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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 27 May 2025 |
| **Zoom details:** |  |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11:30 - 12:00pm |  | **Committee Welcome (30 mins)** |  |  |
| 12:00 - 12:30pm | 2025 FULL 22899 | The effect of home and hospital mask designs on respiratory variables in healthy volunteers: A pilot clinical investigation | Dr William Good | Catriona / Patricia |
| 12:30 - 1:00pm | 2025 FULL 22861 | 849-007 (KRYSTAL 7) | Dr Malcolm Anderson | Jonathan / Albany |
| 1:00 - 1:30pm | 2025 FULL 23068 | A Study of a Potential Disease Modifying Treatment in Individuals at Risk for or With a Type of Early Onset AD Caused by a Genetic Mutation | Dr Campbell Le Heron | Joan / Andrea |
| 1:30 - 2:00pm | 2025 EXP 22767 | Living Well with Memory and Thinking Changes in Aotearoa NZ study | Professor Ngaire Kerse | Cordelia / Patricia |
| 2:00 - 2:30pm |  | **BREAK (30 mins)** |  |  |
| 2:30 - 2:45pm | 2025 EXP 22921 | Feasibility study of lung function testing methods using uncued spontaneous breathing | Dr Ella Guy | Catriona / Andrea |
| 2:45 - 3:00pm | 2025 EXP 22931 | Exposure and health of workers on the Accelerated Silicosis Assessment Pathway | Dr Amanda Eng | Cordelia / Albany |
| 3:00 - 3:15pm | 2025 EXP 22626 | Can social support reduce the impact of stress on gastric functioning? | Dr Elizabeth Broadbent | Joan / Patricia |
| 3:15 - 3:30pm | 2025 EXP 21801 | CPPD Disease Cohort Study | Professor Nicola Dalbeth | Jonathan / Andrea |
| 3:30 - 3:45pm | 2025 EXP 22994 | Evaluating the impact of different tear supplements on the eye | Professor Jennifer Craig | Cordelia / Andrea |
| 3:45 - 4:00pm | 2025 EXP 22122 | AI (artificial intelligence) analysis for adult sleep studies | A/Prof Angela Campbell | Joan / Albany |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Joan Pettit | Lay (Chair) | 08/07/2022 | 08/07/2025 | Present |
| Mrs Sandy Gill | Lay (Consumer/Community perspectives) | 22/05/2020 | 22/05/2023 | Apologies |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Apologies |
| Dr Cordelia Thomas | Lay (the Law) | 21/12/2021 | 21/12/2024 | Present |
| Mrs Patricia Mitchell | Non-lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Mx Albany Lucas | Non-lay (Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Apologies |
| Dr Andrea Furuya | Non-Lay | 03/03/2025 | 02/03/2029 | Present |
| Dr Catriona McBean | Lay | 03/03/2025 | 02/03/2030 | Present |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |

## Welcome

The Chair opened the meeting at 12:00pm with a karakia and welcomed Committee members, noting that apologies had been received from Dr Patries Herst, Ms Sandy Gill and Ms Jessie Lenagh-Glue.   
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mr Jonathan Darby and Dr Catriona McBean confirmed their eligibility and were co-opted by the Chair 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 22 April 2025 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2025 FULL 22899** |
|  | Title: | The effect of home and hospital mask designs on respiratory variables in healthy volunteers: A pilot clinical investigation |
|  | Principal Investigator: | Dr William Good |
|  | Sponsor: | Fisher and Paykel Healthcare |
|  | Clock Start Date: | 15 May 2025 |

Olivia Kennington on behalf of the investigator and Jess Fogarin on behalf of the sponsor 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 Researchers confirmed that the scientific reviewer was not employed by Fisher and Paykel.
2. The Researchers described their Data Management Plan (DMP) in which identifiable personal information of employee participants will be kept confidential. Each participant will be assigned an ID code, and direct supervisors or managers will not have access to individual responses or results.

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 concerns about the inherent power dynamic when employees volunteer for a company-sponsored study. There is a risk employees might feel subtle pressure to participate, especially if recruited via a company-wide email. The Committee requested that the researchers exclude any employees who report directly to a member of the research team or to someone involved in the study to remove even indirect pressure. This change should be reflected in the protocol inclusion/exclusion criteria. The Committee also requested that the provision that participation is completely optional with no impact on one’s job is repeated throughout study materials. They requested more explicit language in the documents to mitigate any perception of coercion.
2. The Committee noted that volunteers receive no compensation or koha aside from participating during paid work hours. The committee felt this could be improved. While extra pay is not expected, a small token of appreciation (such as a voucher or company recognition) would acknowledge participants’ contributions.

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

1. Please ensure that it is clear that the PI, a respiratory specialist, is not employed by Fisher and Paykel, and is engaged as an independent medical consultant for the study. He will not be involved in data analysis as his role is limited to medical oversight. Provide evidence of where those who work in the study are employed and outline how any commercial interest is managed.
2. Please revise the PIS to prominently state that participation is entirely voluntary and that an employee’s decision to participate or not will have no effect on their employment, performance evaluations, or relationship with the employer. This statement should be bold or highly visible. Include phrasing like, “Your choice will not be communicated to your supervisors except as needed for scheduling, and it will not affect your job in any way.”
3. Please add a brief description of the under-mattress sensor in the PIS so participants know what to expect. For instance: “A flat sensor will be placed under the bed mattress to monitor your breathing and heart rate while you are resting. It’s non-invasive and you won’t feel it”.
4. Please outline in the PIS that if anything unusual is detected from the sensor, medical staff are on standby. This addresses curiosity and any concern participants might have about unknown devices
5. Please provide a clear plan for handling any physical injury or adverse event that occurs during study participation and clarify whether such an event would be covered by the employer’s workplace injury policies or ACC.

**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 protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
4. Consider management of power imbalance when making changes to PIS and protocol documents (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.13 – 6.18).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Catriona McBean and Mrs Patricia Mitchell.

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| **2** | **Ethics ref:** | **2025 FULL 22861** |
|  | Title: | A Phase 2 Trial of Adagrasib Monotherapy and in Combination with Pembrolizumab and a Phase 3 Trial of Adagrasib in Combination with Pembrolizumab versus Pembrolizumab in Patients with Advanced Non-Small Cell Lung Cancer with KRAS G12C Mutation |
|  | Principal Investigator: | Dr Malcolm Anderson |
|  | Sponsor: | Mirati Therapeutics, Inc. a Bristol Myers Squibb Company |
|  | Clock Start Date: | 15 May 2025 |

Dr Malcom Anderson and Nicole Cameron 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 Researchers confirmed that someone other than the study oncologist take participants through the consent process. This person is able to answer questions about the in a lay friendly way but not directly responsible for the patient’s cancer treatment decisions.

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 that the follow up time for quality-of-life questionnaires was not clearly explained. A safety plan needs to be in place that will outline the processes if a participant indicates severe anxiety or depression. Explain that the questionnaires are being reviewed the same day they are completed, and that study nurses and oncologists will be alerted to discuss distress with the patient immediately during their clinic visit and appropriate referrals (to psychological services, social work, or GP) would be made as needed.
2. The Committee noted that the current model of expecting participants to keep receipts for reimbursement for food and meals has the potential, in a number of situations, for participants to miss out on repayment. The Committee indicated that the provision of a stipend in this situation would address these issues.
3. The Committee requested that potential participants are given the main trial Participant Information Sheet (PIS) at the same time as the pre-screening consent, before any blood is taken for KRAS mutation testing. The Committee requested that the process be changed so that individuals can review all aspects of the study prior to agreeing. This might mean giving out both the pre-screening information sheet and the full study PIS together, however it should remain clear that pre-screening is the first step of the larger trial and is what will be consented to first. The pre-screening and PIS documents should also be reviewed for repeated information.
4. The Committee requested that the purpose of the additional consent form is fully explained. It may be presented if there is further disease progression in a participant or after finishing the blinded phase, participants are invited to continue therapy in an open-label extension.

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

1. Please indicate in the PIS how many participants are expected to be recruited in New Zealand.
2. Please consider the provision of a lay title and use simple language throughout documents, rephrasing sentences such as “I understand and fully comprehend the information” to “I have read and understood the information.”. Consider also removing descriptions of procedures and data collected as part of standard care as it is not part of this study.
3. Please use millilitres (mL) instead of “teaspoons” to quantify blood draws or other fluids.
4. Please provide information outlining whether participants will be expected to undress for any physical exam and if they can bring a support person. Please also explain whether participants can request that for the researcher of the same gender to carry out the exam.
5. Please remove any references to external documents or guidelines that participants are unlikely to access, for example, “according to FDA industry guidelines...” or “per sponsor’s standards”, and revise documents for accuracy in the New Zealand context.
6. Please clarify clinical procedures in the study in plain terms and clearly describe what procedures will take place during visits, employ a clear format (consider a table or bulleted list by visit). Outline treatment cycles and study stages clearly in lay language or with the assistance of a table or diagram.
7. Please revise the PIS to use gender neutral language. Wording from the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) under the reproductive risks can be adapted into this study PIS.
8. Please revise side effects section to include proportions alongside percentages.
9. Please clearly distinguish which procedures are standard-of-care and which are done solely for research in the PIS, and in the protocol. Explain that the tumour biopsy and PD-L1 testing are part of routine diagnosis/treatment planning for lung cancer (and will happen to all suitable patients regardless of trial participation), whereas the KRAS ctDNA blood test is being done specifically for determining trial eligibility.
10. Please clarify that pembrolizumab can be considered standard therapy for some patients, but in this trial even those who might not otherwise qualify for it may receive it in combination with the new drug. Clearly identify which drug/combination of drugs are approved and/or funded by NZ regulatory authorities, and which are not.
11. Please provide frequency of false negatives.
12. Please revise for consistency in drug naming, refer to each study drug consistently throughout all documents whether that is a generic name, or a brand name.
13. Please ensure that it is clear to participants that information will be stored overseas.
14. Please clarify the policy for notifying the participant’s GP about trial participation. The Committee recommends that GPs are informed by default, in which case include in the PIS and the consent form wording identifying this will take place and is compulsory.
15. Please ensure that it is clear that samples will be kept for at least 10 years.
16. Please revise section on pregnancy testing and treatment cycles, state the required frequency of pregnancy testing in and why this testing is being carried out. Consider if the current frequency of pregnancy testing every 21 days is necessary and if frequency of these pregnancy tests can be reduced. Regardless, make sure participants are aware of how often and why.
17. Please clearly spell out that people of childbearing potential must use effective contraception during the study and for a defined period after and include information for participants who could get a person pregnant. If the trial drug could affect sperm or pose a risk to pregnancies indicate that participants with partners who can become pregnant should also use contraception during the study and for X months after, and that participants should not donate sperm in that period.
18. Please clarify how long the study will go on.
19. Please clarify if a karakia will be available at tissue disposal or collection.
20. Please change wording “tissue destruction” to “tissue disposal”.

**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 protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Johnathan Darby and Mx Albany Lucas.

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| **3** | **Ethics ref:** | **2025 FULL 23068** |
|  | Title: | A Phase II/III Multicenter Randomized, Double-Blind, Placebo-Controlled, Two-Stage Adaptive Design, Platform Trial of Investigational Treatments for Primary Prevention of Disease Progression in Dominantly Inherited Alzheimer’s Disease |
|  | Principal Investigator: | Dr Campbell Le Heron |
|  | Sponsor: | Washington University in St. Louis Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU) Department of Neurology |
|  | Clock Start Date: | 15 May 2025 |

Dr Campbell Le Heron and Dr Nicky Slater 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 Researchers clarified that most participants in the study will have had their genetic testing already and know their status. However, the study also permits enrolment of individuals who have a family history of early onset Alzheimer’s but have chosen not to learn their mutation status, without forcing disclosure of their status.
2. The Researchers clarified that this study uses a blinded genetic testing process where participants give a sample that is tested for the familial gene mutation, but neither the participant nor local investigators are informed of the result. If participants test negative for the mutation, they are not given the experimental drug (they would get placebo) to ensure only mutation carriers are exposed to the treatment.
3. The Researchers clarified that primary recruitment method through an established registry of families (the DIAN registry and coordination via genetic counsellors) was seen as appropriate and sensitive. It targets a known population in a way that respects confidentiality as family members typically reach out through the registry or are referred by their genetic counsellor.
4. The committee commended the research team for their thoughtful inclusion of participants with disabilities or impairments.

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 that brain donation information remains in the protocol at page 47 and page 56. Please either remove or provide limiting language to clarify that this aspect of the study is not part of this study review.
2. The Committee requested that information such as contact details and study advertisements be revised for the New Zealand context.
3. The Committee noted that studies in New Zealand cannot be terminated for purely commercial reasons.
4. The Committee requested that the advertisement include New Zealand based information and that this study has been approved by the Central HDEC.

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

1. Please modify the consent process to make absolutely clear to participants who do not know their mutation status that there is a chance they could learn or infer it during the study if they experience side effects of the study drug, as carriers of the gene mutation will receive the study drug. Participants should explicitly acknowledge this in the consent form with a statement confirming that participants are aware of this possibility
2. Please separate out reference to future research on samples from the PIS and provide a separate "Optional Future Unspecified Research" PIS.
3. Please clarify that, where the PIS states that “participants have the option to receive a summary of their results”, this refers to the overall study results not the results of the results of the study procedures.
4. Please expand on the section of the PIS that describes possible risks and side effects of the drug and study procedures
5. Please clarify the study timeline, including provision of information about the second stage of the study where participants will need to know their genetic results. Outline that participants will have the option to continue receiving the study drug in an open-label phase of the study and that before entering the open-label extension participants will be asked to sign a new consent form and that if they did not know your mutation status, they will be told that information as part of the inclusion criteria.
6. Please revise PIS for repetition and clarity, detailed explanations can be amended to assist in clarity.
7. Please quantify amounts in mL as opposed to teaspoons
8. Please revise references to “tissue destruction” to “tissue disposal”.
9. Please revise the PIS to address aspects related to the PET scans in Australia all in one section. Materials must explain how often this could occur, where abouts in Australia this would take place, what time commitments would be expected, how travel costs and other expenses will be covered.
10. Please ensure that koha and reimbursements for study partners are made clear in the study partner PIS.
11. Please address what will happen if a study partner withdraws and that a new study partner will go through the same consenting process as the previous study partner.
12. Please revise wording “rolled over”.

**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 protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Joan Pettit and Dr Andrea Furuya.

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| **4** | **Ethics ref:** | **2025 EXP 22767** |
|  | Title: | Living Well with Memory and Thinking Changes in Aotearoa NZ study |
|  | Principal Investigator: | Professor Ngaire Kerse |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 15 May 2025 |

Prof Ngaire Kerse, Emme Chacko, Gary Cheung, Sharon Wu, Jo Hikaka and Natasha Urale-Baker 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.

Dr Cordelia Thomas declared a potential conflict of interest which was deemed minor

Summary of resolved ethical issues

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

1. The Researchers identified that their sample sizes for each group were reflective of similar published studies and informed their design.

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 requested that the researchers ensure appropriate protocols are in place if participants become distressed or if caregivers disclose instances of elder abuse or neglect. The application mentioned referring to Age Concern in cases of elder abuse, but the committee noted that any indication of serious harm or illegal activity might necessitate involving the police for the safety of the individual.
2. The Committee queried how participants with dementia who may lack the capacity to consent are intended to be included in this study. If the person with dementia cannot give informed consent or be interviewed the researchers would only be able to collect information or data about that individual if requirements for best interest under right 7.4 of *Code of Health and Disability Services Consumers' Rights* were met.
3. The Committee noted that it is unclear what the different expectations of participation are for participants with dementia and for carers in the study. Carers would be involved as participants in a range of different categories the capacity of their patients to provide consent, and to provide information about their own experience. For clarity, the Committee requested that the Participant Information Sheets provided clearly set out what is expected from the participant groups and what type of information the participants will be asked to provide. It should be outlined for the carers what they may be asked depending on the ability for their patients to provide consent, and that if a person is unable to provide consent that they are not to provide specific information about those individuals in their care. The Committee requested three PIS documents, one for support person who will not be providing information about their affected individual, one for the support person who can talk about the participant with dementia and one for the participant with dementia *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17, 9.7).*
4. The Committee requested the interview schedule document, and broad selection of interview question topics provided in the protocol be provided in a separate document *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
5. The Committee noted that the protocol needs to clarify that the data collected during the interviews from the carer and the participant with dementia will be separated for analysis and clearly distinguished by the transcribers *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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 review PIS documentation for typos, clarity and remove repeated information
2. Please ensure that it is clear that HDECs approve ethical aspects of the study not the entirety of the study
3. Please revise wording regarding transcription to ‘transcribers will be signing confidentiality agreements.’. Additionally, note that there is no time limit on approvals.
4. Please revise the section ‘Māori method’ in the PIS where the current implication is that all Māori participants would participate in wānanga instead of an individual interview. Some Māori participants might prefer individual interviews, and it should be clear to participants that they have a choice in how they engage. Wording describing that Pacific people will be invited to a talanoa makes it clear that the participant can choose how they wish to conduct their interviews.
5. Please include in the risks section that, if participants decide to take part in the group interviews, privacy or confidentiality cannot be guaranteed.
6. Please clarify what emotions or distress would result in the researchers contacting GPs or setting up pathways to counselling. Clarify that these actions would only take place ‘if appropriate’ and remove wording indicating that the interviewer would ‘act as anyone would’ in the case of the participant being distressed.
7. Please provide information in the PIS outlining what will occur in the case that a support person withdraws from the study and what options are available to the participant.
8. Please revise where the ACC statement is within the PIS to be provided in the body of the PIS.
9. Please provide information in the PIS relevant to the statement in the consent form that asks participants if they consent to their information being used in potential future associated research about thinking and memory changes.
10. Please ensure that there is a specific reference for participants to consent to their friends or family members providing information about them.
11. Please ensure that references to questions that participants may be asked are relevant to the patient or caregiver PIS they are included in.
12. Please provide Māori cultural contact number for cultural issues provided separately to the research contact number.

**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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| **5** | **Ethics ref:** | **2025 EXP 22921** |
|  | Title: | Feasibility study of passive spirometry methods in identifying modes and severities of respiratory dysfunction, compared to standard of care pulmonary function testing. |
|  | Principal Investigator: | Dr Ella Guy |
|  | Sponsor: | University of Canterbury |
|  | Clock Start Date: | 15 May 2025 |

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 noted a significant potential conflict of interest with the PI who owns the intellectual property for the novel lung function sensor and software being tested. This means The PI and the company Elementary Ltd could financially benefit if the device proves effective. The application did not explicitly acknowledge this conflict or describe measures to manage it and mitigate bias. The Committee requires assurance that the research will be conducted impartially, with the involvement of independent analysts or governance, and that participants are informed of the researcher’s commercial stake. This information should outline how conflicts will be managed *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.23)*
2. The Committee noted that it was unclear who would cover any harm to participants or device-related injuries. This study involves a device under development being tested on volunteers, the usual ACC coverage for treatment injury may not straightforwardly apply if it is not standard care. The application did not detail if separate research insurance is in place. The committee requires clarification on indemnity indicating who is responsible if a participant is harmed. The Committee requests documentation or confirmation of this coverage *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1, 17.5 - 17.6)*.
3. The Committee queried why a general quality-of-life survey is included for healthy volunteers in a device feasibility study. Researchers need to provide can provide a strong justification for including this survey or it should be removed to avoid unnecessary burden. If it remains, the investigators must implement a safety plan for any concerning responses to the survey *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.23).*
4. The Committee noted that the protocol lacked a clear description of what hypothesis is being tested and how “success” will be measured. The Committee could not determine which lung function parameters the new breathing method will assess as “Normal breathing” is ambiguous. Does this refer to tidal breathing, resting breathing, or non-forced respiratory assessments. The absence of a defined primary outcome or analytic plan means that participants are being exposed to procedures without a clearly communicated goals *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*
5. The Committee noted that the submission indicated that participants will not be divided into different groups, and all will receive standard care along with the additional investigational test. The Committee requested clarification on how the researchers plan to determine whether the new method using the investigational device adds value or makes a meaningful difference, and whether it is worth implementing in the future.
6. The Committee requested that the protocol be revised to clearly explain how data will be analysed, and which statistical methods will be used to evaluate the study outcomes *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
7. The Committee noted that there was reference to ‘chronic disease’ patients however could not find further descriptions of what chronic diseases were being referenced.
8. The Committee requested further detail of the inclusion and exclusion criteria for this study *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8).*
9. The Committee requested clarification on whether participants would be able to request their results, as the submission stated that individual results would not be returned to participants because data would be “de-identified,” yet the protocol and consent form indicated participants could request deletion of their data if they withdraw from the study. The Committee requested that confirmation that the information is truly deidentified rather than coded. Coded data is still potentially identifiable data *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8*.
10. The Committee noted that the Data Management Plan mentioned that data may be used for future research. However, the PIS/CF form did not include this option. Both documents must explain how data might be stored or reused, and whether participants consent to those uses *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15-7.17, 12.15a)*
11. The Committee requested clarification on who will be conducting lung function tests at the respiratory lab. Describe if this procedure will be carried out by a member of the study team and if that person will have indemnity coverage.
12. The Committee noted that data cannot be deleted after one year, data must be held for a minimum of 10 years in accordance with Retention of Health Information regulations *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.28)*.

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 revise the protocol synopsis in the PIS to clearly describe what the new method is and what it’s being compared against
2. Please add a section explaining what happens if a participant is injured. If ACC cover is not assured because this isn’t standard treatment
3. Please ensure that it is clear that HDECs approve only ethical aspects of the study, not the study as a whole.
4. Please ensure the PIS lays out exactly what each participant will do, and what procedures and assessments are involved at which points in the study.
5. Please provide contact details for Māori cultural support
6. Please include a picture or diagram of the device to aid in participant understanding
7. Please remove tickbox options from the consent form unless truly optional.

**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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| **6** | **Ethics ref:** | **2025 EXP 22931** |
|  | Title: | Exposure and health of workers on the Accelerated Silicosis Assessment Pathway |
|  | Principal Investigator: | Dr Amanda Eng |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 15 May 2025 |

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 requested confirmation that information is deidentified
2. The Committee requested that the investigators provide the exact consent form or patient information given to participants when they entered the silicosis screening program.
3. The Committee requested further justification for seeking a waiver of consent for participants who have not consented to participate research

**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 protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

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

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| **7** | **Ethics ref:** | **2025 EXP 22626** |
|  | Title: | The Effects of Social Support on Stress and Gastric Motility during the Maastricht Acute Stress Test |
|  | Principal Investigator: | Dr Elizabeth Broadbent |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 15 May 2025 |

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 noted study involves deception. Participants are told they will be videotaped during the stress test to increase stress, but the protocol indicates that no such recording is intended. This deception was not clearly explained to the ethics committee nor to participants afterwards. NEAC standards require that deception be minimized, and if used, participants must be debriefed afterwards and receive an explanation as to why it was necessary. The Committee requested clarification how this deception is justified and how debriefing will be handled with participants. Participants must also be given the option to withdraw their data if they feel uncomfortable about being deceived. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.32, 7.35-7.37).*
2. The Committee noted that the ‘reviewer independence / objectivity’ section for the scientific peer review document is not completed. The reviewer is from Department of Psychological Medicine at the University of Auckland and the Committee is concerned that the peer reviewer is not sufficiently independent from the study, please explain the independent nature of the reviewer *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.32)*.
3. The Committee noted that the PIS mentions multiple questionnaires, however, only one questionnaire is uploaded for review, please ensure all questionnaire documents are provided.
4. The Committee noted that the study aims to examine social support, yet the protocol indicates that participants are not allowed to have a support person present during the experiment. *The Code of Health and Disability Services Consumers' Rights* (*Right 8*) stipulates that every consumer has the right to have one or more support persons of his or her choice present, except where safety may be compromised, or another consumer's rights may be unreasonably infringed. If this study design is utilised researchers need to justify the reason for not allowing a support person to be present
5. The Committee raised concerns of potential health risks or discomfort for some individuals who are asked to refrain from certain medications for 48 hours prior to study session. The Committee requested that it is made clear in the exclusion criteria for this study that people who are not able to withhold their medications for more than 48 hours will be excluded *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 10.37)*.
6. The Committee queried whether people with disabilities will be contacted prior to their involvement as only one of the sites has disability access *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 5.13)*.

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 update documents with correct spelling of te reo.
2. Please ensure it is clear to participants that in this study social support will be simulated by the behaviour of the researcher running the sessionas opposed to a support person of the participants choosing.
3. Please ensure that it is clearly state that participants can stop the cold pressor test at any moment if it becomes too unpleasant. Explain that there are no negative consequences for stopping early and that the researcher will monitor participants throughout the test.
4. Please note that HDECs only approve ethical aspects of studies.
5. Please amend the Ministry of Health phone number.

**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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| **8** | **Ethics ref:** | **2025 EXP 21801** |
|  | Title: | A prospective observational cohort study of patients with calcium pyrophosphate deposition (CPPD) disease in the Auckland Region |
|  | Principal Investigator: | Professor Nicola Dalbeth |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 15 May 2025 |

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 requested whether someone other than the clinician in charge of a patient care could first approach potential participants about the study. This should be done to avoid any power imbalance present when consenting participants.
2. The Committee noted that tissues will be sent overseas, while also providing that karakia will be available at the point of tissue disposal. The Committee requested clarity on how researchers can be sure this is available.
3. The Committee requested that a safety plan is developed and put in place if participants indicate distress or depression. Currently the plan to ‘encourage the participant’ to see their GP is inadequate and does not cover the duty of care expected of researchers for their participants. A safety plan needs to provide the timing and frequency for which questionnaires will be assessed, and then what procedures researchers will follow to ensure the safety of participants in these situations.
4. The Committee noted that there is no time limit on ethics approval on advertisements and so can be removed.
5. The Committee requested that the Data Management Plan (DMP) provide further detail on where abouts blood samples will be sent overseas.
6. The Committee requested that, if the study genuinely can accommodate non-English speakers via interpreters, remove “must speak English” from inclusion criteria and explain interpreter availability in the PIS. Conversely, if in practice participants need to understand English then the line about translators for Pacific languages should be removed.
7. The Committee requested clarification on what ‘patterns of disease activity’ refers to.
8. The Committee noted that the study will look to obtain blood samples from patients with CPPD disease for future biomarker and genetic analysis and requested clarification on any specific biomarkers or genetic analysis will be done.
9. The Committee noted that researchers alluded to cultural issues regarding genetic analysis in their application and PIS but did not elaborate on what those cultural issues were specifically. As such further detail around these issues should be included.

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

1. Please provide page numbers and footnotes on the PIS.
2. Please revise wording “If you wish an appropriate karakia to be used to dispose of your blood samples’ for clarity.
3. Please include in the consent form that blood samples will be sent overseas
4. Please remove the statement “You have legal rights over any blood samples you give for research" as there is no authority for that proposition.
5. Please clarify what reimbursements and/or koha participants will receive for their participation outlining if parking and travel is reimbursed and if tax is applied to any of these.

**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 protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Johathan Darby and Dr Andreya Furuya.

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| **9** | **Ethics ref:** | **2025 EXP 22994** |
|  | Title: | Evaluating the impact of different artificial tear supplements on tear film and ocular surface parameters |
|  | Principal Investigator: | Professor Jennifer Craig |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 15 May 2025 |

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 requested clarification on the inclusion criteria, as there is both a reference to participants being healthy participants and indication that participants are invited to take part in the study because they have symptoms of dry eye, which is not provided as an inclusion criteria.
2. The Committee requested clarification as to why the healthcare provider can be provided with a clinical summary but that this cannot be provided to the participants.
3. The Committee requested clarification on the research funds for this study.
4. The Committee requested justification as to why participant demographic data will be collected if it will not be analysed at all.
5. The Committee requested clarification of how the junk mail list will be used to recruit participants.
6. The Committee requested clarification on the number of participants intended to be recruited for this study, whether this will be 20 participants total or if there will be four groups of 20, as stated in the protocol.
7. The Committee noted that various eye disorders were outlined as exclusion criteria, but eye infections were not. Eye infection should be added to the exclusion criteria, or explanation as to why they can be included should be provided.
8. The Committee highlighted that the documentation refers to four over the counter drugs, however the fourth test product is water only, used as a placebo/control. Additionally, one of these products is a spray rather than eye drops. In this case the participant will not be blinded to the product as they will know which one is the spray. This information should be amended in the protocol and PIS documents for clarity.
9. The Committee requested an explanation as to how the blinding preparation of product packaging will be done to ensure that products are handled under sterile conditions.

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

1. Please ensure that travel costs will be reimbursed and include a statement that any tax obligations are the participants’ responsibility.
2. Please clarify number of study visits and time commitment expectations in the PIS, outline clearly when participants are expected to come into clinic, participants need to know if they are coming once or multiple times especially if the total time commitment for a single day adds up to over 6 hours.
3. Please revise contradictory statements around data use in the case of participant withdrawal from the study, clarify whether data collected up until participant withdrawal will be used.
4. Please revise consent form and PIS for consistency when addressing how data will be used after withdrawal from the study. The consent form currently indicates that the study can continue to use data for up to two weeks after withdrawal and this is not mentioned in the PIS.
5. Please provide advice on post study visit driving and the safety provision of wearing glasses immediately after.
6. Please clarify what ‘recommendations’ are being made by healthcare providers for this product, and how they are recommended to be used.
7. Please include a statement recognising the tapu of the head.
8. Please note that there are not time limits on HDEC approvals.

**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 protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Cordelia Thomas and Dr Andrea Furuya.

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| **10** | **Ethics ref:** | **2025 EXP 22122** |
|  | Title: | Sleep apnoea assessment based on collaborative explainable AI |
|  | Principal Investigator: | A/Prof Angela Campbell |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 15 May 2025 |

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 requested clarification on whether participants will require decision making support for the consent process and clarification if people who require this support are going to be included in the study *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 5.10-5.11)*
2. The Committee requested that the researchers address the peer reviewer's concern about the small sample size and how you will achieve your goal of representative ethnic diversity
3. The Committee requested clarification on the funding for the sleep study, outlining whether the participants pay to be a part of the study or if the study is paying. The Committee raised concern around the commercial benefits from the study while collecting data from a clinical procedure for no cost. Given the volunteer nature of the study and in recognition of participation the payment for the sleep study could be a reimbursed cost to the participant *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.57, 11.20-11.22)*.
4. The Committee requested clarification on what the data analysis processes are. Specify what datasets are being analysed by whom *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
5. The Committee requested clarification on which results participants will be receiving, and that clear distinction between the clinical results and study results are provided *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8, 11.52)*.
6. The Committee requested further information about the commercial aspects of the study, any potential conflicts of interest that may arise and how they will be handled *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.23)*.
7. The Committee requested clarification on why this study is being done in New Zealand if this is being carried out internationally.
8. The Committee requested further detail on what kind of AI model is going to be used, whether this is being developed in house or adapted from elsewhere. Outline what the functionality and the validation processes are for the model *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 13.5, 13.7, 13.4)*.
9. The Committee noted that this is a device and needs to adhere to the guidelines for specificity and accuracy testing for such a device *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 13.5, 13.7, 13.4)*. Please provide a mechanism for validation.

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 ensure that participants are aware that they can withdraw from the study at any time, remove the word ‘practicable’ when outlining the withdrawal process.
2. Please ensure that it is clear to participants that they have the right to access their information and request correction *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.44).*
3. Please provide Māori contact numbers for cultural support.
4. Please provide more information about the same study that will occur in China and how the data from the current study will be analysed along with the sister study.
5. Please explain that this research is to develop a tool that could make sleep study analysis faster in the future and help patients generally, but “It will not directly improve your diagnosis or treatment right now.” This would reduce any therapeutic misconception.
6. Please ensure that it is clear to participants that sleep studes are available outside of the research.
7. Please provide necessary information for participants given that this is an overnight study. Outline if parking will be available, if participants need to bring anything for the overnight stay and clearly state what the participant can expect as taking part in the study.

**Decision**

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

## General business

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

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| **Meeting date:** | 24 June 2025 |
| **Zoom details:** | To be determined |

The following members tendered apologies for this meeting.

* Mx Albany Lucas

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 4:00pm.