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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 10 December 2024 |
| **Zoom details:** | 96507589841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 10:30-11:00am | 2024 EXP 21369 | Biological rhythms of recovery in mood disorders | Professor Richard Porter | Dominic / Nicola |
| 11:00 - 11:30am | 2024 EXP 21500 | The Trans-Tasman Internet-delivered Prevention of youth Suicide (TIPS) Study: Testing apps to reduce suicidal thoughts in young people and young adults | Associate Professor Sarah Hetrick | Helen / Amy |
| 11:30am - 12:00pm | 2024 FULL 21117 | Improving Care for possible Traumatic Brain Injury using Point-Of-Care technology (ICare-TBI POC) - Phase 2 | Prof Martin Than | Jonathan / Amy |
| 12:00 - 12:30pm | 2024 FULL 21708 | Phase 2 Study Investigating Efficacy and Safety of Sonrotoclax Plus Azacitidine vs. Venetoclax Plus Azacitidine in Patients With Acute Myeloid Leukaemia Who are Ineligible for Intensive Chemotherapy | Ms Sophie Leitch | Maree / Patries |
| 12:30-1:00pm | 2024 FULL 21667 | Feasibility study of feeding time-matched donor human milk to preterm infants | Dr Ying Jin | Dianne / Andrea |
| 1:00 - 2:00pm |  | BREAK (60 mins) |  |  |
| 2:00 - 2:30pm | 2024 FULL 20945 | Can eye drops safely replace reading glasses in older adults? | Dr Alyssa Lie | Dianne / Nicola |
| 2:30 - 3:00pm | 2024 FULL 21430 | AA Prospective, Non-Inferiority Randomised Trial Evaluating Regional anaesthesia versus a modified ankle block for Pain Control of Operatively Treated Ankle Fractures | Dr Wayne Hoskins | Jonathan / Patries |
| 3:00 - 3:30pm | 2024 EXP 21263 | Occlusion of the left atrial appendage after a stroke in patients with atrial fibrillation - ELAPSE | Dr Phil Adamson | Maree / Andrea |
| 3:30 - 4:00pm | 2024 FULL 21441 | Youth Health and Wellbeing Survey 2025 | Mrs Emma Moselen | Dominic / Nicola |
| 4:00 - 4:30pm | 2024 FULL 21752 | DR-01-HV-001: A Study to Evaluate DR-01 in Healthy Participants. | Dr. Rohit Katial | Helen / Patries |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Devonie Waaka | Non-lay (Intervention studies) | 18/07/2016 | 18/07/2019 | Apologies |
| Mr Dominic Fitchett | Lay (the Law) (Chair) | 05/07/2019 | 05/07/2022 | Present |
| Dr Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Dr Nicola Swain | Non-lay (Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Dianne Glenn | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Neta Tomokino | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Apologies |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Mrs Helen Walker | Lay (Consumer/Community perspectives) (Chair) | 22/12/2020 | 22/12/2024 | Present |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Present |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Dr Andrea Forde | Non-lay (Intervention studies) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 10:00am and welcomed Committee members, noting that apologies had been received from Ms Neta Tomokino and Dr Devonie Waaka.   
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mrs Helen Walker, Dr Patries Herst, Mr Jonathan Darby and Dr Andrea Forde confirmed their eligibility and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 12 November 2024 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2024 EXP 21369** |
|  | Title: | Predicting bipolar disorder course from the 24-hour rest-activity rhythm. |
|  | Principal Investigator: | Professor Richard Porter |
|  | Sponsor: | Te Whatu Ora - Waitaha Canterbury |
|  | Clock Start Date: | 28 November 2024 |

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

Potential conflicts of interest

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

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

Summary of 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 upload attached and labelled as the AI risk assessment was not the [HDEC new technology form](https://ethics.health.govt.nz/guides-templates-and-forms/health-data-and-new-technologies-supplementary-form), please fill and provide this for review.
2. The Committee requested clarification as to how data is transferred from the devices to the University and whether there is any third party access to data or additional software involved. If there is no access by third parties then state this in the protocol. *National Ethical Standards* para *9.7a & 9.8.*
3. The Committee requested more information in the protocol concerning the data collection, including whether researchers will be going to the participants homes to collect the devices. Please clarify as well where the tests will be administered and by what means. If this is different depending on the recruitment, then also state this. *National Ethical Standards* para *9.7a & 9.8.*
4. The Committee noted that the [data management plan](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx) is missing key information that needs to be included to meet the requirements of the standards. Please refer to the HDEC template for these missing elements. *National Ethical Standards* para *9.7a & 9.8.*
5. The Committee requested safety plans for both the safety of participants in distress and for researchers.
6. The Committee queried the tax implications, and implications for a benefit, of the $200 voucher. Please note that so long as it is specifically stated as a gift voucher that this would be fine so long as it is listed everywhere as a *gift voucher*.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *National Ethical Standards* para *7.15 & 7.16*:

1. Please refer to the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/PISCF-template-intervention-studies-1.docx) for sections missing. Please consider following this should there be 2 new forms provided (one shorter version and one long) as discussed.
2. Please include Māori data sovereignty information and a cultural support contact for Māori.
3. Please include the Ministry of Health general enquiries number and details for HDECs.
4. Please include the Heath and Disability Commission contact details for advocacy.
5. Please provide more information on how participants may be selected and how many participants overall will be recruited into the study.
6. Please clarify that results will be published, including when and how.
7. Please detail what benefits if any may be gained by the individual participant.
8. Please clarify that participants will not be keeping the equipment provided in the study.
9. Please specify the study procedures and consider using a table or diagram to show what is expected of participants and when.
10. Please include an ACC statement per the HDEC template.
11. Please include a statement concerning the future use of data.
12. Please provide information about the right for participants to access and or withdraw data.

**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:** | **2024 EXP 21500** |
|  | Title: | TIPS (The Trans-Tasman Internet-delivered Prevention of (youth) Suicide): A four-arm superiority randomised controlled trial of three New Zealand and Australian developed apps to determine their effectiveness in reducing suicidal ideation in young people |
|  | Principal Investigator: | Associate Professor Sarah Hetrick |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 28 November 2024 |

Associate Professor Sara Hetrick, Dr Nicola Ludin and Dr Inge Meinhardt were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee requested the advert be amended to remove the words “we’d love to help”. As this is a research study, this statement could be misconstrued for treatment.
2. The Committee requested a peer review from an independent expert in the field or the comments from the HRC reviewing board.
3. The Committee noted that the response formulated to follow up with participants may not be appropriate from a New Zealand context with the differences between the NZ and Australian health system.
4. The Committee after discussion noted that the 3 day follow up was not swift enough for the follow up for participants. This must be shorter for those in distress as part of research duty of care, and further details around how this would be done faster should be documented.
5. The Committee queried whether and what information the apps would use and collect and how this information would be shared. Please clarify this in the data management plan.
6. The Committee queried the exclusion of disabled people who are visually impaired individuals. If there is the possibility for this to be facilitated then this should be removed from the exclusion criteria.

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

1. Please review for consistency.
2. Please provide more information on the structure of the study. A diagram showing that this is a randomised clinical trial with 4 arms and how people will be allocated may be beneficial to show this, including the mention of interviews and focus groups if possible.
3. Please amend “ensure that you have access to support 24/7” in references to suicide prevention phone lines to clarify that these are 10-20 minute conversations with a peer support worker who will try and find further assistance if needed, and is not treatment.
4. Please state when and how the clinical team will meet its duty of care and respond to signs of distress, and what care would be available if required.
5. Please state if/when the general practitioner will be notified.
6. Please include information about the risk of privacy breach and what will happen should there be a breach.
7. Please note that some health data should be kept for 10 years following a participant turning 16. The PIS has conflicting information around this.
8. Please state if the data collected on the Tirohia will be identifiable. Please state why identifiable data will be collected and the safety measures used.
9. Please clarify if the study will involve focus groups or if interviews will be one-on-one. If there are focus groups, please include a statement regarding the maintenance of privacy of other attendees.
10. Please state whether participants can choose to attend a one-on-one meeting or a focus group.
11. Please provide a cultural statement using the HDEC template for guidance.
12. Please clarify if the future use of data section includes the interviews, or if it will just be the survey results.
13. Please ensure that there is consistency with the font and size.
14. Please clarify what is meant by the $30 koha, if it is 2 $15 vouchers, state this and whether this is in NZD. Please note they will receive these payments for being in the study, whether they complete the survey or not.
15. Please remove the Australian support number from the NZ PISCF.
16. Please remove the repeated researcher information.
17. Please clarify and expand on the “using the app” section. Please spell out exactly what is expected of the participants in their participation.
18. Please provide more information about the control group.
19. Please clarify if there may be benefit for continued use of the app. Please give details on the PISCF or after the survey.
20. Please clarify what happens if the participants have used one of these apps before.
21. Please state clearly that the best-known treatment for suicidal ideation is talk therapy.
22. Please include a statement to the effect of: “in addition to crisis services free treatment is available in your area, you can find this by accessing the website accesssupport.org.nz”
23. Please include the HDC and HDEC contact details.
24. Please note that there is no time limit on HDEC approval and that it lasts in perpetuity as long as annual progress reports are provided. Amend the language as possible.
25. Please amend the wording around the young person contacting the psychologist should they be experiencing distress. This onus should be on the researchers as there is a likelihood that they will not contact anyone in that moment, and this should be done by researchers if they are concerned as per their duty of care.

**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. The Committee required further clarity in the documentation that demonstrates the researcher’s understanding regarding duty of care regarding these participants for further assurance of their safety. These need to be fully addressed in order to safely proceed.
3. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
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 Mrs Helen Walker and Dr Amy Henry.

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| **3** | **Ethics ref:** | **2024 FULL 21117** |
|  | Title: | Improving Care for possible Traumatic Brain Injury using Point-Of-Care technology (ICare-TBI POC) - Phase 2 |
|  | Principal Investigator: | Prof Martin Than |
|  | Sponsor: | Health New Zealand / Te Whatu Ora |
|  | Clock Start Date: | 28 November 2024 |

Professor Martin Than,Dr Laura Joyce, Professor John Pickering and Ms Alieke Dierckx were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the CT timing is randomised depending on initial clinical results from testing.
2. The Committee clarified with the researcher the consenting process and that each person in the study will be providing their own informed consent. This was also clarified in respect to the submission form.
3. The Committee queried the use of the whānau information sheet and that it is important from the researcher’s perspective for the whānau to have some role in consultation and the consenting process. This is not to seek proxy consent or support for best interest enrolment.
4. The Committee queried the exclusion of Multiple Sclerosis and Motor Neuron Disease. The Researcher explained this was based on a validated biomarker looking for neuronal damage. Studies on patients with underlying neurological conditions have not been performed so it is not known if the test is safe or not.

Summary of outstanding ethical issues

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

1. The Committee suggested utilising a simplified participant information sheet to gain the initial consent.
2. The Committee requested a NZ specific peer review given the context of this is significantly different from overseas.
3. The Committee suggested making the Whānau information sheet to be an appendix that details they are being asked to support and to just state what is required of them and then refer them to the information sheet for the participants.
4. Following discussion, the Committee concluded that this is a commercially sponsored study and as such this needs to be insured by the commercial sponsor which has been decided to be Abbot. Indemnity and some form of insurance needs to be provided.
5. The Committee requested clarification on the possible inclusion or exclusion of those with seizure disorders.
6. The Committee requested that the benefit to participants be listed as reduced waiting time/time in hospital and that this be described to participants.

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

Main PIS

1. Please include that karakia is available at point of tissue disposal.
2. Please remove the phrase “you have been chosen”.
3. Please clarify why general practitioners will be informed of a point of care blood test.
4. Please ensure that a correct insurance statement for a commercially sponsored intervention study is provided for participants.

Whānau PIS

1. Please amend the document to state “your family member” not “you”. Please review for consistency in this.
2. Please amend the line “Declaration by member of the research team once consent is given by the participant” as it states “I believe that the family member/whanau understands the study and that they are of the opinion that …would have wanted to participate in the study if they had been able to consent at this point in time" as consent will not have been given by the participant at this stage.

**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 ensure that proof of insurance certification is provided to the Committee per the discussion.

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Jonathan Darby and Dr Amy Henry.

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| **4** | **Ethics ref:** | **2024 FULL 21708** |
|  | Title: | BGB-11417-206: A Randomized, 3-Arm, Phase 2, Open-Label Study to Investigate Efficacy and Safety of Sonrotoclax Plus Azacitidine Compared With Venetoclax Plus Azacitidine in Adult Patients With Newly Diagnosed Acute Myeloid Leukemia Who Are Ineligible for Intensive Induction Chemotherapy |
|  | Principal Investigator: | Dr Sophie Leitch |
|  | Sponsor: | Beigene NZ Ltd |
|  | Clock Start Date: | 28 November 2024 |

Dr Sophie Leitch, Ms Soo Kee Lee, Mr Yu Liu and Mr Mark Arnedo were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried if participants test positive to a notifiable disease if counselling is available. The Researcher confirmed this would be available.
2. The Committee advised a trial may not be terminated solely for commercial reasons in New Zealand.
3. The Committee queried why information would be stored for 25 years as 10 – 15 is more common. The Researcher stated 25 years was the minimum requirement to comply with new EU regulations.
4. The Committee encouraged the Sponsor to apply for licensure in New Zealand if the study is successful.
5. The Committee advised the trial requires registration in a clinical trials registry prior to commencement.

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 page 19 of the information sheet stated some circumstances would require whole genome sequencing and queried what these were. The Researcher stated this was not known as it may be used for future unspecified research. The Committee requested limitations are placed around this (eg related to the drug or condition under study only) so it does not allow unlimited access to analyse the participant’s whole genome. The Researcher agreed to consult with the Sponsor.

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

1. Please consider changing efficacy in the lay title to a lay-equivalent word if possible.
2. Please remove ‘survival’ from ‘survival follow-up visit’ on page 9.
3. Please include the approval status in New Zealand on page 2 as well as referencing other countries.
4. Please undertake a revision to condense information where possible and reduce the length of the sheet.
5. Please revise the statement that patients may consider other treatment options as, per the protocol, there are no other treatment options.
6. Please include information about notifiable diseases that are being tested, that a positive result requires mandatory notification to the Medical Officer of Health and that counselling and appropriate referrals will be available.
7. Please give more information about reimbursements, travel and parking expenses and whether participants need to keep receipts or have a nominal value (e.g. a petrol voucher per visit). Please state if participants are travelling a longer distance whether things such as hotel accommodation would be covered.
8. Please add ‘with your consent’ to the information about following a pregnancy. This consent will need to be recorded on a separate form. If a pregnancy on the study does occur please submit this form via the amendment pathway, it does not need to be created prior to this.
9. Please specify what circumstances would require a whole genomic analysis on page 19.
10. Please include information about genetic research in the cultural statement on page 19 as genetic samples have wider implications for whānau.
11. Drug and medication are used interchangeably throughout, please be consistent and specify it is an investigational medicine or product.
12. Please consider revising the language about pregnancy to state pregnancy outcome to avoid the assumption that any pregnancy will result in a live birth.
13. Please revise the ‘side effects’ heading and table to ‘adverse events or ‘ adverse events previously identified’ as COVID-19 is listed. Covid infection is not a side effect of the drug.

**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 Dr Patries Herst.

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| **5** | **Ethics ref:** | **2024 FULL 21667** |
|  | Title: | Feasibility of feeding circadian time-matched donor human milk to preterm infants and the impact on infant sleep, growth and hospital outcomes |
|  | Principal Investigator: | Dr Ying Jin |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 28 November 2024 |

Associate Professor Louise Bourgh 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 confirmed registration with the ANZCTR was underway.

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 the Researcher supply any peer review comments from the HRC grant approval if these are available.
2. The Committee requested the Researcher include applicable local data policies and governance structure (e.g. university, hospital, New Zealand privacy law etc) in the data management plan.
3. The Committee advised health information needs to be kept for 10 years after the youngest participant turns 16 and requested this is reflected in the data management plan.
4. The Committee noted reference to Badger and MAP in the data management plan and requested more information on what these are and whether they collect or transmit data elsewhere. If these apps need to be used by participants please include information in the PIS.
5. The Committee noted that collection and storage process maybe standardised for the Human Milk Bank but that these also need to be included in the protocol and PIS/CF for this study.
6. The Committee queried if participants during the trial using less than 50% PDHM would remain in the trial. The Researcher stated they would need to consider this. The Researcher confirmed any participants who need to leave the trial early would be entitled to the full koha for participation.
7. The Committee requested the Researcher upload for review any interviews and surveys.
8. The Committee requested the contents page is updated in the data management plan and the template instructions to researchers are removed.

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

1. Please review the pronouns of the recipient sheet to ensure it reflects consent for both the consenting participant and their baby.
2. Please include information on notifiable diseases that are tested and that a positive result requires notification to the Medical Officer of Health.
3. Please include instructions around storage of milk and provision of containers.
4. Please include any relevant Māori cultural information around the storage and use of milk.
5. Please ensure any acronyms are defined the first time they are used (e.g. PDHM).
6. Please include information on reimbursement for parking and travel expenses and state the value of the koha for participation.
7. Please fix the following grammatical errors
8. Donor PIS page 2
   1. 1st bullet point ‘have’ to ‘has’
   2. 2nd bullet point add ‘is resident’
   3. 3rd bullet point change ‘have’ to ‘has’
   4. 4th bullet point change ‘satisfy’ to ‘satisfies’
9. Recipients’ PIS page 2
   1. 6th bullet point amend to ‘has any medical conditions preventing them from using PDHM or has any significant health complications’
10. Health Professionals’ PIS page 2
    1. 3rd paragraph under the bullet points amend to “we will be assured that you are happy”

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Dianne Glenn and Dr Andrea Forde.

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| **6** | **Ethics ref:** | **2024 FULL 20945** |
|  | Title: | Investigating the effects of pilocarpine use for presbyopia treatment on posterior ocular structures |
|  | Principal Investigator: | Dr Alyssa Lie |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 28 November 2024 |

Dr Alyssa Lie, Dr John Philips, Dr Lucy Goodman 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 noted the application form stated the data would be used to estimate prevalence in Māori but this would not be feasible as the study involves volunteers only.
2. The Committee noted the peer reviews had raised methodological concerns and queried the Researcher’s rebuttal. The Researcher explained these were performed on a previous version of the protocol that has now been amended to address these concerns. The Researcher confirmed the trial was going to SCOTT.

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 the Researcher update the data management plan to remove information not applicable to the study e.g. future use of data, use of medical records, contacting a clinical team and references to the study sponsor.
2. The Committee noted ‘do you want to be free from reading glasses’ is not an appropriate invitation to a research study. The Committee requested this is amended to state ‘Do you want to help us investigate how eye drops may work instead of glasses’ or something similar that does not over-promise benefit. The Committee noted the email version of the advertisement does not have this issue. Please state the ethical aspects of the study have been approved by the Southern HDEC.
3. The Committee queried the exclusion of pregnant and breastfeeding participants. The Researcher stated the drug has not been studied in this population yet. The Committee noted as a phase 4 study it is not sufficient to routinely exclude pregnant and breastfeeding participants,
4. Although the age ranges of pregnancy and presbyopia are different, and pregnancy or conception may be unlikely, the Committee requested a contraception statement from the HDEC template is inserted in the information sheet.

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

1. Please remove ‘there is a small risk’ on page 3 and give an indication of frequency of risks (e.g. rare, common, between 1 and 10 people in 100 will experience.)
2. Please state that Vuity may cause blurred vision or temporary dark vision and risks to driving or operating machinery as per the investigator’s brochure and to avoid night driving.
3. Please include available accessibility provisions for travel and parking and the ability to have a support person.
4. Please state how much the voucher is for and separate it from reimbursement for travel and parking expenses.
5. Please consider inserting ‘relevant’ or some limiting language to the statement allowing Māori organisations access to deidentified data.
6. Please insert a very clear statement advising participants that even if it is beneficial the medication will not be available after the study.
7. Please insert a diagram of visits to make it clear what order they are in.
8. Please amend the statement that there is no fee to state there is no cost.
9. Please correct the typo on page 2 ‘before Vuity eye drops as instilled’ to ‘are instilled’.
10. Please include information explaining why to avoid makeup and other skincare products.
11. Please remove the 0800 4 ETHIC number as this is no longer in use and insert the Ministry of Health general enquiries number (0800 400 569).
12. Please include lay descriptions for vitreous haemorrhages and retinal detachment.

**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 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).*

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| **7** | **Ethics ref:** | **2024 FULL 21430** |
|  | Title: | Regional anaesthesia (popliteal and saphenous nerve block) versus a modified ankle block for acute post-operative pain following ankle fracture fixation (APPLE): a single blinded, non-inferiority randomised controlled trial |
|  | Principal Investigator: | Dr Wayne Hoskins |
|  | Sponsor: |  |
|  | Clock Start Date: | 28 November 2024 |

No researcher was present for the 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 the application indicated public health care resources would not be used but the study will take place at Whangarei hospital and involve public health care staff.
2. The Committee noted the application referenced ethical standards from 2007 and it would need to comply with the [2019 National Ethical Standards for Health and Disability Research.](https://neac.health.govt.nz/national-ethical-standards/)
3. The Committee queried the exclusion of pregnant participants as a pregnant person would not be denied treatment for an ankle fracture. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.15)*
4. The Committee queried the exclusion of prisoners and noted while it would be appropriate if informed consent could not be obtained due to their status as prisoners the inability to follow-up is not sufficient for exclusion given the short nature of the study, the importance of follow up as a standard of care, and therefore follow-up in this study should be possible.
5. The Committee queried who developed the ropivacaine (injection route) document as it did not contain headers, footers or identifiers.
6. The Committee noted this cannot be a non-inferiority study because there is currently no “best practice block”. Comparing two blocks when it is not established if any block is better than no block is flawed. The Committee suggested the Researcher include either a third arm of participants not having a block or to simply compare one of the blocks with no block to demonstrate if a block is better for patients.
7. The Committee noted the peer review was very minimal and requested an additional comprehensive peer review, from an anaesthetist or other peer, is undertaken.
8. The Committee noted the question about study structure in the data management plan was answered ‘not applicable’. This question refers to the study sponsor and lead site and must be filled out. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15)*
9. The Committee advised health data should be kept for 10 years.
10. The Committee queried how PACU and nursing staff would be blinded when the treatment given will be recorded in the patient clinical notes.
11. The Committee queried post-operative risks if nursing and physio staff do not know which treatment has been administered and if there are differences in waiting times before patients can weight bear, risk of foot drop differences, a falls risk in older patients.
12. The Committee noted a space for the hospital sticker at the top of the questionnaires and queried how they would be deidentified.
13. The Committee noted the VAS will be used but this scale includes the ‘faces’ pain scale and will not yield a continuous 0-10 measure.

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 adapt the [intervention study template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates) available on the HDEC website.
2. Please revise the line about doctors jumping to conclusions to avoid eroding trust.
3. Please revise the sentence on page 2 “There are no costs associated with participating in this research project, nor will you or the participant be paid” to refer to “you”.
4. Please revise the sentence on page 3 “The benefits of participating will be reduction in your pain levels post-operatively” as this cannot be guaranteed, and the study will be investigating this effect.
5. Please include additional potential side effects from ropivacaine and adverse drug interactions that are not listed.
6. Please remove the exclusion criteria as participants will be screened by the medical team.

**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:** | **2024 EXP 21263** |
|  | Title: | Early closure of Left atrial Appendage for Patients with atrial fibrillation and ischemic StrokE despite anticoagulation therapy – ELAPSE |
|  | Principal Investigator: | Dr Phil Adamson |
|  | Sponsor: | Te Whatu Ora; Bern University Hospital |
|  | Clock Start Date: | 28 November 2024 |

Dr Teddy Wu 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 discussed whether the trial was commercially sponsored by the university hospital in Bern. The Researcher explained the local legal team had reviewed the arrangement and concluded it was collaborative. The Committee was satisfied the study was investigator-initiated and additional insurance would not be required.

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 the data management plan would need to comply with New Zealand law and ethical standards and these must take precedence over Swiss law. The Committee requested the Researcher adapt the [HDEC data management plan template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx)
2. The Committee advised a legally authorised representative is not applicable in New Zealand and next of kin cannot give proxy consent and requested all references to this are removed from study documentation.

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

1. Please remove any references to legally authorised representatives, powers of attorney or next of kin consenting.
2. Please include a consent clause and information regarding people other than the treating clinician having access to medical records.
3. Please include a statement advising that any future data used overseas will not be subject to New Zealand law or privacy protections.
4. Please include a statement that the fee per participant paid goes into a research trust managed by Te Whatu Ora Canterbury.
5. Please include information explaining the involvement of a neurologist in the study.
6. Please amend the form so GP notification is mandatory.
7. Please change the word patients to participants or ‘you’.
8. Please divide risks into categories (e.g. common, rare), this is stated on page 10 but does not appear.

**Decision**

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

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

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

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| **9** | **Ethics ref:** | **2024 FULL 21441** |
|  | Title: | Youth Health and Wellbeing Survey 2025 |
|  | Principal Investigator: | Mrs Emma Moselen |
|  | Sponsor: | Ministry of Social Development |
|  | Clock Start Date: | 28 November 2024 |

Mrs Emma Moselen, Mr Neil Tee, Ms Heni Tupe, Ms Eleanor Briggs and Ms Zoe Taptikilis were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried the consenting process and the assessment of children under 16 and their competency to consent. The Researcher explained the schools would assist and previous experience has shown most children will provide their own consent. Some are likely to require parental consent. The community sample will allow parents to opt-out. The Committee advised this approach is acceptable, but the researchers will retain ultimate responsibility for ensuring participants have competence to consent.
2. The Committee queried the safety plan for participants who may experience distress. The Researcher explained this is in the protocol and a local youth worker will be present for all sessions to arrange support or provide an information card.

Summary of outstanding ethical issues

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

1. The Committee queried if the study had a safety plan for staff door knocking. The Researcher confirmed there was, with a field force that used tracking devices monitored by GPS. Staff go through safety training and have a safety plan. A regional field lead monitors them and an 0800 number is available to check in with work plans. The Committee requested this is supplied.
2. The Researchers acknowledged that the measures used from the last survey may be imperfect to capture nuance regarding disability data and the potential narrow scope, but commented on the care and consideration they are undertaking for its dissemination. The Committee encouraged the Researchers to review the questions with a disability lens to avoid reinforcing existing barriers and stigma with questions regarding climbing steps and difficulty with self-care as this questionnaire is designed for older adults and are very broad. The Committee also encouraged the Researchers to review the questions with contact with services or agencies to include education related services such as reader writer, communication or support worker to access all social and community environments as cohort or peers.

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

1. Please include information that the Ministry of Social Development and StatsNZ will retain a copy of the data in a secure data lab. Please explain the protections and, access requirements and storage arrangements.
2. Please specify if parents opt *out* if participants are 13, 14 or 15.
3. Please review for formatting consistency as some footers and images appear to blend with text.
4. Please review the sentence in the school PIS encouraging to talk about the survey with family, whānau, or aiga, and “to talk if they support you to take part.”
5. Please review the opt out status between all sheets, one refers to school year level and the other refers to age. The Committee suggested having it consistent as age between sheets or stating a school year may contain certain ages.

**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 supply the researcher safety protocol.

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

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| **10** | **Ethics ref:** | **2024 FULL 21752** |
|  | Title: | A Randomized, Double-blind, Placebo-controlled, Phase 1 Study Evaluating the Safety and Pharmacokinetics of Subcutaneous Administration of Single Ascending Doses of DR-01 in Healthy Volunteers. |
|  | Principal Investigator: | Dr Rohit Katial |
|  | Sponsor: | Dren Bio, Inc. |
|  | Clock Start Date: | 28 November 2024 |

Dr Rohit Katial, Ms Kayla Malate, Ms Julia O’Sullivan and Ms Lucy Druzianic were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researcher confirmed a six-hour time period would be appropriate to look for adverse events as these would be related to the injection site or anaphylaxis.
2. The Committee noted the exclusion of participants with certain viral infections, including certain Human Herpes Viruses (HHV). The Researcher clarified that recent reactivation of Varicella Zoster Virus (VZV also known as HHV3) – shingles - was an exclusion. The Committee encouraged the Researcher to review the inclusion/exclusion criteria for participants with a history of chicken pox (VZV) or documented vaccination against varicella, or known varicella antibodies, and include them if it would be safe.
3. The Committee queried what happens to photos after the study. The Researcher explained they would be source data and kept with the dataset for the duration of the study.

Summary of outstanding ethical issues

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

1. The Committee queried why a hysterectomy requires documentation but salpingectomy or tubal ligation or vasectomy do not. The Researcher noted the protocol states both female and males require a documented result. The Committee requested the information sheet is updated to reflected this.

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

1. Please include information on how photographs will not be identifiable and their length of storage.
2. Please note if a karakia will not be available.
3. Please specify different alcohol volume limits for females and males.
4. Please define the word subcut.
5. Please note that although acetaminophen is the INN this medicine is referred to as paracetamol in NZ. Please use paracetamol or explain the use of the INN
6. Please explain what cytokine release syndrome (CRS) is.

**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).*

## General business

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

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| **Meeting date:** | 11 February 2025 |
| **Zoom details:** | 96507589841 |

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.