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| **Committee:** | Ad hoc Health and Disability Ethics Committee |
| **Meeting date:** | 22 May 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 10:00 - 10:30am |  | Committee welcome |  |  |
| 10:30 - 11:00am | 2025 FULL 22904 | Oral ketamine for bipolar depression - resubmission post decline | Associate Professor  Ben Beaglehole | Maree / Nicola |
| 11:00 - 11:30pm | 2025 FULL 22735 | CND261-101 A Phase 1b study of CND261 in Seropositive Rheumatoid  Arthritis | Dr Paul Hamilton | Joan / Andrea |
| 11:30am - 12:00pm | 2025 FULL 22942 | FB102-301: A Phase 2 study evaluating safety and efficacy of FB102 in participants with coeliac disease on gluten-free diet. | Dr Paul Hamilton | Catherine /Pat |
| 12:00 - 12:30pm | 2025 FULL 22134 | OCEANiC: Osimertinib plus Chemotherapy Evaluation in Adjuvant NSCLC incorporating CtDNA | Dr Alice Minhinnick | Catriona / Andrea |
| 12:30 - 1:00pm |  | *Break 30 mins* |  |  |
| 1:00 - 1:20pm | 2025 EXP 22611 | The role of physiotherapy rehabilitation in improving health outcomes for Māori with matepukupuku. | Ms Rachel Swann | Catriona / Pat |
| 1:20 - 1:50pm | 2025 EXP 22216 | Te Iti Kahurangi: Neonatal mortality and morbidity among term pēpi | Associate Professor  Liza Edmonds | Catherine / Andrea |
| 1:50 - 2:00pm |  | *Break 10 mins* |  |  |
| 2:00 - 2:20pm | 2025 EXP 21216 | A One Health Approach to Investigating Leptospira in Aotearoa New Zealand | Prof Jackie Benschop | Maree / Pat |
| 2:20 - 2:40pm | 2025 EXP 22070 | Track-PINK1 PD | Dr Viswas Dayal | Catherine / Nicola |
| 2:40 - 3:00pm | 2025 EXP 22353 | STEP-FMD: Study of Transcranial Magnetic Stimulation Enhanced Physiotherapy for people with Functional Movement Disorder. | Prof Cathy Stinear | Joan / Nicola |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Catherine Garvey | Lay (the Law) (Chair) | 11/08/2021 | 11/08/2024 | Present |
| Ms Joan Pettit | Lay (Intervention Studies) (Chair) | 08/07/2022 | 08/07/2025 | Present |
| Ascc. Prof Nicola Swain | Non-lay Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Dr Andrea Furuya | Non-Lay | 03/03/2025 | 02/03/2029 | Present |
| Mrs Patricia Mitchell | Non-lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Dr Catriona McBean | Lay | 03/03/2025 | 02/03/2030 | Present |

## Welcome

The Chair opened the meeting at 10:00am and welcomed Committee members, noting that no apologies had been received.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

N/A

## New applications

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| **1** | **Ethics ref:** | **FULL 22904** |
|  | Title: | Feasibility of oral ketamine for bipolar depression: a 20-week open-label study |
|  | Principal Investigator: | Ben Beaglehole |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 9 May 2025 |

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

Potential conflicts of interest

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

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 commended the researcher on the comprehensive resubmission of this application.
2. The Researchers confirmed that notes from the peer reviewer around risks for patients already treated with Lamotrigine have been addressed.
3. On the concern about the use of recreational ketamine, the Researchers outlined that the literature indicates that participants enrolled in ketamine studies tend to have lower risk of going on to self-administration of ketamine post study. Efforts such as screening for people without substance use disorders are made to minimise risk of participants going on to self-administer ketamine after the trial.
4. Researchers confirmed that ketamine is approved in New Zealand for clinical use in pain relief and anaesthesia. It is not approved for use in depression and researchers are investigating use in an alternative population group. Researchers do not believe that the side effect profile would change for this new population and believe that the literature is promising in regard to use of ketamine in treatment of bipolar depression, with no substantial risks being reported in mood elevation.
5. Researchers confirmed that physical letters are sent out to participants and electronic versions are stored.

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 qualitative interview protocol be expanded to include more information about the interview process as well as the list of the questions that will be asked. This should also include processes around the interview opening, checking consent, outlining the recording and transcription aspects of the interview, and the ending of the interview.
2. The Committee requested that information around the recordings of the qualitative interview be included in the Data Management Plan (DMP).
3. Please ensure that there is a safety plan in the event that qualitative interviews are carried out in participant homes or other locations away from the study site.

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

1. Please add summarised table of assessments to PIS to make it easier for participants to understand.
2. Please revise wording ‘using ketamine for fun’ to ‘recreational use of ketamine’.
3. Please introduce ketamine as a bladder irritant earlier in the PIS.
4. Please ensure that the fact a GP and/or specialist will be informed of inclusion in the study is provided earlier in the PIS.
5. Please revise wording ‘psychiatry review available and/or on request’ to reflect the plan in place if further review is indicated.
6. Please include in the PIS information about the questions that will be asked in the qualitative interview, as well as indication of transcription of the interview and where the data from this interview will be kept.
7. Please include the timing of assessment schedule in the PIS to provide additional clarity of the study to the participants.
8. Please include information that ketamine is a bladder irritant in the PIS, this information is provided throughout other documents such as the protocol and questionnaires and can be adapted from there.
9. Please separate and put in bold that participants are not to drive and will need to organise alternative transport.
10. Please revise the PIS future research section from ‘use of information’ to be clear that it will involve the use of deidentified data.
11. Please describe to participants why actigraph data is being collected and include any intended use of the data collected to be used with data from other studies.
12. Please describe the data collected by the watch that is provided, explain whether the data is stored on the watch and downloaded at the end by study team and not uploaded, if there is any collection of identifiable data and include instructions around constant use of the watch regarding daily activities such as showering.
13. Please revise the use of the word ‘treatment’ and other language implying benefit in both PISs, ensuring that this is qualified eg “investigational treatment.”
14. Please clearly state in the PIS how long the study is expected to go on for.
15. Please clearly state how often post treatment calls will take place and how long they will last

**Decision**

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

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

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| **2** | **Ethics ref:** | **FULL 22735** |
|  | Title: | CND261-101 A PHASE 1B, OPEN-LABEL, MULTICENTER STUDY EVALUATING THE SAFETY, TOLERABILITY, PHARMACOKINETICS, PHARMACODYNAMICS, IMMUNOGENICITY, AND PRELIMINARY CLINICAL ACTIVITY OF CND261 IN PATIENTS WITH SEROPOSITIVE RHEUMATOID ARTHRITIS |
|  | Principal Investigator: | Dr Paul Hamilton |
|  | Sponsor: | Candid Therapeutics, CA, USA |
|  | Clock Start Date: | 9 May 2025 |

Dr Paul Hamilton, Charlene Botha and Jonathan Gall 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 the possible stay for 48 hours for clinical visits refers primarily to the first dose, where researchers want to have the option of overnight safety monitoring.

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 standard of care screening procedures and screening procedures that are specifically part of the study are clearly explained to participants. In regard to screening, the researcher may consider a separate Participant Information Sheet (PIS), or otherwise clearly delineate screening procedures in the main PIS.
2. The Committee requested that the advertisements be revised to clarify how 5 weekly doses can occur within one month, provide that doses are given at intervals of 7 days starting on day 1 and on to day 29.
3. The Committee requested that the investigational product is consistently referred to as CND261 across all study documentation.
4. The Committee noted that weekly pregnancy testing is overly invasive and potentially patronising and requested that the need for such frequent testing be reviewed and revised. The Committee noted the sponsor’s indication that the initial frequency of the urine pregnancy testing was based on having an abundance of caution for an early phase clinical trial, however, indicated that such frequent pregnancy testing is invasive regardless off the method of testing. The Researchers agreed that weekly frequency of such testing seems excessive and would explore lowering the frequency of such testing.
5. The Committee noted that the time and assessments required for participant in the study are extensive and requested that the researcher address reimbursement for time and travel in line with these expectations. If any extended or overnight stays are expected then meals need to be provided.
6. The Committee requested that the wording in advertisements ‘all doctors and nurses will be trained New Zealand doctors and nurses’ be changed for clarity to provide for doctors and nurses who are registered in New Zealand.

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

1. Please explain to participants the different stages and tests involved in the screening process.
2. Please revise the table on page seven, where all the procedures are listed, to include information on which results from which tests may exclude people from participation.
3. Please ensure it is clear to participants what will happen to their data if they are excluded after the screening process.
4. Please revise the use of the word ‘treatment’ throughout as it suggests benefit, instead ensure that it is clear that this is experimental.
5. Please ensure that it is clear that notification of study participation is mandatory language on page 3 and 17, not optional.
6. Please add the risks of pre-medication to page 13.
7. Please add any benefits provided by study procedures (testing, monitoring), if any, that are not readily accessible to people outside of the study.
8. Please provide more context about the possibility of the participant remaining in study clinic/associated facilities and when this may be necessary.
9. Please clarify the alternative section to ensure that the possibilities for someone in New Zealand outside of the study are provided.
10. Please adapt the section on study costs to be relevant to New Zealand. Explain what procedures or medications are not paid for by the study or the government medical system.
11. Please update the exclusion criteria/PIS/CF to specify that individuals currently enrolled in other clinical trials should not be considered for participation in this study.
12. Page 3 of PIS: add in the word “world” in the following sentence: “the study will take place in approximately 6 study centres with 47 people around the world…”
13. Please clarify on page 10 of the PIS whether the proposed testing is genetic or genomic in nature. Additionally, provide more detail regarding the testing methodology, specifically, what the testing will involve, which genes or genomic regions will be examined, and how this relates to the objectives of the trial.
14. Please include information on genetic testing in the CF.
15. Please ensure that any compensation, reimbursement, or lack of, is clearly communicated to participants.
16. Please provide information on how any positive results from study testing for HIV or hepatitis for people who were unaware of infection will be handled.
17. Please ensure that the rationale behind the pregnancy testing is clearly provided to participants in the PIS.
18. Please remove the additional bullet point broadly stating that identifiable data would be sent to the sponsor. This is appropriately limited in another bullet point to data in the event of a compensation claim.
19. Please revise the compensation statement which refers to Medicines New Zealand guidelines, this can be removed if not relevant to this study. Please refer to compensations statement in the HDEC intervention PIS template.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

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

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| **3** | **Ethics ref:** | **FULL 22942** |
|  | Title: | FB102-301: A multicenter, randomized, double-blind, placebo-controlled Phase 2 study to evaluate the efficacy and safety of FB102 in adult participants with celiac disease on a gluten free diet |
|  | Principal Investigator: | Dr Paul Hamilton |
|  | Sponsor: | Forte Biosciences Australia Pty Ltd |
|  | Clock Start Date: | 9 May 2025 |

Dr Paul Hamilton, Charlene Botha and Thomas Stock 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 experience with the phase one study indicates that the proposed level of gluten for this study is well tolerated and explained steps taken at the site to support participants where possible and when needed. Researchers clarified that there is not any approved medicine or treatment for coeliac disease. While the wording on the extension study indicates that participants can’t take medications for their disease while still on this study, if a breakthrough approved treatment or another trial option becomes available participants are free to remove themselves from extension study to use any other medication.
2. Researchers confirmed that no clinically relevant findings could come up from blood tests in the extension study, as researchers are not monitoring for safety and do not have access to those results, rather, only specific biomarkers are investigated.

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 Data and Tissue Management Plan (DTMP) does not reference optional tissue samples. If participants have additional optional blood tests this needs to be covered in the DTMP.
2. The Committee noted that the insurance period provided ends before the expected end of the study and request that researchers ensure the insurance rolls over to cover the entire study period.
3. The Committee requested that the protocol include information describing where bowel biopsies will take place and indicate who will be performing these biopsy procedures. This information should also be provided in the PIS.
4. The Committee noted that weekly pregnancy testing is overly invasive and requested that the need for such frequent testing be reviewed and revised. The Committee noted the sponsor’s indication that the frequency of the pregnancy testing was based on having an abundance of caution for an early phase clinical trial and aimed to provide adequate response to any discovered pregnancy before any further exposure of the treatment drug to a foetus. However, the Committee reiterated that a blanket inclusion of such frequent pregnancy testing is unnecessarily invasive for participants where intermediate measures can be taken to mitigate pregnancy risks. The Committee indicated that a separate, distinct conversation with participants around the topic of pregnancy testing in this study and a clear description as to why these tests would take place and why they are proposed to take place with such regularity could be implemented to address this.

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

1. Please review the PIS for plain language and review for relevance to all participants. Not all participants need to know that 16 vitiligo patients will be enrolled in the study.
2. Please clarify if participant diaries and logs are available online so participants are aware they can choose these options.
3. Please clarify how the ‘5 doses’ of the IMP are administered by infusion.
4. Please ensure lay language eg when referring to ‘challenge’.
5. Please revise wording for the Extension PIS title to remove ‘Non-Treatment…’ as it is experimental.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* please 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).*
* Please update the data and tissue 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, 14.16&14.17).*

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| **4** | **Ethics ref:** | **FULL 22134** |
|  | Title: | A Phase II, Open-label, Multi-centre Clinical Trial of Osimertinib With or Without Adjuvant Chemotherapy Guided by Tumour NGS Co-mutation Status and ctDNA Detection in Patients With Stage IIA-IIIA EGFR-Mutant Non Small Cell Lung Cancer Following Complete Surgical Resection |
|  | Principal Investigator: | Dr Alice Minhinnick |
|  | Sponsor: | NHMRC Clinical Trials Centre The University of Sydney, Faculty of Medicine and Health |
|  | Clock Start Date: | 9 May 2025 |

Dr Alice Minhinnick, Nel Peiris and Jessica Lalanne 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 bone marrow ‘function’ testing is not a bone marrow biopsy, rather is informed from a full blood count from a blood test.
2. The Researchers clarified that any indication of cancer growth on study is a sign that a participant would need to go off the study drug and return to multidisciplinary team discussion to determine what the best course of action is for the patient.
3. Researchers confirmed that there is no specific payment or reimbursement to participants in the study and do not anticipate additional costs. However, the researcher clarified that standard practice is that if transport or support is needed this is considered on an individual basis.
4. Researchers confirmed that the holding of samples for 50 years was a maximum specified to avoid the indefinite storage of samples.

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 screening procedures and research procedures are clearly delinieated. Please clarify what test results are required for eligibility. A segmented PIS or separate screening PIS could aid in providing clarity. This should also outline what will happen to data of participants who are determined to be ineligible after screening.
2. The Committee requested that ethnicity data is collected at the site level as it is a reporting requirement for annual progress reports that are to be submitted to HDEC.
3. The Committee noted that there are good provisions in place to provide support to participants who seek such support, however, it is indicated in the protocol that quality of life questionnaires are not reviewed in a timely manner by the researchers. The Committee requested that the checks made by nurses for questionnaire completion as well as screening for any indications of distress, as described by the Researcher in the meeting, is described in the protocol.
4. The Committee noted that the Data Management Plan (DMP) and the Participant Information Sheet (PIS) reference New Zealand and Australia interchangeably and requested that these documents be revised for consistency.

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

1. Please ensure differences between study procedures and standard of care procedures are clearly outlined for participants.
2. Please clarify what standard of care would be for early phase non-small cell lung cancer (NSCLC) as the study drug is approved for use but not funded. Please outline what steps potential participants would have to take if they wanted access to the study drug outside of the trial and what the funded treatment is in New Zealand. This will help patients understand what they are being offered as part of this study.
3. Please revise the wording saying that the drug company was ‘sponsoring’ the study as this is not a sponsored study.
4. Please include in the PIS that participants may be referred on to relevant specialists if the nurses who are checking the quality-of-life questionnaires find indications of distress.
5. Please consider the use of ‘kaumātua’ as opposed to ‘kaitiaki’ in the PIS.
6. Please revise wording for notification of HIV or hepatitis to also include ‘any other notifiable disease’.
7. Please consider using alternative wording in the contraception section to ensure that for particularly male participants, that they are aware that if they have a female partner who is not on, and will not go on, contraception they would be excluded from the study.

**Decision**

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

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

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| **5** | **Ethics ref:** | **EXP 22070** |
|  | Title: | Track-PINK1 PD: A prospective, longitudinal observational study of people with PINK1 Parkinson's disease and heterozygous carriers compared to controls |
|  | Principal Investigator: | Dr Viswas Dayal |
|  | Sponsor: | Te Whatu Ora Te Toka Tumai Auckland |
|  | Clock Start Date: | 9 May 2025 |

Dr Richard Roxburgh, Dr Viswas Dayal and Dr Christina Buchanan were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researchers clarified that they do not expect cognitive impairment in many of the participants and that, based on clinical judgement, for those who require supported decision making this option would be available.
2. The Researchers confirmed that recruitment of participants into Group A is not affected by whether or not family members of Group A participants consent to participate in Group B and Group C. However, Researchers noted that most contact with patients is in a group setting with their families present, and the researchers anticipate that many will be supportive of the study.
3. Researchers confirmed that, when family members of the participants are approached to be involved in the study, discussion for informed consent can be done individually.
4. Researchers confirmed that they would not be including any participants under the age of 16.
5. Researchers confirmed that the information provided in the submission form indicating that study on ethnicities is excluded is incorrect.
6. Researchers confirmed that ongoing Pacific consultation has been taking place as the Pacific population is disproportionately affected by this disease. The Committee noted that written evidence of Māori consultation has not been updated since 2019. The researchers advised that no Māori participants with the gene variant have been identified.

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 all advertising materials be provided.
2. The Committee queried the rationale behind performing genetic testing in cohorts B, C and D with no intention of sharing results with participants. Researchers indicated that standard precautions around predictive genetic testing are in place to protect people finding out incidental findings when they are unaware of their disease status and highlighted that genetic counselling would not be available through this research if those results were disclosed to participants. Researchers explained that if a participant wanted to find out their results they would need to do so through the clinical pathway, where all of the standard of care and counselling pathways are available and confirmed that they would be able to facilitate contact and refer participants to predictive testing pathways. The Committee noted that the *National Ethical Standards for Health and Disability Research and Quality Improvement* (*para 14.15)* require the results of testing of human tissue to be returned appropriately. The Committee is concerned that participants are not to be offered the opportunity to receive results. The Researchers stated that they do not have the funding or resources to provide timely genetic counselling as a result of any positive findings. The Researchers and the Committee discussed “actionable results” and what is covered by this phrase.
3. The Committee requested that it be made explicitly clear to participants in Cohorts B, C and D that they will not be given the option of receiving results from the genetic testing through the study If a participants wants access to their results they should pursue that information through clinical channels and the researchers will do their best to assist that process outside of the study. The Committee requested that a separate PIS be created for cohorts B, C, and D to provide the information outlined above.
4. The Committee requested that the PIS for cohorts B, C, and D indicate how participation in these cohorts could benefit their family members in cohort A.
5. The Committee noted that as follow up assessments could occur over extended periods of time, consent may also need to be revisited.
6. The Committee noted that some assessments will be done in homes, requiring a researcher safety plan to be in place.

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

1. Please state the period of time over which participants are expected to be in the study. Please include information in the PIS that home visit assessments are available.

**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 provide a Researcher safety plan *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62).*

After receipt of the information requested by the Committee, a final decision on the application will be made by the Full Committee.

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| **6** | **Ethics ref:** | **EXP 22611** |
|  | Title: | The role of physiotherapy rehabilitation in improving health outcomes for Māori with matepukupuku/cancer |
|  | Principal Investigator: | Ms Rachel Swann |
|  | Sponsor: |  |
|  | Clock Start Date: | 9 May 2025 |

Researchers were not present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee requested that the PIS clearly state who the intended participants are (that is professionals or for the whānau voice) Separate PISs may be required for the different groups.
2. The Committee queried how the questions from the questionnaire would be used to answer the study question and achieve the aim of the research. Please clarify.
3. The Committee noted inconsistency around what the aim of the research is across all of the submitted documents and the submission itself.
4. The Committee identified that the protocol needs to include more detail about the Sponsor, researchers, funding and locations.
5. The Committee requested that the list of questions that will be asked are provided in the protocol.
6. The Committee noted that there are inconsistencies across study documents and requested that researchers review for consistency. For example, the Data Management Plan (DMP) refers to future use of data and there is no mention of this in the PIS. The DMP states that data will be held for 5 years, however, the Participant Information Sheet (PIS) indicates that data will be held for 10 years.
7. The Committee requested that the DMP describes what happens with the recordings and transcripts, identifying whether they are deleted or deidentified.
8. The Committee indicated that this application did not portray a clear understanding of the purpose of the research, the processes that will take place, who the participants are and linking the survey to the research outcomes.
9. The Committee noted that seeking support from an academic research network would assist in constructing clear research goals, relevant methods, clear analysis, and dissemination plans for this study.
10. The Committee requested that a new scientific peer review be submitted from an academic reviewer not from a clinician. [The HDEC peer review template](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2021.docx) can be used for the peer review document.

The Committee requested justification for the number of participants to be included in this study.

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

1. Please include information that interviews will be recorded (audio, or audio/visual to be clarified). Advise participants of their right to stop the recording and if relevant, who transcribes these interviews and whether the participant is allowed time to review the transcript.
2. Please remove Yes/No options from the consent form where items are a mandatory.
3. Please amend 0800 ethics contact number.
4. Please provide information on who is funding this study.
5. Please state what koha is for people who participate in the study.
6. Please remove “anonymous” as researchers will know who the participants are
7. Please include information explaining that data will remain in New Zealand under "Maori data sovereignty".

**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 Full Committee.

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| **7** | **Ethics ref:** | **EXP 22216** |
|  | Title: | Te Iti Kahurangi: Neonatal mortality and morbidity among term pēpi |
|  | Principal Investigator: | Associate Professor Liza Edwards |
|  | Sponsor: | Te Herenga Waka-Victoria University of Wellington |
|  | Clock Start Date: | 9 May 2025 |

Researchers were not present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee requested peer review for the individual components of this study, as the current peer review document addresses a related study.
2. The Committee requested clarity on how ethnicity groupings are determined and that descriptors of different ethnicities be revised *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.1c)*.
3. The Committee noted that the data collection from NICU is unconsented and identifiable and requested that the data sought to be collected is clearly defined and access to this data is clearly justified *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.29)*.
4. The Committee requested that the protocol clearly outline what specific data will be collected from participants and from what databases as described in the Data Management Plan (DMP). The analysis plan should include what is being compared and what outcome measures are. This is especially relevant to a study for which a waiver of consent is being sought *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
5. The Committee requested that a privacy breach should be notified to individuals notwithstanding that a waiver is granted to collect data without consent *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.10).*
6. The Committee requested clarity on the dissemination strategy *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8).*
7. The Committee requested clarity on the study hypothesis and recommended the researchers consider rewording the hypothesis to clarify the specific measurable outcomes, target population, and presumed causal pathways to maintain scientific objectivity, separating the empirical hypothesis from the ethical interpretation in the design and discussion sections while still addressing the broader social justice context (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8).*
8. The Committee indicated that it is currently unclear what specific actions are proposed to address the observed disparities from the study. As such, the Committee requested further information about any future planned research with this data and what the next steps are *National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8).*
9. The Committee queried how morbidity data will be linked to socioeconomic factors and requested an explanation of whether morbidity and disability data collected, and if not, justification as to why that data is not included in the study when it is known to be high amongst Māori infants.
10. The Committee noted that the HRC funding was awarded in 2022, and requested clarification on what activities or progress has occurred between 2022 and 2025 and that the awarded funding is still current.
11. The Committee requested that the data storage statement indicating that the data will be retained for 10 years be revised to indicate that it will be retained for 10 years after the youngest participant reaches 16 *National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.13).*

**Decision**

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

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| **8** | **Ethics ref:** | **EXP 21216** |
|  | Title: | A One Health Approach to Investigating Leptospira in Aotearoa New Zealand |
|  | Principal Investigator: | Prof Jackie Benschop |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 9 May 2025 |

Researchers were not present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee noted a lack of consistency or clarity in protocol and PIS around how many participants will be enrolled in the study, how many will be completing questionnaires and how many are expected to have blood tests. Clarity is required on whether a participant who declines a blood sample will be excluded.
2. The Committee requested that the information regarding Māori data sovereignty, which is described thoroughly in the PIS, be included in the protocol.
3. The Committee requested that the protocol be amended to include the provision that GPs will also be notified of the blood results, even if negative, as this is a notifiable disease. Additionally, provisions need to be in place to notify the Medical Officer of Health of any positive results. This information should also be provided in the PIS and assent forms.
4. The Committee noted provisions for reimbursement of initial and follow up GP visits in case of a positive result need to be clearly outlined in the protocol, PIS, and assent form.
5. The Committee requested clarification on how the study will collect good quality ethnicity data.
6. The Committee requested that any advertising intended to be used be submitted to the Committee for approval.
7. The Committee requested that the age range for inclusion is consistent across the study documentation.
8. The Committee requested clarification around the data for which a waiver of consent is being sought. Additionally, a description of how this data will be integrated into the study analysis should be provided. If the dataset is deidentified aggregate data a waiver of consent is not required.
9. The Committee requested further consideration of the impact of a positive result for a younger participant, and steps that can be taken by the researchers if this occurs. This should also be outlined in the assent form.
10. The Committee requested that a koha be made available to participants if possible.
11. The Committee queried how the researchers can be confident that the sample will be representative of the population.
12. The Committee queried whether community members who wish to be tested for the disease but not included in the study will be offered the opportunity have the test.
13. The Committee noted that there should be distinction between PCR positive results and serological positive results. The committee queried if the inclusion of these individuals and doing serological testing would give better understanding of who may have been exposed at some point.
14. The Committee requested that advertisements be submitted for HDEC approval.

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

1. Please review the assent form in consideration of the age group that will be reading it and revised as appropriate.
2. Please reword the assent form so it is clear that consent from parent or guardian is only needed from one parent or guardian.
3. Please consider removing the ‘occupation’ question in assent form.
4. Please ensure that the PIS and assent form describes what will take place in the event of a positive result after a blood test.
5. Please revise reference to biological waste for sample disposure.
6. Please revise ‘providing a blood sample’, to ‘providing an optional blood sample’.
7. Please provide that data will be kept for 10 years after the youngest participant turns 16.
8. Please revise wording ‘you can consult with your GP about your results’, to ‘you should consult your GP about your results’.
9. Please revise ‘positive results’ section to be clear that not all results are expected to be positive.
10. Please ensure that, if there are any costs associated with blood and urine testing of domestic animals, that this outlined in the 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 Dr Maree Kirk and Mrs Patricia Mitchell.

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| **9** | **Ethics ref:** | **EXP 22353** |
|  | Title: | A phase 2a, single arm study of Transcranial Magnetic Stimulation Enhanced Physiotherapy to Restore Movement Agency and Walking Independence in people with Functional Movement Disorder. |
|  | Principal Investigator: | Prof Cathy Stinear |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 9 May 2025 |

Researchers were not present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee noted that physiotherapists will be taking notes and indicated that these notes need to be included as a data source.
2. The Committee noted that a ‘witness’ was going to be used in the consent process for those who are unable to sign their name. The Committee queried the requirement of this as verbal consent can be given by a participant and clearly documented by the study team.
3. The Committee queried if there will be any safety checks of the device prior to use on the participant to ensure that the device is operated safely.
4. The Committee requested further information about the device and its previous use in New Zealand and overseas including any relevant approvals.
5. The Committee requested that the ‘compensation’ section in the protocol is revised to refer to any payment for study participation, and any koha for study participants. A separate heading for ACC information should be provided.
6. The Committee requested that transcranial magnetic stimulation (TMS) not be referred to as "treatment", as it is an experimental intervention. Consider using "test procedure" or "study intervention".
7. The Committee requested clarification on the feasibility of conducting the research on a hospital ward given the length of time require. Please clarify how confidentiality will be maintained for participants who are inpatients on the ward.
8. The Committee noted that the Protocol states that participants in the hospital will have access to emergency services on site but that participants off site will be reliant on first aid at the research centre and 111 emergency services. As such, the Committee requested clarification on whether there are any adverse events that may require emergency treatment that is not available at the study centre and if a more detailed safety plan could be provided outside if calling 111.

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

1. Please adapt consent form to follow the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc).
2. Please describe more clearly what the physiotherapist will be doing throughout the six-hour session. This may include information provided in the protocol on page 13
3. Please explain that the experimental aspect of this study is to add TMS to the standard of care physiotherapy that people with functional movement disorder receive. Please revise to explain that the physiotherapy proposed for the study is the same that the participants would be given outside of the study, and that the TMS component is the innovation.
4. Please ensure the PIS is explicit about cultural safety, including consideration of the head as tapu, and the availability of karakia.
5. Please describe clearly the qualitative interview. This could be written as a separate consent form.
6. Please ensure that the list of adverse events provided in the protocol are also included in the risk section of the PIS. Rare adverse events need to be communicated to participants.
7. Please revise consent form to clarify that notification of GP is not optional.
8. Please include information about the case studies and anecdotal evidence that suggests why TMS in addition to physiotherapy might be an effective combination.
9. Please revise wording describing TMS as an assessment.
10. Please clarify what compensation for participation in this study is, and ensure that all participants receive the same reimbursement, compensation and koha.
11. Please consider rewording “unable to walk independently at least 10 metres without a walking aid.” to Unable to walk independently and without a walking aid at least 10 metres.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

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

## General business

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

The meeting closed at 3:30pm.