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| **Committee:** | CEN Health and Disability Ethics Committee |
| **Meeting date:** | 24 June 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11.30am-12.00pm |  | Committee Welcome |  |  |
| 12.00-12.30pm | 2025 EXP 22987 | Acoustic therapy for better breathing: Helping patients with nasal congestion | Dr Kelvin Lau | Dr Cordelia Thomas / Dr Andrea Furuya |
| 12.30-1.00pm | 2025 EXP 22845 | Hypertension: a modifiable risk factor in patients with aortic dissection | Associate Professor Nishith Patel | Ms Sandy Gill / Ms Joan Pettit |
| 1.00-1.30pm | 2025 FULL 23059 | Children's SABA Use Study  | Dr. Rowan  Biggs  | Dr Cordelia Thomas / Mrs Patricia Mitchell |
| 1.30-2.00pm |  | *Break (30 mins)* |  |  |
| 2.00-2.30pm | 2025 FULL 23157 | ASCEND First in Human Study | Dr Andrew Holden | Ms Jessie Lenagh-Glue / Dr Andrea Furuya |
| 2.30-3.00pm | 2025 FULL 22936 | AQUA Pilot Trial | Professor Paul Young | Dr Cordelia Thomas / Ms Joan Pettit |
| 3.00-3.30pm | 2025 FULL 23200 | Aplastic Anaemia and Other Bone Marrow Failure Syndromes v2.0 | Dr Nathanael Lucas | Ms Jessie Lenagh-Glue / Dr Andrea Furuya |
| 3.30-4.00pm | 2025 FULL 22378 | Haumanu Whakaohooho Whakaaro Māori ā Ipurangi.  Māori perspectives on cognitive stimulation therapy over zoom for kaumatua with mate wareware.  | Dr Tai  Kake | Ms Sandy Gill / Mrs Patricia Mitchell |
| 4.00-4.30pm | 2025 FULL 22851 | Understanding the online delivery of Cognitive Stimulation Therapy: Perspectives from people with dementia, their families and communities | Associate Professor Gary Cheung | Ms Sandy Gill / Mrs Patricia Mitchell |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Ms Joan Pettit | Non-Lay (Intervention Studies) (Chair) | 08/07/2022 | 08/07/2025 | Present |
| Mrs Sandy Gill  | Lay (Consumer/Community perspectives)  | 22/05/2020  | 22/05/2023  | Present  |
| Dr Patries Herst  | Non-lay (Intervention studies)  | 22/05/2020  | 22/05/2023  | Apology |
| Dr Cordelia Thomas  | Lay (the Law)  | 20/05/2017  | 20/05/2024  | 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 | Apology |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Present |
| Dr Andrea Furuya | Non-Lay | 03/03/2025 | 02/03/2029 | Present |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members noting that apologies had been received from Mx Albany Lucas and Patries Herst.

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 27 May 2025 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **EXP 22987** |
|   | Title:  | Exploring the Feasibility of Acoustic Therapy for Nasal Health and Well-being in Allergic Rhinitis and Chronic Rhinosinusitis |
|   | Principal Investigator:  | Dr Kelvin Lau |
|   | Sponsor:  | Auckland University of Technology |
|   | Clock Start Date:  | 12 June 2025 |

Dr Kelvin Lau, Jude Alao and Dr Chris Puli’uvea 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 study is not commercially sponsored. Devices are provided in-kind by the manufacturer without its influence on study design or expectations of receiving data.
2. The Researchers clarified there is no personal conflict of interest for the study team with the device or its manufacturer and that the study’s motivation is to explore changes in the microbiome and immune markers rather than to test the efficacy of the device itself.
3. The Researchers explained that each participant will serve as their own control (pre- vs post-treatment) and that, due to high inter-individual variability in nasal microbiome and immune markers, a placebo arm would not be used.
4. The Researchers clarified that all testing will occur at AUT facilities, with consistent procedures across sites and confirmed that additional research using stored samples will not involve overseas shipment of human samples.
5. The Researchers clarified that the use of “nasal congestion” in patient facing documentation is used to make the study more easily understandable for lay individuals who may not know or understand what chronic rhinosinusitis and allergic rhinitis are.

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 title of the protocol references ‘patients’ with nasal congestions and requested that this be changed to ‘individuals’ with nasal congestions as patients indicates sickness and healthy volunteers are being enrolled.
2. The Committee requested clarification on the inconsistencies on study duration and timeline where the submission indicated a three-year study, however, also indicated a conclusion date of 2027.
3. The Committee requested a more immediate safety plan for any participant indicating severe distress (e.g. depression, anxiety, suicidal ideation) on questionnaires. The current plan to contact participants “within 24 hours” is not sufficient. The Researchers indicated that the responses can be reviewed at the time they are filled out and intervene or refer immediately if any acute mental health concerns arise. This procedure should be clearly described in the Participant Information Sheet (PIS) to assure participants of their safety.
4. The Committee requested that the Data Management Plan (DMP) and the PIS include that the nosebuds are provided my Better Breathing Ltd.
5. The Committee requested that compensation wording in the advertisements be revised so reference to ‘money’ being paid is removed to avoid inducement.
6. The Committee requested that the advertisements include information indicating that the nosebuds will be used twice daily for four weeks.

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

1. Please add details on how to use the device is used to ensure the PIS clearly explains how to use the nasal therapy device at home.
2. Please clarify in the PIS where the data will be stored if in overseas servers provide where, so participants understand where their information goes.
3. Please add a specific consent checkbox in the PIS/consent form for future use of data. Participants must explicitly opt in to any potential future research use of their samples or data.
4. Please outline in the PIS which immune biomarkers will be analysed from blood samples, provide a list indicating that cytokines, proteins, and cells will be looked at, understanding that novel findings also want to be captured.
5. Please revise language in the PIS “complete a written consent form” to “sign a consent form” since participants will be signing (not filling out) the form. In the consent form, please remove the phrase “I am happy to take part…” and replace with a formal consent agreement such as “I agree to take part…”.
6. Please clarify whether travel costs will be reimbursed. If travel is not reimbursed, please state that clearly to avoid misunderstandings. If it free parking is available during study visits provide this information as well.
7. Please remove sentence indicating that HDEC review study procedures and findings, as HDEC review only ethical aspects of the study.
8. Please specify on page 10 that the reference to ‘Māori support’ is in fact ‘Māori cultural support’
9. Please ensure information provided around notification of GP of abnormal results and participation in the study are consistent across consent form and PIS, whether a requirement or not.
10. Please simplify the withdrawal statement in both PIS and consent form for clarity, a statement such as “If you withdraw, any data collected up to that point will remain in the study but no new information will be collected” could be used. This ensures participants understand they cannot retroactively delete data already used, and it removes any conditional “if not already analysed” language
11. Please state under ‘Benefits section, that you "may or may not" benefit from wearing the nosebuds.
12. Please remove the word ‘valuable’ from the ‘Indirect benefits’ section.

**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. Please update the data management plan, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).

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

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| **2**   | **Ethics ref:**   | **EXP 22845** |
|   | Title:  | Hypertension: a modifiable risk factor in patients with aortic dissection |
|   | Principal Investigator:  | Associate Professor Nishith Patel |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 12 June 2025 |

Dr Nishith Patel, James Fisher, Ryan Sixtus ad Kelly Henderson 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 briefly discussed the pilot phone survey of 50 past patients and reminded the Researchers of the need to seek ethical approval for any future analyses combining patient data beyond clinical care.
2. The Researchers clarified that informed consent may be obtained remotely using REDCap for electronic signatures and are stored securely.
3. The Researchers clarified that patients often be referred from aortic clinic in Waikato and that many of the healthy volunteers will be recruited from Auckland.
4. Researchers clarified that the grant is valid for two years.

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 quality of life questionnaires are currently indicated to be reviewed within three months, which is not adequate timing for review of these questionnaires. As these questionnaires may disclose acute distress for some participants, they need to be reviewed as immediately. Researchers indicated that a research nurse will be present when the questionnaires are filled out and so responses can be reviewed in real time. The Researchers further explained that if distress is indicated, and if required, the research team can engage participants with the local network of mental health professionals. The Committee requested that this information be properly outlined in a safety plan. This safety plan should also be outlined in the Participant Information Sheet to ensure that participants are also aware that these procedures are in place *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.1-8.3, 9.7-9.8)*.
2. The Committee requested that all questionnaires that will be used in the study be uploaded for HDEC review.
3. The Committee noted that this is a very vulnerable population and there is little information provided on the risk for the population in participating in the study. While risk mitigation has been addressed with patients and standard guidelines for cardiovascular disease will be followed, the Committee requested that the investigator provide evidence that it is safe for this specific population group to participate in these tests, in particular the exercycle portion. The Committee noted that one of the peer reviewers raised this safety concern. The provision that there is no specific exclusion of patients with aortic dissection does not address this in enough detail *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4-8.6)*.
4. The Committee noted that the Data Management Plan mentions possible future research use of collected data. However, the PIS and consent form did not include any provision for this option. The Committee requested adding a specific consent option for future use of de-identified data *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7, 12.15a)*.
5. The Committee noted significant technical feedback from peer reviewers and requested that responses to these concerns be provided in a separate document.

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 it is clear to participants that the quality of life questionnaires involve sensitive personal concerns that could be distressing and, as described earlier, what will be done if distress occurs.
2. Please revise the PIS where it indicates the “risks are minimal” and instead provide a description of known and unknown risks for this study. Currently the PIS presents the participation in this study is as a no risk study with no outline of the possible risks of performing the activities.
3. Please provide an information outlining the safety precautions in place during the study should an adverse event happen during study procedures. What procedures are in place, who will be available and what training will support personnel have? The investigators provided reassurance that the proposed tests will be done in a hospital and emergency support is available. This should give participants enough information to feel confident they understand the safety aspects of the study.
4. Please ensure the PIS clearly explains what healthy volunteers in the study can expect as part of the study.
5. Please remove the section at the beginning of the PIS describing mortality statistics for people with aortic dissection as this may be distressing for people who have survived and is not necessary for study purposes.
6. Please adjust the PIS statements that overpromise outcomes. For example, change “…allow us to develop new therapies” to “may allow us to develop new therapies.” This sets realistic expectations that this research is exploratory.
7. Please clarify travel compensation in the PIS. Currently the PIS does not explain whether travel costs and parking will be reimbursed. If not, explicitly state that travel expenses are not covered.
8. Please replace wording stating that participants can “withdraw at any practicable time” with “withdraw at any time.” Participants have the legal right to withdraw whenever they wish.
9. Please revise references to general practitioners, usual doctors, or current providers to ensure they are addressed consistently throughout the PIS.

**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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| **3**   | **Ethics ref:**   | **FULL 23059** |
|   | Title:  | An Observational Study of Community and Hospital Short Acting Beta Agonist Use in Children with Asthma Exacerbations |
|   | Principal Investigator:  | Dr Rowan Biggs |
|   | Sponsor:  | Medical Research Institute of New Zealand |
|   | Clock Start Date:  | 12 June 2025 |

Dr Rowan Biggs and Tasmin Barry 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 data will be stored on REDCap database in NZ, and so data is not being ‘sent overseas’.
2. The Committee inquired whether the timeframe given for the study would be practical for the number of participants needed. The investigator acknowledged the study may need to run longer as the study was initially planning to cover winter illness season.
3. The Committee noted that the submission stated that the study size is inadequate to analyse results around ethnicity and that there are no specific plans to specifically target these groups. However, the researchers indicated that as Māori and Pacific people are inequitably overrepresented in the system for asthma that they are likely to collect more data on these ethnic groups because of this without specific targeting, with the hope that further research could be done in the future around the overrepresentation in these ethnic groups.

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 upload allquestionnaires mentioned in the protocol. These documents need be reviewed by HDEC.
2. The Committee requested that assent forms be developed for the child participants in addition to the parent Participant Information Sheet (PIS). For this participant group two versions appropriate to the age range should be provided, one simple assent form for younger children and one slightly more detailed form for older children. These forms should explain in child-friendly terms what the study involves. The [HDEC templates](https://ethics.health.govt.nz/guides-templates-and-forms/) can be used and adapted to the specifics of this study*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.27)*.
3. The Committee noted the investigators intention to share findings within Wellington Hospital and requested that and findings are disseminated across the whole of Health NZ/Te Whatu Ora.
4. The Committee requested that page numbers are provided in the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
5. The Committee requested that the duplication of ‘study aims’ be removed from the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
6. The Committee noted that the data collection tool is referred to variously as a questionnaire, a survey, or an interview throughout and requested that this is revised to refer to it as consistently throughout documentation for clarity *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
7. The Committee noted that the Data Management Plan references future research, however, this is not mentioned in the PIS. If future research could occur, there needs to be specific consent to this in the consent form and the provision of re-consent once participants turn 16 years old *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*.

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 PIS to be clear that the child is the participant, for which the parent will be providing information. Wording such as “You will be asked to…”, can be revised to “We will ask you (the parent) questions about your child’s asthma and how it’s managed.”
2. Please clarify that any questions for the parents during interviews will include questions about their child, please provide examples of what type of questions will be asked.
3. Please revise reference to Māori health support to Māori cultural support. A cultural statement should also be included in the PIS as information is taonga.
4. Please provide a statement informing participants (or parents) of their right to access their information and to request corrections.
5. Please provide an ACC statement, even though this is a low-risk observational study, it is mandatory to inform participants that in the unlikely event of harm from the research, they are covered by ACC.
6. Please ensure that parents are aware that, when asked for their contact details, it would be for the purpose of collecting more information about their child. If this is not optional remove it as a tickbox option.
7. Please ensure that PIS provides wording in a way that acknowledges that people other than a parent or guardian may have been the one to administer the medication to the child.
8. Please add a section on withdrawal stating clearly in the PIS that participation is voluntary, and that the child may withdraw from the study at any time without affecting the child’s medical care.

**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:**   | **FULL 22936** |
|   | Title:  | Assessment of Quantity and Utility of water for ICU-Acquired hypernatraemia. A Pilot, Six-Centre, Open-Label, Safety and Physiological Efficacy Randomised Controlled Trial |
|   | Principal Investigator:  | Professor Paul Young |
|   | Sponsor:  | Te Whatu Ora Capital, Coast and Hutt Valley |
|   | Clock Start Date:  | 12 June 2025 |

Professor Paul Young and Thomas Huges-Gooding 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. Committee noted that this research relies on Right 7(4) of the Code of Health and Disability Services Consumers’ Rights for participant enrolment in this study. Right 7.4 permits enrolment of participants who cannot give consent themselves in if participation in the research is determined to be in the best interests of the participant. Researchers explained that inclusion in this study offers a clinical monitoring benefit in the form of more frequent blood tests from once daily to every 6 hours, from which complications can be identified earlier than in standard care. The Committee agreed this additional monitoring constitutes a potential health benefit and is satisfied the requirement that enrolment is in the patients’ best interest for both the standard care arm and the protocolised arm.
2. The Researchers acknowledged that treating doctors might adjust fluid treatment in response to the extra study tests even in the control arm and that this potential deviation from SOC would be described as a limitation in the study analysis and write up.
3. Researchers clarified that there would not be any participants who have the capacity to consent to enrolment in the study.
4. Researchers clarified that some participants may recover rapidly enough to be able to give consent for ongoing participation while study treatment is ongoing or increased monitoring is ongoing. The Committee noted this and indicated that provisions for this can be included in the reconsent form at the Researchers discretion.
5. The Committee noted that the protocol includes an independent doctor assessing each patient’s eligibility and best interests before enrolment. When it was raised that this decision should be documented the Researchers confirmed that this will be documented for each participant as a note to file on both the participant clinical record and in the study file.
6. Researchers clarified that the $500 AUD ‘per patient enrolled’ would go to the research department in the ICU to support salaries of research nurses.

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 current information sheet for whānau could, as it is currently written, be interpreted as a form to give consent for their whānau member to participate in the study which is not the case. This could further give the impression that they can withdraw the participant from the study. The Committee requested that this consultation information sheet be revised to clearly state that the family member is not giving formal consent but is providing their opinion on the study and what the participant might have wanted. Language such as “you can withdraw them from the study” should be revised to explain the family can express if they think the patient should not continue in which case the researchers would remove the participant from the study. Additionally, if the family member initially agrees that their whānau member would agree to be in the study but decide later that they think they would have not wanted to be enrolled, the researchers also respect this view and remove the participant from the study.
2. The Committee requested that a separate Participant Information Sheet (PIS) and consent form for participants to review once they recover capacity to consent be provided. The purpose of this PIS would be to allow participants to consent for ongoing participation in the study and for the data previously collected to be used up until this consent. This document should be written with the awareness that this participant has already been enrolled in the study and information about them already collected.
3. The Committee requested that any statements or references to consenting for Future Unspecified Research (FUR) be removed from the whānau information sheet, as this can only be a decision made by to the participant once they regain ability to consent for themselves. This should also be the case for the right to access and correct information.
4. The Committee discussed that participants in the “standard care” arm will also have their sodium monitored every 6 hours per study protocol, while the protocol indicates that standard care will not change, even though normal standard care would check once every 24 hours. As such, the Committee requested that this be made clear in the whānau PIS that all patients in the study will receive more frequent monitoring of salt than usual regardless of what arm they are randomised to. Treating clinicians in the standard care arm are free to adjust treatment as they normally would as they are not limited to following the protocolised care laid out by the study.

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

1. Please revise PIS to consistently refer to participants in first person
2. Please remove bold formatting for the statement ‘...lead to better outcomes and faster recovery’ as this is research; the study outcome is yet to be decided. It is possible, but uncertain, that there will better outcomes to participants.
3. Please ensure wording is clear that there are no additional tests required for this study other than those for additional monitoring.
4. Please revise section in the re-consent form highlighting exclusion of pregnant or breastfeeding people from participation, as this should not be relevant for reconsent. These criteria could be stated in the whānau consultation information sheet.
5. Please change ‘deanonymised’ information to ‘deidentified’.

**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 Cordelia Thomas.

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| **5**   | **Ethics ref:**   | **2025 FULL 23200** |
|   | Title:  | Aplastic Anaemia and Other Bone Marrow Failure Syndromes Registry (AAR) - New Zealand |
|   | Principal Investigator:  | Dr Nathanael Lucas |
|   | Sponsor:  | Monash University |
|   | Clock Start Date:  | 12 June 2025 |

Dr Nathanael Lucas, Lucy Fox, Naomi Aoki, Siobhan Cross, Erica Wood 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. On the question of opt-out consent, the Committee acknowledged the investigators’ explanation that this is a rare disorder registry spanning NZ and Australia, and that opt-out models have historically been used for similar registries to maximize inclusion. The Researchers highlighted how valuable comprehensive data is in rare conditions. The Committee recognize the importance and potential benefit of the registry and is supportive of the registry’s aims.
2. The Researchers confirmed that the registry will have an alert system that will notify when participants reach age 16 and will be informed that they can decide to withdraw from the registry.
3. Researchers clarified that there is not data being collected on family members. Clinicians would be provided with a whānau information sheet that could be provided to participant family members. If they wish, family members may decide to pursue genetic analysis via the standard pathway with a clinical geneticist. If these family members are then found to have the specific G mutation, they may choose to be included in the study registry.

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 need for opt-out consent for this registry, given that patients will be approached directly by an on-site clinician who will inform them about the registry and invite them to participate. In doing so, patients will receive much of the information typically required in an opt-in process. The Committee observed that many elements of opt-in consent are already incorporated and described within the study. Additionally, the Committee noted that the feasibility of opt-out consent In New Zealand is very limited as opt-out or passive consent does not meet the legal requirements of prospective informed consent in Right 7(1) of the Code of Rights. The Committee further noted that while there may be some difficulties in establishing opt-in consent for this project they are manageable.
2. The Committee requested that eligible patients (or their parent/guardian, if a minor) be provided with the registry information and a consent form, and their signed consent/assent must be obtained before their data is included in the registry. The Committee recognised that the expectation that this consenting be done in person may not possible for all potential participants. However, the Committee outlined that this consent may be obtained electronically, and could be done as a two-step process. The consent must be documented.
3. The Committee queried the need for registry data to be stored in an identifiable format, as opposed to coded data. While the Committee recognises that there are robust data management procedures in place for protecting data, there seems no rationale to justify retaining identifiable data instead of coded date. Identifiable data should not be part of an international registry *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
4. The Committee requested clarification on the aims, noting they currently quite broad. The phrase “better define the incidence of acquired and inherited bone marrow failure syndromes, aplastic anaemia and hereditary predisposition to blood cancer” does not make clear whether the goal is to define individual incidence rates or explore connections between these conditions *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
5. The Committee requested more details of what future hypothesis-driven research in this area might entail*.*
6. The Committee requested that the PIS provide further detail about how the registry will “document the specific genetic causes that underlie bone marrow failure”, and information on how the genetic data will be used (such as for diagnosis, prognosis, family screening, or treatment) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8).*
7. The Committee requested clarification in the PIS on the source of funding and how it is secured or anticipated through to the listed conclusion date of 2045.
8. The Committee noted that in the case of withdrawal participant “info will be removed from the database... The research team may retain information such as record ID, etc.”. The Committee queried what the retained record ID remains linked to, noting that if it still connects to identifiable data (even indirectly), then the data has not truly been removed.
9. The Committee noted that the submission states that GPs will not be informed of abnormal findings with potential clinical significance. However, the submission stated that biological data will be collected and analysed. The Committee queried how confident the researchers are that no clinically actionable or previously unknown information will emerge from future analyses. The committee requested clarification on the plan for managing such findings in a way that safeguards participant health and respects their right to know. The committee also requested a definition of what constitutes a “clinically significant” finding, including incidental findings *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.48)*.
10. The Committee noted that the audit plan described in the protocol is unclear. The protocol refers to three arms of an audit plan, but only two are described *(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 revise the Participant Information Sheet to be an active consent information sheet, it should clearly invite the person to consent and language that implies automatic inclusion removed.
2. Please state where data will be stored, what data is being stored and who will have access to this data. The study documents should be clear that the data will be entered into a secure database managed by Monash University in Australia and that data will be protected under Australian privacy laws during storage as well as New Zealand’s during collection and prior to sending to the Registry. Any risks associated with the storage of data or of data breaches also need to be provided.
3. Please ensure that it is clear that this is a long-term registry, and data will be kept indefinitely. However, participants can withdraw at any time in the future if they change their mind, and if so, their identifiable data will be removed from the registry.
4. Please explain there is no direct personal benefit to the participants information being on the registry, however it can be outlined that collective benefit in improving knowledge and possibly future care.

**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:**   | **FULL 22378** |
|   | Title:  | Haumanu Whakaohooho Whakaaro Māori ā Ipurangi.Māori perspectives on cognitive stimulation therapy over zoom for kaumatua with mate wareware: a Kaupapa Māori qualitative study |
|   | Principal Investigator:  | Dr Kai Kake |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 12 June 2025 |

Dr Kai Kake, Mau te Rangimarie Clark, Gary Cheung, Kathy Peri 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 was confirmed that the kanohi-ki-te-kanohi (face-to-face) culturally adapted Cognitive Stimulation Therapy (CST) for Māori with mate wareware (dementia) has been previously researched and evaluated with positive outcomes.
2. The Researchers clarified that informed consent will be obtained directly from each kaumātua participant and that a whānau member may be present to support them in the consent process if needed.
3. The Researchers clarified, in light of whānau members participating in their own capacity, that koha will be available for them in addition to their kaumatua. However, health professionals who will participate in the study will not have the koha available as they will be participating during work hours. All participants will be supported with kai and reimbursement of travel costs in addition to the koha. Researchers further explained that sessions with kaumātua and whanau will be held separately from health professionals as the two groups will have different pacing.
4. Researchers confirmed that they will be looking at recruiting 10 kaumātua from two sites and 10 whānau members from each of the sites. When asked about whether they would aim to have 50/50 kuia and koro the Researchers indicated that that they would like to have a balance, however, also recognise that recruitment can be challenging and will run the study with whoever they are able to include in the study.
5. Researchers confirmed that that they can facilitate access to CST after the study if a participant expresses interest in continuing access to CST.

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 support people will be involved, whether there were separate considerations between the support person for consent process and a support person who would be contributing their feedback on the virtual CST therapy. If a whānau support person is only assisting the kaumātua in the consent process they would not be considered a participant and would not need their own PIS or consent form. If a whānau support person will be providing their feedback, they would be considered participants as their perspectives are being actively sought in addition to kaumātua. As such, they should also be given an information sheet and consent to participate in the study. This distinction should be made clear to the whānau and the kaumātua.
2. The Committee noted that participants in this study will be referred by Māori groups and indicated, as part of a safety plan, that these groups can be alerted to any issues or concerns that may arise during the CST sessions. Provision of this information should be provided in the Participant Information Sheet (PIS).
3. The Committee noted that whakamā needs to be considered throughout the study documentation and study activities, as whakamā around mate wareware and levels of reo for kaumātua and kuia could arise. The Committee requested that levels of reo in patient facing documentation and questionnaires are considered carefully.
4. The Committee requested documentation of a safety plan describing what will happen if referrers of the participants (or police if required) would be alerted to any safety/neglect issues or concerns that may arise during the CST sessions. Provision of this information should be provided in the Participant Information Sheet (PIS).
5. The Committee requested that the response/ rebuttal to the peer reviewer comments be provided. This may include the comments from the peer review regarding the feasibility of people with dementia being able to handle the online format have been addressed. Please include the evidence that there is published research and feedback from similar groups in New York that address these concerns and indicate that the online format is feasible with this group of people
6. The Committee queried whether any of the participants recruited to this study could have past experience with in-person CST and requested that the considerations for this be included in the questionnaires so that this information is collected.
7. The Committee requested that at the beginning of the session a brief explanation of CST be provided even before the formal CST presentation begins. This explanation could outline that CST is not a new treatment in New Zealand, rather the possibility of CST via zoom or video is being investigated.

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

1. Please refer to the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) and adapt to the study where relevant. This template will include all the necessary information required of a PIS.
2. Please include an overview of what CST is, as it is currently mentioned in the PIS but not described.
3. Please include cultural statements that acknowledge cultural considerations
4. Please ensure Māori cultural contact details are provided in the PIS, groups that referred participants could likely provide this support as long as they are able to do so.
5. Please provide more detail about the consent process in the PIS, outlining that consent will be taken outside of a group setting. However, the PIS should also recognise that the group setting environment means that other people participating in the focus group will be aware that other participants do have dementia.
6. Please remove references to a support person for healthcare professionals.

**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 Sandy Gill and Mrs Patricia Mitchell.

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| **7**   | **Ethics ref:**   | **FULL 22851** |
|   | Title:  | Virtual Cognitive Stimulation Therapy: Qualitative Foundation Phase for General New Zealand Population |
|   | Principal Investigator:  | Associate Professor Gary Cheung |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 12 June 2025 |

Dr Kai Kake, Mau te Rangimarie Clark, Gary Cheung, Kathy Peri 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, while this study does not specify Māori as a target ethnicity they can be included in this study if they do not wish to participate in the associated Kaupapa Māori study.
2. The Researchers clarified, in light of support people/ family members participating in their own capacity, that koha will be available for them in addition to their family member with dementia. However, health professionals who will participate in the study will not have the koha available as they will be participating during work hours. All participants will be supported with kai and reimbursement of travel costs in addition to the koha. Researchers further explained that sessions with people with dementia and their designated support person will be held separately from health professionals as the two groups will have different pacing.
3. The Researchers was confirmed that face-to-face Cognitive Stimulation Therapy (CST) for people with dementia has been previously researched and evaluated with positive outcomes.

Summary of outstanding ethical issues Provisional approval

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

1. The Committee queried how support people are involved, whether there were separate considerations between the support person for consent process and a support person who would be contributing their feedback on the virtual CST therapy. If a support person is only assisting the person with dementia in the consent process, they would not be considered a participant and would not need their own PIS or consent form. If a support person will be providing their feedback as part of the study, they would be considered participants as their perspectives are being actively sought in addition to the person with dementia. As such, they should also be given an information sheet and consent to participate in the study. This distinction should be made clear to the participating support person and the person with dementia.
2. The Committee requested documentation of a safety plan describing what will happen if referrers of the participants (or police if required) would be alerted to any safety/neglect issues or concerns that may arise during the CST sessions. Provision of this information should be provided in the Participant Information Sheet (PIS).
3. The Committee requested that the response/ rebuttal to the peer reviewer comments be provided. This can include the comments from the peer review regarding the feasibility of people with dementia being able to handle the online format have been addressed. Explaining that there is published research and feedback from similar groups in New York that address these concerns and indicate that the online format is feasible with this group of people
4. The Committee requested that more detail on how the different ethnicities will be recruited, be provided in the protocol. Explaining that the Researchers will use existing connections with services who will then disseminate to their workers.
5. The Committee requested that the inclusion criteria be updated to reflect the flexibility of recruiting Māori participants.
6. The Committee requested the protocol clearly state that recruitment emails will be coming from the organisations.
7. The Committee requested that the DMP, which references potential future research, and the PIS, which does not reference future research, be revised so that both documents provide the same information about the possibility of future research.

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

1. Please refer to the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) and adapt to the study where relevant. This template will include all the necessary information required of a PIS.
2. Please adapt the PIS to address the more diverse population that will be participating in this study, as it currently still reads as kitanga Māori
3. Please include cultural statements that acknowledge cultural considerations
4. Please ensure Māori cultural contact details are provided in the PIS for both studies. Contacts from the related Kaupapa Māori study could be used if available.
5. Please include consent to be recorded in the consent form.
6. Please include in the PIS that participants will be covered by ACC in the event of an injury.
7. Please revise the confidentiality statement as the group setting will mean that participation is not confidential.
8. Please revise wording ‘old age psychiatrist’ to ‘psychiatrist specialised in older adults’

**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 Sandy Gill and Mrs Patricia Mitchell.

## General business

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

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| **Meeting date:** | 22 July 2025 |
| **Zoom details:** | To be determined |

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 4:30pm.