. If a discrepancy between the surgeon and algorithm is detected (eg grading of the gallbladder) the researchers can discuss with the surgeon after the procedure. The Committee suggested developing an information sheet and consent form for the surgeons so they can formally document participation and their understanding of what the algorithm does and what will happen if a discrepancy is detected. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
2. The Researcher clarified at this stage there is no potential commercialisation of the algorithm. The Committee suggested adding this to the information sheet.
3. The Committee noted the data management plan stated data would be deleted after 10 years and queried if this was applicable to the AI. The Committee advised it can be kept longer with justification if required such as to avoid having to generate new data in the future. If it is kept longer, please amend the information sheet to reflect this.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please include a simplified version of the response to E4 in the application form regarding abnormal results of clinical significance.
2. Please state if the study will contribute toward a tertiary qualification.
3. Please include more information about use of data and deidentified video from the data management plan and include it in the information sheet. Please state who will have access to data and what it will be used for.
4. Please state how long data will be kept for and if the video may be used to develop the algorithm. If data will be kept indefinitely, please specify this will be coded.
5. Please include contact details per the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
6. Please state that no identifying features (e.g. face) will be in the video.
7. Please state how many other participants will be taking part in the study.

**Decision**

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Catherine Garvey and Dr Amy Henry.

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| **6** | **Ethics ref:** | **2025 FULL 22189** |
|  | Title: | A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Dose-Finding Study to Assess the Safety and Effectiveness of Tovinontrine in Patients With Chronic Heart Failure With Reduced Ejection Fraction |
|  | Principal Investigator: | Dr James Pemberton |
|  | Sponsor: | Cardurion Pharmaceuticals, Inc. |
|  | Clock Start Date: | 27 February 2025 |

No researcher was present for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of outstanding ethical issues

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

1. The Committee queried if home visits would be undertaken in New Zealand. If so please clarify who will conduct these. If it is the research team then please supply a home visit safety plan for study staff. If it is a third party then please explain who it is and what data is shared with them. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62 – 11.63).*
2. The Committee advised that ACC-equivalent insurance would need to be maintained for the entire duration of the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
3. The Committee queried how soon the EQ-5D-5L would be reviewed after completion and what action the study team would take if a participant indicated severe distress or suicidal ideation. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*
4. The Committee queried why a participant who is HIV+ cannot participate.
5. The Committee requested justification for not providing ongoing access if therapeutic benefit is achieved. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 10.15).*
6. The Committee queried how researchers will mitigate the influence of the treating clinician when recruiting/consenting.
7. Please include the HDEC reference number (22189) on the study advertisements and brochure.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please clarify in simple language what the drug is expected to do, how it works and if participants are expected to feel any better as a result. Please state whether any benefit will disappear once medication is ceased.
2. Please simplify to “regular doctor” and remove “from whom you take treatment for ailments”.
3. Please rephrase “you will not lose any medical benefits to which you are entitled” to “this will not affect your usual care”.
4. Please include the inclusion / exclusion criteria near the front as this may save participants time if they are not eligible.
5. Please state that participants may bring their prescribed and non-prescribed medicines to show study staff what they are taking. This assists with language and literacy barriers and confidence.
6. Please review the sentence “If you become pregnant, a pregnancy test will be carried out on your blood. The result must be negative for you to be in the study” as this does not make sense.
7. Please state whether gender-matching of the person performing the scan is possible and if the participant is required to undress.
8. Please frame all potential side effects as numbers of out 100.
9. Please include information on what support is available if the participant indicates concerning responses in the quality of life questionnaire.
10. Please state what a participant should do if they miss a dose (eg wait until the next scheduled dose).
11. Please review for typos e.g. “the study team will monitor how accurate you take the study medicine” on page 6.
12. Please include cultural support contact details on page 10.
13. Please amend unborn baby to foetus as this is less emotive. Please amend “father a baby” to gender neutral language (e.g. “planning to get someone pregnant”) and “provide her with contact information” to “them” or rewording the statement.
14. Please remove ‘yes / no’ tickboxes for information collected prior to withdrawing unless this is truly optional.
15. Please remove “if that is needed” when discussing appropriate support on page 11.
16. Please remove “reasonable” when discussing journey costs on page 13.

**Decision**

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the study advertisements.
3. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mx Albany Lucas and Dr Maree Kirk.

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| **7** | **Ethics ref:** | **2025 EXP 21655** |
|  | Title: | Multimodal Computer Vision Enhanced Analysis of Bile Duct Cytology in Pancreatic and Bile Duct Cancer |
|  | Principal Investigator: | Professor Tim Eglinton |
|  | Sponsor: | The University of Otago |
|  | Clock Start Date: | 27 February 2025 |

Prof Tim Eglington, Dr Hannah Kim and Dr Arthur Morley-Bunker were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

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

1. The Researcher confirmed tissue is returned to the lab. Slides are digitised and no tissue is manipulated or tested.
2. The Committee requested more detail is added to the justification that seeking consent is not practical due to age and quantity of records. The Researcher explained many of the patients will be deceased and due to the age of patients there is likely a high mortality rate. The Committee agreed the threshold for granting a waiver of consent was met.
3. The Researcher confirmed there is a remote possibility that a finding of clinical significance may be made on review of the slides and that appropriate follow up with the treating clinician would occur.

Summary of outstanding ethical issues

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

1. The Researcher confirmed a memorandum of understanding with participating labs would be established. The Committee requested this is supplied via the amendment pathway.

**Decision**

This application was *approved* by consensus, subject to the following non-standard conditions:

* please supply the memorandum of understanding with the lab via the amendment pathway

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| **8** | **Ethics ref:** | **2025 FULL 21555** |
|  | Title: | ACT-GLOBAL - A multi-faCtorial, mulTi-arm, multi-staGe, randomised, gLOBal Adaptive pLatform trial for stroke |
|  | Principal Investigator: | Dr Teddy Wu |
|  | Sponsor: | The George Institute for Global Health |
|  | Clock Start Date: | 27 February 2025 |

Dr Teddu Wu and Ms Sara Parkin were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of resolved ethical issues

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

1. The Researcher confirmed Māori consultation has been undertaken through the local research office and approved.
2. The Researcher clarified the drug is pending Medsafe approval which should be finalised shortly.
3. The Committee advised that consent cannot be given retrospectively in New Zealand and one adult may not give proxy consent for another. The Committee explained whānau can be included in the consenting process but they can only offer an opinion if they believe their whānau member would have wanted to participate. The ultimate decision must be made by the clinician that it is in the best interests of the participant.

Summary of outstanding ethical issues

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

1. The Committee suggested simplifying the whānau sheet so it briefly describes the study but does not need to contain the full information in the main sheet. Please amend the signature box to reflect that the discussion has occurred, not that the whānau are giving consent on behalf of the participant.
2. The Committee advised that participants who are enrolled under Right 7(4) need to have a modified information sheet that explains they were enrolled because it was believed to be in their best interest and to ask them for consent for ongoing participation and use of information.
3. The Committee queried what support is available if someone indicates severe distress or suicidal ideation when completing the EQ-5D-5L. The Committee noted asking these questions places a duty of care on clinicians and it is not sufficient to expect the participant to follow-up with their GP. The Committee advised if there is no support available then the questions should not be asked if they are asked as a research component and not standard practice. The Researcher stated crisis lines can be used if required. The Committee requested this is summarised in the information sheet.
4. The Committee suggested a short plain language form for participants who are acutely unwell but have the capacity to consent. When participants recover they can be consented on the full sheet.
5. The Committee advised that in New Zealand participants may withdraw verbally and are not required to sign a form.
6. The Committee requested the Researcher supply evidence of professional indemnity for the coordinating investigator.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please supply simple plain language sheets for the participant and whānau in addition to the full versions.
2. Please write as ratio as well as percentages (e.g. 3 in 100 people)
3. Please amend "if you decide to withdraw from the study, please notify a member of the research team immediately, who will arrange an appointment to discuss this with you" to clarify that this is optional. A participant should be able to withdraw without meeting to discuss.
4. Please be clear if "we would request that we continue to collect data on treatment received whist in hospital..." is mandatory or optional.
5. Please reword “will be followed up for 90 days (or until death, if prior to 90 days)" to be less confronting.
6. Please state the drug has Medsafe approval.

**Decision**

This application was *provisionally approved* by consensus, subject to the following information being received:

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent forms, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Patries Herst and Mrs Neta Tomokino.

## General business

1. The Chair reminded the Committee of the date and time of its next scheduled meeting:

|  |  |
| --- | --- |
| **Meeting date:** | 08 April 2025. |
| **Zoom details:** | 96507589841 |

The following members tendered apologies for this meeting.

* Dr Nicola Swain

1. **Review of Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 3:30pm.