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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 25 March 2025 |
| **Zoom details:** | 96507589841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 11:30am - 12:00pm |  | Committee Welcome |  |  |
| 12:00 - 12:30pm | 2025 FULL 20595 | Reducing cardiac risk in outpatients with serious mental illness | Dr Mayanna Lund | Sandy / Patricia |
| 12:30 - 1:00pm | 2025 FULL 20511 | Screening Concussion to Identify the Need for Neck Rehabilitation | Dr Olivia Galea | Cordelia / Nicola |
| 1:00 - 1:20pm |  | Break (20 mins) |  |  |
| 1:20 - 1:50pm | 2025 FULL 22441 | Head cooling in ischaemic stroke patients undergoing endovascular thrombectomy: a phase 2 randomised controlled trial (COOLHEAD-2b) | Professor Alan Barber | Jessie / Albany |
| 1:50 - 2:20pm | 2025 FULL 22351 | Sacitizumab Tirumotecan Alone or in Combination with Pembrolizumab versus Treatment of Physician’s Choice in Participants with advanced Triple Negative Breast Cancer | Dr. Soizick Mesnage | Joan / Patricia |
| 2:20 - 2:50pm | 2025 FULL 22108 | Aplastic Anaemia and Other Bone Marrow Failure Syndromes Registry (AAR) | Dr Nathanael Lucas | Jessie / Albany |
| 2:50 - 3:00pm |  | Break (10 mins) |  |  |
| 3:00 - 3:30pm | 2025 FULL 22321 | ORKA-002-211: A Study to Evaluate ORKA-002 in Healthy Volunteers Following A Single Dose. | Dr Chris Wynne | Joan / Andrea |
| 3:30 - 4:00pm | 2024 EXP  20600 | Augmented breathing and stress, anxiety, depression, and sleep **(Reconsideration of approval)** | Dr Imran Khan Niazi | Full Committee |
| 4:00 - 4:30 | 2024 EXP  11375 | Vibration Therapy for Better Breathing: Helping Patients with nasal congestion**(Reconsideration of approval)** | Dr Kelvin Lau | Full Committee |

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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  | Present  |
| Dr Patries Herst  | Non-lay (Intervention studies)  | 22/05/2020  | 22/05/2023  | Apology  |
| 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 | Present |
| Dr Andrea Furuya | Non-Lay | 03/03/2025 | 02/03/2029 | Present |
| Ascc. Prof Nicola Swain | Non-lay Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 11:30 and welcomed Committee members, noting that apologies had been received from Dr Patries Herst.

The Chair noted that it would be necessary to co-opt a member of another HDEC in accordance with the Standard Operating Procedures. Dr Nicola Swain confirmed her eligibility and was co-opted by the Chair as a member 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 25 February 2025 were confirmed.

## New applications

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| **1**  | **Ethics ref:**   | **2025 FULL 20595** |
|   | Title:  | Reducing cardiac risk in outpatients with serious mental illness: Feasibility of cardiovascular risk assessment in outpatients with serious mental illness receiving ECG surveillance |
|   | Principal Investigator:  | Dr Mayanna Lund |
|   | Sponsor:  | Aotearoa Clinical Trials Trust |
|   | Clock Start Date:  | 13 March 2025 |

Dr Mayanna Lund was present via video conference 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 raised that there may be issues with literacy in the target group and fully understanding the participant information sheet (PIS) for potential participants. Additionally, this could result in consent being given based on the position held by the consenter and not the information within the PIS itself. The Researchers confirmed that there will be someone to take people through the participant information sheet step by step, in detail, to ensure that the information sheet is understood by the potential participant and that they are not unduly influenced to participate because of the position of the consenter.

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 request that the researchers provide more detail in the documentation around whakamā, whanau support, and cultural support for participants as discussed. This should include the information that this study is not an additional intervention to standard care and identified that a physical examination as a part of an overall mental health examination can be consistent with peoples’ beliefs and understanding the conjunction of physical health and mental health. This approach, along with experienced support staff, will aid in reducing barriers between people considering participation and the consenters and outline appropriate cultural support including whakamā *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.8, para 9.7-9.8, para 11.7)*.
2. The Committee noted that the lifestyle choice questionnaire is unlikely to cause distress in such a way that would require such wording in the Protocol or PIS and can be removed from the documentation.
3. The Committee request that the questionnaire and PIS be reworded to provide information in more easily understandable, plain English, when describing the foods (eg sprouted beans or saturated fats).
4. The Committee identified that the protocol, as currently written, does not provide documentation or literature around food insecurity issues affecting Māori and Pacific communities who are likely to be included in the study and reads as if people are not eating foods because of a lack of education as opposed to poverty or access concerns. As such, the Committee request that the literature around this be addressed and the section in the protocol reworded *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8).*
5. The Committee request that, as part of addressing food insecurity in these communities, the questionnaire also be reassessed and additional questions included, such as whether participants buy their own food, prepare their own food etc *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
6. The Committee requested that questions asked in the study and the study objectives be clarified concisely in the submission and protocol. Clarify that the main objective of the research is to evaluate whether education of patients with complex mental health issues alongside healthy eating impacts cardiovascular health. In this case the inclusion of information about the ECG as part of the study may be introducing unnecessary information into the study documentation. ECG related information can be removed from study documentation as it is a quality improvement activity that the study will take advantage of *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.

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 mention whakamā in cultural statement and how the researchers intend to support participants throughout the study and that they can bring a support person.
2. Please revise the current PIS content and format to be more participant friendly and less dense. Inclusion of bullet points and examples of what questions will be asked in the questionnaire can aid readability.
3. Please explain clearly to participants what will occur after the study ends or if a participant decides to withdraw. Include information such as study interventions after withdrawal and who to contact for support.
4. Please remove repeated information.
5. Please provide ACC compensation information.
6. Please include information that GP will be informed of participation and that any adverse results will be provided to GP.
7. Please remove yes/no boxes unless consent is truly optional on CF.
8. Please clarify what participation involves; the initial testing and then testing again at the 12-month mark.
9. Please clarify for participants if this study is purely observational or if it incorporates an educative approach to behaviour change.
10. Please provide details on the type of advice and/or support participants will receive throughout the study.
11. Please specify if there are any costs associated with participation.
12. Please include a description of the physical exam, the level of uncovering necessary and provisions for support person to be present.
13. Please remove the wording "a healthy heart is a happy heart, and a happy heart helps to make you feel better physically and mentally".
14. Please reword the sentence “…provide you with personalised advice to improve your heart health" to be more specific on what advice might include and do not promise too much.
15. Please include information outlining whether participants can withdraw their information after results have been analysed. Currently the PIS indicates that data can be withdrawn at any time.

**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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| **2**   | **Ethics ref:**   | **2025 FULL 22441** |
|   | Title:  | Head cooling in ischaemic stroke patients undergoing endovascular thrombectomy: a phase 2 randomised controlled trial (COOLHEAD-2b) |
|   | Principal Investigator:  | Dr Alan Barber |
|   | Sponsor:  | Te Whatu Ora, Te Toka Tumai Auckland |
|   | Clock Start Date:  | 13 March 2025 |

Doug Cambell and Davina McAllister 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 indicated that participants randomised into the control group, who will not receive the cooling cap, may still receive benefit from participating in the study as they will be provided with improved adherence to normal clinical pathways, which in turn results in better overall care. The committee noted that the control group appeared to only receive standard of care.
2. The Committee and Researchers discussed the possibility of the control group data not coming from active participants but from retrospective data. However, agreed that in this case would not provide the best data for this study.
3. The Researchers clarified that coded information would only be used for future research related to stroke and will not be for future unspecified research.

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, in this case, the protocol and consenting process for the study is based around Right 7.4 in the Code of Health and Disability Services Consumers' Rights 1996(the Code). Right 7.4 of the Code indicates that if the participant lacks capacity to consent, then the provider can proceed without consent if it is determined that it is in the best interest of the participant to be included in the study , and provided the person’s views if known are followed or is not that the provider takes into account the views of available suitable persons who are interested in the welfare of the consumer. The committee did not accept that participation was in the best interests of each participant and noted that individual clinicians could be found to have breached the Code if a complaint was made to the HDC. the Committee believes that an alternative consenting process that does not rely on Right 7.4 should be implemented. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.59 – 7.71)*
2. The Committee noted that the majority of potential participants will be conscious but will have diminished competence. As provided by right 7.3 in the Code; if the person has diminished competence, they have the right to make choices and give consent to the extent appropriate to the level of their competence. In this case, under provisions of right 7.3, a brief talk with patients indicating to them that having a cap might help them, and, on a case-by-case basis providing differing levels of detail into the cooling cap and then collecting some form of consent could be a viable alternative process. Although under right 7(6) consent must be in writing it could be completed by the clinician who talked to the consumer indicating that the consumer agreed or indicated approval This should be later followed up by a full PIS and consent process where participants can agree that data collected earlier can be used. This, in turn means that extra care needs to be taken in the consent process to ensure that participants have understood well enough what they have consented to. This would mean that any patients who are not believed to have understood what they have been asked to consent to, or are not conscious, will need to be excluded from the study.
3. The Committee requested the protocol provide more clarity on the temperature monitoring of the control group compared to the intervention group. Where during transport temperature measurements can be done via axillary or tympanic methods, not via more invasive methods as would be done as part of standard care during general anaesthesia. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7 - 9.8)*
4. The Committee requested that processes around acknowledgment of the tapu of the head be included in the study protocol and PIS documentation. The documentation should also explain how the respect to the tapu of the head will be given. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.3)*
5. The Committee requested that scientific peer review be completed by someone more independent from the study and study team than the current review.

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 provide the script for the initial consent of the participant as well as a more detailed PIS to provide once the participants are better able to provide fully informed consent.
2. Please clarify who and where “hospital doctors” are, and if it is intended that they are at the admitting hospital, how they are able to withdraw the participant after they have been transferred.
3. Please amend the Consent Form to state that participants are able to withdraw consent related to the original data collected as well as all other data collected about them.
4. Please remove the comment about HDECS checking research from the Consent Form
5. Please reword sentence that participants are ‘happy’ for future stroke research to use their coded data to instead say that they ‘agree’ or ‘consent’ to this future research.
6. Please clarify whether participants will be consenting to their GP being informed of their participation in the research. If so, include this in the PIS and provide in the Consent Form.
7. Please remove the requirement for a signed form to withdraw, as participant withdrawal does not have to be signed by the participant.
8. Please include photos of the cooling cap with and without the swim cap in the detailed information sheet and the protocol

**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:**   | **2025 FULL 22351** |
|   | Title:  | A Phase 3, Randomized, Open-label Study Comparing Efficacy and Safety of Sacituzumab Tirumotecan (sac-TMT, MK-2870) as a Monotherapy and in Combination with Pembrolizumab (MK-3475) Versus Treatment of Physician’s Choice in Participants With Previously Untreated Locally Recurrent Unresectable or Metastatic Triple-Negative Breast Cancer Expressing PD-L1 at CPS Less than 10 (TroFuse-011) |
|   | Principal Investigator:  | Dr. Soizick Mesnage |
|   | Sponsor:  | Merck Sharp & Dohme (MSD) |
|   | Clock Start Date:  | 13 March 2025 |

Dr. Soizick Mesnage was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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 there is a referral pathway for any participants who find out that they have active HIV or Hepatitis as a result of tests run during the study screening.
2. The Researchers identified that standard of care procedures, results and any subsequent investigations will be faster for participants on the trial than for people only receiving standard care in the public system.
3. Researchers confirmed that there is no reliance from Merck Sharp & Dohme (MSD) on any US government funding for this trial.

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 indicated that the study needs to have a lay title that is easy to understand for participants.
2. The Committee request that the renumeration be identified and clearly outlined in the documentation for participants to understand that they will be receiving the rate equal to travel related expenses.
3. The Committee noted that insurance expires in 2026, study ends in 2030. Ensure that the insurance covers the whole duration of the study *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.5)*.
4. The Committee requested clarification why potential participants with HIV or Hepatitis are excluded from the study, and queried why well controlled HIV or Hepatitis could not be included in the study. Whether or not this remains as exclusion criteria needs to be clearly outlined and rational needs to be provided. Additionally, all of this information needs to be clearly outlined for potential participants in the PIS.
5. The Committee noted that the study cannot be stopped for commercial reasons in New Zealand.
6. The Committee requested that the study documentation explain what is involved in the ‘physicians choice’ of what drugs the participant will receive *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
7. The Committee requested that it be made clear to study participants that in arm three they will have access to drugs through the study that they would not have access to through standard of care pathway.
8. The Committee noted that the proof of indemnity is a ‘bill’ and not proof of indemnity please provide correct document.
9. The Committee noted that the protocol mentions a ‘legally authorised representative’, which is not relevant to New Zealand unless children are participants. As such, an appendix should be added to include all New Zealand specific information *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
10. The Committee requested further information on how potential participants are identified, how they are approached to inform them of the study, and how they are consented. Outline these processes to the participants *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*.
11. The Committee requested clarity around the process involved in emailing the PIS to individuals. Identify in documentation that there will be someone available in person to go through the PIS with potential participants and able to answer related questions *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.

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 complete a plain language review of the PIS and consider including a table for ease of reading and understanding.
2. Please confirm in the wording on page 1 “if you leave this will not affect medical care” is referring to leaving the study and amend as needed.
3. Please amend the PIS to indicate that HIV or Hepatitis tests need to be reported to the medical officer of health not ministry of health.
4. Please clarify the difference between clinical procedures and research procedures in the PIS. Explain what will happen in the study that is different to standard care, and what is specifically part of the study.
5. Please revise wording in the PIS stating that the study "will test the safety of [investigational drugs] and standard chemotherapy." as standard chemotherapy has already been tested for efficacy. The PIS could instead outline that the study is investigating different combinations of drugs to help identify which has the best outcomes.
6. Please explain that some of the study drugs are approved by Medsafe NZ and some are not, and which ones they are, and whether they are accessible through Pharmac in New Zealand.
7. Please explain to participants why the new drug/ drug combinations are being tested and why the study believes it might be effective. Include a participant friendly description of how the drug works the why you think this drug may help.
8. Please do not use the word "treatment" in the documentation as "treatment" suggests potential improvement of a health condition. When an intervention is experimental, you are looking for efficacy, so should be careful not to represent that it works.
9. Please state that this is not a first in human trial and provide the number of how many people have received sac-TMT.
10. Please remove double negative for clarity, when outlining who can be in trial.
11. Please clarify that, if participants stop getting the trial drug the follow up will occur ‘with participant consent’.
12. Please outline whether clothing will need to be removed during the physical exam and if participants can they bring a support person.
13. Please revise process outlined where, for each visit, participants will have to provide demographic information. This does not need to be repeatedly collected.
14. Please revise and clarify wording on page four referencing tissue sample or biopsy.
15. Please revise wording on page seven for New Zealand context, Medsafe approves medicines not USFDA.
16. Please clarify what items of small value are, give examples of what they may be or remove.
17. Please revise explanation as to why the trial drug will not be available after trial, as even if a drug is not approved it can be provided off label. Explain if any of these drugs will be provided off label.
18. Please provide further information about photographs, describe what they are of, if they are they identifiable and when are they might be taken.
19. Please remove wording in sections of the PIS that says participants will be penalised or lose any benefits if they leave the study. Instead, there should be wording outlining that the participants will continue to receive the care they require whether or not they join the study.
20. Please combine the contraceptive device information for pregnancy, breast-feeding and sperm into one section.
21. Please revise or remove the statement in section 21 indicating impacts of ‘trial payments’ or eligibility for future trials.
22. Please revise wording that outlines who will be able to access and see identifiable information. The Sponsor representatives should not have access to any identifiable data.
23. Please adapt answer from E.3 of the submission to a safety plan in the PIS related to quality-of-life questionnaires.
24. Please add contact numbers into the progression PIS.

**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 Mrs Patricia Mitchell.

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| **4**   | **Ethics ref:**   | **2025 FULL 22108** |
|   | Title:  | Aplastic Anaemia and Other Bone Marrow Failure Syndromes Registry (AAR) |
|   | Principal Investigator:  | Dr Nathanael Lucas |
|   | Sponsor:  | Monash University |
|   | Clock Start Date:  | 13 March 2025 |

Dr Nathanael Lucas was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researcher identified that the primary aspect of this ethics application is for the AAR, and that the AI/machine learning is a supplementary part of a PhD. The Researcher further clarified that the model for helping diagnoses may not end up being a machine learning model but a logistic model. As such, the Committee identified that this could be provided as an amendment in the future when appropriate.
2. The Researcher confirmed that Pasifika consultation has taken place, and that the Māori consultation is under way and will be completed before the study takes place.
3. The Researcher clarified that current methodology for family member consent is opt-in. Furthermore, family members are generally included after patients themselves ask family members to be tested and then they can be included in registry. Family members are not being actively sought by researchers.

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 identified that Opt-out consent applications are very limited in New Zealand due to tensions with the legal requirements for prospective informed consent. This tension creates a legal barrier to some research that may otherwise meet ethical standards. If opt-out consent methodology is applied for it must be justified under the NEAC standards. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.44 – 7.45).*
2. The Committee suggested exploring standard, opt-in, consent as a viable option for this registry. If this route was taken, then new documents for PIS/CF would need to be provided. Also, assent forms for older and younger children, and reconsent forms at 16 years for those whose parents gave proxy consent are required, and will need to include further information outlined in the ‘changes to Participant Information Sheet and Consent Form’ below. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. The Committee advised that if the study team were to continue with an opt out method it would require justification that consent is neither practical nor feasible in addition to criteria outlined in NEAC standard 7.45 *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.45).*
4. The Committee identified that a very large amount of information is being collected, including family history, where relatives have not consented.
5. The Committee queried whether a document can be provided to the diagnosed patients who can then share with their families, to explain the registry to family members in a clear way, that is not a PIS and can help indicate that genetic counselling is available. If such documentation is created it will need to be reviewed by the HDEC.

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 be to be more appropriate for the New Zealand context. This would include a cultural statement that knowledge is taonga and that appropriate steps will be taken to act as kaitiaki of this taonga. Adapting the HDEC PIS/CF template will address all information required to meet NEAC standards.
2. Please make clear that the information is to be sent to Australia and stored there (not NZ).
3. Please include a local New Zealand opt-out 0-800 number.
4. Please include footers and pagination.
5. Please include more information to participants about what sort of information is going to be collected. Please amend the paragraph about “what happens to information about me” to be consistent with outlining all of the information that will be collected either by questionnaire and/or from medical records.
6. Please include more information in PIS about who to contact with questions about the study and about Māori cultural considerations. The information required has been provided in the DMP can be adapted into 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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| **5**   | **Ethics ref:**   | **2025 FULL 22321** |
|   | Title:  | Phase 1, First-in-human, Double-blind, Placebo controlled, Single Dose Escalation Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of ORKA-002 in Healthy Participants |
|   | Principal Investigator:  | Dr Chris Wynne |
|   | Sponsor:  | Oruka Therapeutics |
|   | Clock Start Date:  | 13 March 2025 |

Dr Chris Wynne was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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 future genetic research is optional and specified that the whole genome will not be sequenced. Only specified, relevant, sequences will be looked at.
2. Researchers confirmed that payments and reimbursement information is outlined in more detail in appendix 2 of the PIS.
3. The Committee discussed the importance of privacy and security of identifiable data, to which the Researchers provided reassurances around the safety of the privacy data involved in the study.
4. The Committee noted that future submissions utilising confirmation of consent to access medical details from participants via text message include more detail. Outline the discussions that will occur between doctors and participants prior to any requests made via text message to ensure clarity.

**Decision**

This application was *approved* by consensus

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| **6**   | **Ethics ref:**   | **2024 EXP 20600** |
|   | Title:  | Effects of using an augmented breathing device on stress, anxiety, depression, and sleep |
|   | Principal Investigator:  | Dr Imran Khan Niazi |
|   | Sponsor:  | New Zealand College of Chiropractic |
|   | Clock Start Date:  | 29 November 2024 |

The following discussion related to a reconsideration of approval by the HDECs.

Dr Imran Niazi was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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 notified that the Committee that some participants have already been recruited. The Committee then indicated that recruitment would have to be suspended until the suspension of approval is lifted. However, the currently recruited participants can have their timepoint data collected, and then be reconsented with updated PIS and allow previously collected data to be used.
2. The Researchers clarified that there has been consultation with both Māori and the Pacific communities.
3. Researchers confirmed that participants will have the choice to keep the devices after the research has finished.
4. Researchers confirmed that the recruitment was able to take place without locality approval as the pilot study is not part of the PhD project which is what requires the approvals.

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 whether the research is covered by ACC or by the New Zealand College of Chiropractic (NZCC) insurance policies in which case provide confirmation that there is ACC equivalent insurance in place for this study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
2. The Committee requested that the funding relationships be described in detail and provided clearly in documentation. As discussed in the meeting this will outline the relationship between the NZCC and the collaboration with researchers in the US. Outlining the funding pathway from the US researchers, who apply for and receive funding from the US defence department, through the NZCC, who then apply for funding and support from the US based researchers.
3. The Committee requested that it be clearly stated in the protocol and in the PIS that there is no direct contact with the US military, confirming that no data or information is being sent offshore, and that there is no obligation to share any data with the device manufacturer.
4. The Committee noted that including Dr White as an investigator requires strong management of COI in the study and mitigations need to be adequately described in the documentation. As such, the Committee identified that limiting Dr White's role to only providing advice on the devices themselves could be an effective way to manage this COI *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.23)*.
5. The Committee requested that a clear safety plan be put in place, highlighting processes for those with a serious underlying health concern and mental wellbeing. The safety plan should provide necessary care as quickly as possible. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*
6. The Committee requested that the information in the Data Management Plan (DMP) indicating that participants’ data collected “for additional purposes that the participant has explicitly consented to” needs to be clearly outlined in both the DMP and provided to participants. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*
7. The Committee requested that it be made clear in all participant facing documentation that all funding, manufacturing, and research relationships are clearly described between all parties involved in the study. If any potential conflicts are present describe how they are being managed.

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

1. Please include a cultural statement that indicates understanding that knowledge is tāonga, acknowledgment of the tapu of the head, and the way in which the respect to the tapu of the head will be given throughout the study. This can be adapted from the submission which did provide this information.
2. Please clarify that both koha and reimbursement for travel costs are separate things and will both be provided. For koha, please give participants with the choice of either a petrol voucher or a supermarket voucher.

**Decision**

This application had its approval *suspended* by consensus after reconsideration, suspension can be lifted 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 confirm the study is eligible for ACC or provide evidence of ACC-equivalent insurance for the duration of the trial *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
4. 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 Full Committee online.

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| **7**   | **Ethics ref:**   | **2024 EXP 11375** |
|   | Title:  | Investigating the Effects of Acoustic Therapy on the Nasal Microbiome and Well-being |
|   | Principal Investigator:  | Dr Kevin Lau |
|   | Sponsor:  | Auckland University of Technology |
|   | Clock Start Date:  | 15 November 2024 |

The following discussion related to a reconsideration of approval by the HDECs.

Dr Kevin Lau was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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 the motivation for the study is to look at treatment for allergic rhinitis (AR) and chronic rhinosinusitis (CRS) via acoustic therapy. The device can deliver the ‘humming’ effect (acoustic therapy) in a more consistent and controlled way than if the participants were to hum themselves.

Summary of outstanding ethical issues (Commercial and COI aspects)

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

1. The Committee requested that contact be formally made with ACC to confirm, in writing, whether they consider this a commercial study, and if the participants would be covered by ACC or not. If the study will not be covered by ACC then evidence of ACC-equivalent insurance will need to be supplied *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
2. The Committee requested that it be made clear in all participant facing documentation that all commercial, funding, manufacturing, and research relationships and conflicts are clearly described between all parties involved in the study. How the conflicts are being managed should also be included. Include that AUT is minor shareholder in the device manufacture company, that the device is being provided to the study for free by the manufacturer, and that the manufacturer is focused on entering the commercial market for nasal decongestion. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. The Committee requested all documentation that outlines the management of any COI for Dr White be provided in the ethics submission. This includes the memorandum of Conflict Of Interest (COI), and the NDA documents mentioned in the meeting.
4. The Committee noted that including Dr White as an investigator requires strong management of COI in the study and mitigations need to be adequately described in the documentation. As such, the Committee identified that limiting Dr White's role to only providing advice on the devices themselves could be an effective way to manage this COI.
5. The Committee requested that inclusion of the PhD student is reflected in study documentation and participants are informed in the information sheet.
6. The Committee noted that previous studies conducted with this device does not eliminate the possibility of commercial benefit from further studies and testing. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
7. The Committee requested that the separation between identifiable and coded information is clearly outlined in the DMP, and clearly stated for participants in order for them to understand the protections and mitigations in place for their data.

**Summary of outstanding ethical issues (Other study aspects)**

1. The Committee requested further details around rationale for pregnancy in the exclusion criteria. Currently the consent form indicates that there may be risks associated with the device for pregnancy which is inconsistent with information provided in the PIS. Without clear risk to pregnant people, they should not be excluded from the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.15).*
2. The Committee requested further details around the rationale for including individuals with asthma and other respiratory conditions in the study. Please clarify how the study will ensure that participants with respiratory conditions continue to use their prescribed medications when necessary to prevent potential serious health risks.
3. The Committee requested clarification on whether tissue samples can be returned to participants, there is currently discrepancy between the answers to F6 and F8 in the submission form.
4. The Committee request clarification of where data is being sent from the study, currently the DMP indicates that genomic information is being sent to China. Please include this information in the PIS and CF.
5. The Committee requested that the scientific peer review document be revised and adapted to the HDEC Peer review template to ensure that it is an appropriately independent and robust scientific review.
6. The Committee requested that further supporting experimental evidence in the proposal would enhance its scientific foundation and rationale for conducting clinical studies, along with citations of peer reviewed literature that provides a validated and evidence-based basis for the study.
7. The Committee requested that copies of the well-being surveys are provided and further clarity on what processes and safety protocols are in place if these forms indicate distress.
8. The Committee requested clarification on whether or not there will be treatment by a registered health practitioner.
9. The Committee requested that the advertisements be amended into lay language, to include ethics approval and to revise wording ‘groundbreaking study’ to be less optimistic and more grounded.
10. The Committee requested confirmation that the recommendations from Komiti Mātauranga Māori have been implemented.

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 remove information in the PIS that describes what is NOT happening, this does not need to be included.
2. Please amend “what will happen in this research” section for clarity.
3. Please remove unnecessary tick boxes from consent form.
4. Please include a diagram or picture of the device
5. Please provide contact numbers for cultural support
6. Please include processes around acknowledgment of the tapu of the head in the PIS. The way in which the respect to the tapu of the head will be given should be also laid out in the documentation and can be adapted from C5 of the submission.

**Decision**

This application had its approval *cancelled* by consensus after reconsideration, as the Committee did not consider that the study met 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:** | 22 April 2025 |
| **Zoom details:** | To be determined |

 The following members tendered apologies for this meeting.

* Ms Patricia Mitchell
* Ms Jessie Lenah-Glue
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.