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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 30 January 2024 |
| **Zoom details:** | https://mohnz.zoom.us/j/9738756003 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:00 - 12:30pm | 2023 FULL 13208 | ZERO2 Precision Medicine for Every Child with Cancer | Dr Andrew Wood | Helen / Albany |
| 12:30 - 1:00pm | 2023 FULL 19188 | Remotely Controlled Capsule Endoscopy | Dr Cameron Schauer | Cordelia / Patries |
| 1:00 - 1:30pm | 2023 FULL 19418 | He Kōwhiringa Hōu - A new primary care treatment pathway for whānau impacted by treatment-resistant depression 2.0 | Director of Awa Associates Ms Suaree Borell | Sandy / Albany |
| 1:30 - 2:00pm | 2023 FULL 19372 | Talk That Heals: Evaluating Collaborative Discovery | Dr Lillian Ng | Jessie / Barry |
| 2:00 - 2:20pm |  | **BREAK (20 mins)** |  |  |
| 2:20 - 2:50pm | 2023 FULL 17797 | Investigating the impact of micronutrients and mindfulness on emotional dysregulation in children aged 6-10 years. | Miss Parris Theobald | Cordelia / Patries |
| 2:50 - 3:20pm | 2023 FULL 19395 | YST-162-102: A Study to Evaluate the Safety and Tolerability of Single Ascending Doses of Investigational Drug 162 in Participants with Chronic Hepatitis B Infection | Dr Paul Hamilton | Helen / Albany |
| 3:20 - 3:50pm | 2024 FULL 19276 | A phase 1 study to evaluate the safety, tolerability and pharmacokinetics of a ginger tincture extract in healthy volunteers. | Dr Alexander Semprini | Jessie / Barry |
| 3:50 - 4:20pm | 2024 FULL 19509 | SWiFT study of whole blood in frontline trauma - 2nd resubmission | Dr Richard Charlewood | Sandy / Patries |
| 4:20 - 4:40pm |  | **BREAK (20 mins)** |  |  |
| 4:40 - 5:10pm | 2024 FULL 18109 | The effect of pre-operative antibiotics on Anastomotic Leaks in Colorectal Surgery | Dr John Woodfield | Sandy / Barry |
| 5:10 - 5:40pm | 2024 FULL 19038 | Pilot study of administration of psilocybin in healthy volunteers within a marae setting. | Dr Patrick McHugh | Cordelia / Albany |
| 5:40 - 6:10pm | 2023 FULL 19181 | ITL-3001-CL-101: An Open-Label Study to Investigate the Safety and Tolerability of NTLA-3001 in people with Alpha-1 Antitrypsin Deficiency (AATD)-Associated Lung Disease | Dr Mark O'Carroll | Helen / Patries |
| 6:10 - 6:40pm | 2023 FULL 19233 | AROCFB-1001: A Study to Investigate the Safety and Tolerability of ARO-CFB in Healthy Participants and in Participants with Complement-Mediated Kidney Disease. | Dr Christian Schwabe | Jessie / Barry |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Mrs Helen Walker  | Lay (Consumer/Community perspectives) (Chair) | 22/12/2020  | 22/12/2024 | Present  |
| Mrs Sandy Gill  | Lay (Consumer/Community perspectives)  | 22/05/2020  | 22/05/2023  | Present  |
| Dr Patries Herst  | Non-lay (Intervention studies)  | 22/05/2020  | 22/05/2023  | Present  |
| Dr Cordelia Thomas  | Lay (the Law)  | 22/12/2020  | 22/12/2024 | Present  |
| Mrs Patricia Mitchell  | Non-lay (Health/Disability service provision)  | 08/07/2022 | 08/07/2025 | Apologies |
| Mx Albany Lucas | Non-lay (Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Present |
| Mr Barry Taylor (co-opted) | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Mrs Patricia Mitchell.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mr Barry Taylor from the Northern B HDEC confirmed his eligibility and was co-opted by the Chair as a member of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 28 November 2023 were confirmed.

## New applications

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| **1**  | **Ethics ref:**   | **2023 FULL 19188** |
|   | Title:  | Feasibility and Safety of PillBot™ - Remotely Controlled Capsule Endoscopy |
|   | Principal Investigator:  | Dr Cameron Schauer |
|   | Sponsor:  | Mayo Clinic, Florida, USA |
|   | Clock Start Date:  | 18 January 2024 |

Dr Cameron Schauer 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 queried what data the image vendor would receive The Researcher explained study data would be entered into REDCap and deidentified images with no participant data would be sent into a separate database.

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 study did not involve kaupapa Māori methodology and the application stated engagement with Māori has not occurred. The Committee advised that as Māori participants would be recruited then an engagement process should occur. The Committee noted whakamā and other cultural issues would need to be addressed before the research commences. The Researcher agreed to consult with Māori.
2. The Committee requested the Researcher develop a safety plan to respond to participant distress and include it in the study protocol.
3. The Committee noted a $5 million limit may be insufficient for an early device trial with 20 participants and requested this be increased to $10 million to ensure ACC-equivalent insurance would be available.
4. The Committee advised the device would require registration in Medsafe’s [WAND Database](https://www.medsafe.govt.nz/regulatory/DevicesNew/3WAND.asp).
5. The Committee noted the application stated information would be held at the hospital and stored indefinitely. The Committee queried if this would be identifiable and why it would be held indefinitely. The Researcher confirmed the data would be deidentified with a study code. The Committee advised information should only be held for as long as necessary after compliance with the Public Records Act 2005 and suggested 15 years would be appropriate.
6. The Committee noted a payment for ‘time’ would be taxable and may affect payments such as benefits. The Committee requested information advising this is included in the information sheet.
7. The Committee queried the process for if the device becomes stuck. The Researcher stated if this occurred it would be likely due to underlying pathology and if the device could not be retrieved with a camera a surgical operation would be required to remove it. The Committee requested information explaining this is included in the information sheet.

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

1. Please specify that nil by mouth is food only and participants may drink water during the eight hour period.
2. Please specify whether travel expenses and parking will be reimbursed.
3. Please specify all images taken during the study are internal images and no pictures of the participant’s face will be taken.
4. Please include more information on data management (how identifiable vs non-identifiable will be managed, where it will be stored, who can access it and for what purpose etc). The Committee recommended adapting the prompts from the [HDEC information sheet template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
5. Please include information regarding a participant’s right to access and correct information held about them. A prompt for this is included in the HDEC template.
6. Please include the commercially-sponsored alternative compensation section from the HDEC template to advise participants they would not be covered by ACC and participation may have implications for their own private insurance.
7. Please include a Māori cultural statement. One is available on the HDEC template.
8. Please include information explaining that a participant’s GP will be informed of their participation and any abnormal results and include a non-optional clause on the consent form for this. A prompt is available on the HDEC templates (the ‘yes / no’ boxes can be removed).
9. Please include a clause on the consent form for participants to agree to their deidentified information being sent overseas. A prompt is available on the HDEC template.
10. Please include a version number, date and page numbers in the document footer.
11. Please state how long the guidance procedure for the PillBot will take.
12. Please include a statement advising participants that the study Sponsor may benefit financially if the study is successful and participants will not be entitled to any commercial gain.
13. Please include a contact number for Māori cultural support.
14. Please include a quantification of any possible risks.
15. Please remove the ‘yes’ tickboxes for any mandatory clauses in the consent form. By signing the form participants will agree to any non-optional clauses so a tickbox is not necessary.

**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 develop a safety plan to respond to participant distress (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4-8.6).*
5. Please supply evidence of ACC-equivalent compensation available to all participants in the event of injury during the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
6. 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 Cordelia Thomas and Dr Patries Herst.

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| **2**   | **Ethics ref:**   | **2023 FULL 19418** |
|   | Title:  | He Kōwhiringa Hōu – A new primary care treatment pathway for whānau impacted by treatment-resistant depression |
|   | Principal Investigator:  | Ms Suaree Borell |
|   | Sponsor:  | Awa Associates |
|   | Clock Start Date:  | 18 January 2024 |

Ms Suaree Borell 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 was difficult to assess as two separate entities were doing the clinical side and kaupapa Māori side. The Committee recommended a representative of the clinical team attend the review of the resubmission.
2. The Committee queried how soon questionnaires would be assessed after completion and what the process would be if concerning responses or participant distress were identified. The Researcher stated results would be analysed on completion and any concerning responses would be raised with the project manager who would coordinate a clinical response with the National Hauora Coalition.
3. The Researcher agreed any clinical/technical questions not raised in the meeting the HDEC requires answers to can be listed in the decision letter and addressed in the resubmission.
4. The Researcher confirmed any whānau involvement would be with the consent of the participant.
5. The Committee noted whakamā is likely to be present in some participants and suggested this be considered when completing the cultural section in the resubmission.

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 Researcher confirmed the peer review was independent from the study. The Committee requested they complete the [HDEC peer review template](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance/) and provide more detail in the review. *(HDEC Standard Operating Procedure, para 10)*
2. The Committee requested any questionnaires / surveys that will be used are included in the resubmission.
3. The Committee noted the study involves esketamine and should follow a Risk Evaluation and Mitigation Strategy (REMS) protocol. The Committee recommended the following resource <https://www.spravatorems.com/outpatient-hcs.html>.
4. The Committee requested the protocol include a process for pre-dosing preparation for participants as esketamine has dissociative properties.
5. The Committee queried if GP clinics will be compensated for their involvement in the study and how it would affect their workload.
6. The Committee queried if participants who are not taking or prescribed any antidepressant medication could participate in the study.
7. The Committee recommended adapting the [HDEC information sheet template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) as this contains prompts for all information required by the national ethical standards.

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

1. Please include information on the study’s safety plan and describe what will happen if concerning responses are identified in the questionnaires.
2. Please remove the numbers from the yellow sentences.
3. Please include a higher resolution version of the image on page 4.
4. Please include a description of what participation in the study will involve and remove the list of bullet points.
5. Please discuss koha under the section of who funds the study instead of under benefits.
6. Please include more information on the interviews and focus groups including where they will be held, who will be facilitating, how long they will take, whether participants can see and/or correct a transcript, and the types of questions that may be asked. If these are optional then please consider a separate optional PIS for them.
7. Please include more information on identifiable and coded data and where it will be stored (see the HDEC template for prompts).
8. Please specify whether information generated from this study may be combined with other datasets for future research.
9. Please include a statement on Māori data sovereignty (see the HDEC template for an example which may be used or adapted).
10. Please include the ACC statement from the HDEC template.
11. Please simplify technical language such as ‘outcome measures’ for a lay audience.
12. Please revise the reference to SPRVATO on page 2 to esketamine for consistency.
13. Please refer to ‘participants’ instead of patients.
14. Please explain why participants need to start a new antidepressant medication for the study.
15. Please include information on the study medication, what it is and any possible side effects.
16. Please use gender-neutral language, particularly when discussing contraception.
17. Please specify what a ‘male EAP patient’ is.
18. Please state nurse instead of RN.
19. Please include a study procedures section where all components of the study are described in chronological order so that the participant can easily understand what is required of them. Please include information on any questionnaires / assessments here.
20. Please clarify what a “HIP coach” is.
21. Please clarify what a Health Improvement Practitioner is, how they are involved in the study and what their relationship with participants will be.
22. Please include information on what the PTPT/Hua Oranga sessions will involve and what is expected of participants.
23. Please include more information about participants talking about their experiences (this is first mentioned on page 5)
24. Please clarify if the facilitator and HIP are the same or different people on page 5. If it is the same person please be consistent when referring to them.
25. Please clarify the “when starting a new medication” information and whether this is referring to esketamine or a new antidepressant. The side effects of both esketamine and the new antidepressant need to be included as well as the frequency of their side effects (rare vs common).
26. Please remove the statement on page 6 under benefits of the study “access to free medication that could improve your TRD” as this is not guaranteed and if it did may only be temporary as participants will not have access after the study.
27. Please clarify the reference on page 6 “information collected as part of these groups” as it is unclear what groups it is referring to.
28. Please remove the ‘yes’ tickboxes for any mandatory clauses in the consent form. By signing the form participants will agree to any non-optional clauses so a tickbox is not necessary. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**Decision**

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

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| **3** | **Ethics ref:**   | **2023 FULL 19372** |
|   | Title:  | Talk That Heals: Evaluation of a Collaborative Discovery Intervention for Parents with a Mental Illness |
|   | Principal Investigator:  | Dr Lillian Ng |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 18 January 2024 |

Dr Lillian Ng 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 the questionnaires would be completed with a clinician in the room who could respond to any concerning responses or distress.
2. The Committee noted whakamā is likely to be present in some participants and suggested the researchers consider this.

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 what follow up care is available if participants have a delayed response to distress. The Researcher stated the route of recruitment would be through a maternal mental health service or primary care and the researchers intend to contact participants to offer them follow up support if required. The Committee requested information explaining this is added to the information sheet.
2. The Committee requested the Researcher update the protocol to specify that would happen in the event of a significant adverse event (eg suicidality).

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

1. Please include information on potentially triggering questions in the questionnaire (eg questions asking about a bad relationship with the participant’s parents).
2. Please include information on the study’s safety plan and what will happen if a participant indicates distress during responses.
3. Please revise the invitation for fathers to attend to specify any partners or co-parents.
4. Please remove the ‘yes’ tickboxes for any mandatory clauses in the consent form. By signing the form participants will agree to any non-optional clauses so a tickbox is not necessary.
5. Please include a number for Māori cultural support.
6. Please adapt the ‘What will happen to my information?’ section from the [HDEC template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
7. Please specify whether data may or will not be used for future research. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Jessie Lenagh-Glue and Mr Barry Taylor.

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| **4**   | **Ethics ref:**   | **2023 FULL 17797** |
|   | Title:  | Broad-spectrum micronutrients delivered via oral mucosa alongside an online mindfulness programme as a treatment for emotional dysregulation in children aged 6–10 years: a randomised controlled trial |
|   | Principal Investigator:  | Miss Parris Theobald |
|   | Sponsor:  | The University of Canterbury |
|   | Clock Start Date:  | 18 January 2024 |

Miss Parris Theobold, Dr Jula Rucklidge and Dr Mairin Taylor 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 advised a caregiver who is not the child’s guardian cannot give consent on behalf of the child and this may only be done legally by a guardian.

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 as the eligibility questionnaires would be collecting health information from participants an informed consent process would be required first. The Committee requested the Researcher develop information about the eligibility questionnaire explaining it is to screen for the study and giving information about the study so participants are aware and their consent can be obtained before they complete it.
2. The Committee queried whether the study would collect information about the children only or also caregivers/guardians and if this would make them participants. The Researcher confirmed data on caregiver stress would be collected and so they would be study participants. The Committee requested this is made clear in the information sheet. The Committee suggested the Researcher could either have one combined information sheet that makes this clear or an additional information sheet specific to caregivers. Consent boxes to consent for the child to participate as well as the caregiver themselves will be required.
3. The Committee requested the Researcher develop a safety plan in the protocol to respond to any participant distress. Information explaining the psychometric questionnaires and what the researchers will do if the participant provides concerning responses should be included in the information sheet.
4. The Committee requested the information on optional saliva and stool samples is removed from the main information sheet and adapted into an optional future research sheet. The main sheet can include a statement mentioning the optional components will be consented on a separate sheet if the participant agrees. Please be specific when referring to DNA samples and make it clear it is the child’s DNA that will be sent, not the caregiver.
5. The Committee suggested one of the sticks could be provided to children during the assent process so they understand what they are and what is required of them.
6. The Committee expressed concern at the number of questionnaires required and whether these contribute to answering the study question. The Committee noted the food questionnaire had the potential for stigmatisation. The Researcher agreed to review the number of questionnaires and if the food one can be adapted to be more inclusive.
7. The Committee requested the Researcher develop a study card that states the name of the study and contact details they can refer to in the event of an emergency.

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

1. Please include a statement in the risks section that the potential risks are based on previous studies and the sticks have been used with children before.
2. Please revise the statement in the assent form that the sticks taste good as this may vary. The Committee suggested a statement that previous studies showed most children thought they tasted good.
3. Please include a picture or diagram of the stick in the assent form and include a description that it dissolves on the tongue similar to sherbet.
4. Please revise the statement “no one will be mad with you if you don’t want to be in the study” in the assent form as this cannot be guaranteed.
5. Please include a statement in the assent form alongside “If you want to take part in this study let us know” to state “If you do not want to take part in this study let us know” to give children the option to say no.
6. Please include a very brief cultural statement regarding tissue samples in the assent form.
7. Please include a cultural tissue statement in the main form. One may be adapted from the [HDEC template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
8. Please remove the repeated information in page 11.
9. Please include more information in the sheet on the number of questionnaires involved, the information they are collecting and what they are assessing.
10. Please include a statement in the risks section that previous studies showed headaches and other side effects in the micronutrient arm but it is unknown if this occurs in children.
11. Please revise the consent clause that participants understand withdrawing will not affect medical care to specify it applies to both child and caregiver.
12. Please remove the ‘yes / no’ tickboxes regarding informing the participant’s GP if this is a mandatory component of participation.
13. Please include a clause to consent for data and tissue to be sent overseas if this will occur.
14. Please be consistent when discussing improving emotional regulation vs improving emotional dysregulation and include a brief description of what this is when it is first mentioned.
15. Please revise the first paragraph on page 3 and in the assent form where it reads as if the saliva and stool samples are mandatory and specify these are optional.
16. Please remove the reference to face-to-face meetings as interactions will be online.
17. Please add “with your consent” to the statement on follow-up after discontinuation on page 7.
18. Please include information on the study’s safety plan and what will happen if participants indicate any distress in their responses during the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**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 to include a safety plan that will respond to participant distress. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4-8.6).*

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

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| **5**   | **Ethics ref:**   | **2023 FULL 19395** |
|   | Title:  | YST-162-102: A Multi-center, Randomized, Double-blind, Placebo-controlled Phase 1b Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of 162 with a Single Ascending Dose in Subjects with Chronic Hepatitis B Virus Infection |
|   | Principal Investigator:  | Dr Paul Hamilton |
|   | Sponsor:  | Yangshengtang Co., Ltd |
|   | Clock Start Date:  | 18 January 2024 |

Dr Paul Hamilton 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 a trial may not be terminated solely for commercial reasons in New Zealand.
2. The Committee noted the pregnancy PIS had not been reviewed. If a participant or their partner becomes pregnant this may be submitted as an amendment form through the post-approval pathway.

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 inclusion criteria stated males and females and queried whether intersex people would be eligible. The Researcher confirmed they would. The Committee requested this be revised to be gender neutral wording and suggested stating ‘Anyone between the ages of 18-65’. The Committee noted the website also had male and female options only and suggested this be revised.
2. The Committee recommended the Researcher adapt the gender-neutral wording from the [HDEC reproductive risks template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
3. The Committee noted the application stated if participants wished to have a karakia performed they would have to organise their own cultural support and requested this be revised so a karakia is available.
4. Please revise technical / medical terms such as “neutropenia” and “arthralgia” to lay friendly terms or explanations.
5. Please include whole numbers for possible side effects (eg approximately 1 in 10 people).
6. Please revise the statement “you will be followed to determine the outcome of your pregnancy” to specify this will be done with the participant’s consent.
7. Please revise the statement on page 10 regarding “decisions made by the study sponsor” as a clinical trial may not be terminated for commercial reasons in New Zealand.
8. Please advise participants of any physical examinations and whether undressing or the removal of clothing will be necessary.
9. Please include a statement advising whether a chaperone or support person can be present during any examinations.
10. Please include a ‘yes /no’ tickbox on the consent form for participants to request a lay summary of the study results. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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

**Decision**

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

* 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).*

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| **6**   | **Ethics ref:**   | **2024 FULL 19276** |
|   | Title:  | A First-in-Human, Phase 1, Double-Blind, Randomised, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Ginger Tincture extract (Carelwon®; zingerone 12.5 mg/mL) in Healthy Volunteers. |
|   | Principal Investigator:  | Dr Alexander Semprini |
|   | Sponsor:  | Evithé Biotechnology Pty Ltd |
|   | Clock Start Date:  | 18 January 2024 |

Dr Alexander Semprini 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 the study would offer a flat rate for reimbursement that could be increased if participants incurred higher travel costs and that tax would be withheld.

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 people with HIV or Hepatitis C would be excluded from the study. The Researcher agreed to discuss this with the Sponsor.
2. The Committee requested the Researcher upload the Coordinating Investigator’s renewed indemnity certificate. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.6).*

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

1. Please make it clear that reimbursement includes tax that will be deducted before payment.
2. Please specify that only the ethical aspects of the study have been approved by the Central Health and Disability Ethics Committee.
3. Please undertake a general revision of technical terms to be lay-friendly.
4. Please revise the statement regarding no vegetarian form of nutrition to specify participants will be provided with meals as part of the study.
5. Please specify whether blood samples will be returned as it currently states they may or may not.
6. Please remove the reference to Māori data in the risks section and discuss it with the Māori data sovereignty statement.
7. Please revise the conflicting information in page 15 which states participants will not be informed whether they receive the drug (under the ‘Change my mind’ section) and page 3 which states participants can find out at the end of the study whether they received the active drug or placebo.
8. Please revise ‘you should not’ incur any costs with ‘you will not’.
9. Please advise participants of any physical examinations and whether undressing or the removal of clothing will be necessary.
10. Please specify on page 5 that vaccination includes the COVID-19 vaccine.
11. Please clarify the reference to chocolate to specify this includes solid chocolate and not just drinks.
12. Please remove gendered language from the sheet. The [HDEC reproductive risks template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) may be adapted for gender-neutral language.
13. Please remove the ‘yes / no’ option for GP notification as this should be a mandatory component of study participation. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**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 supply evidence of professional indemnity for the coordinating investigator *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.6).*

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| **7**  | **Ethics ref:**   | **2024 FULL 19509** |
|   | Title:  | SWiFT study of whole blood in frontline trauma |
|   | Principal Investigator:  | Dr Richard Charlewood |
|   | Sponsor:  | NHS Blood and Transplant; New Zealand Blood Service |
|   | Clock Start Date:  | 18 January 2024 |

Dr Richard Charlewood, Dr Alana Harper and Dr Christopher Denny 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 advised that in order to approve an application intending to enrol a nonconsenting adult participant under Right 7(4) of the Code of Health and Disability Services Consumers’ Rights it needed to be satisfied that participation would be in that individual’s best interest as determined by a clinician at the time of enrolment. The Committee noted the helicopter’s blood product would be already randomised and participants would receive whichever product was on board as part of a delivery of standard healthcare and so their participation in the trial and consent for ongoing data collection would not begin until after they arrived at hospital. The Committee noted that receiving the blood transfusion would not be a contributing factor as this has already been done in the helicopter. The Committee queried how participation in the trial after receiving the blood transfusion would be in an individual’s best interest as the intervention has already occurred. The Researchers stated participation in the trial involved increased monitoring with psychological follow-up and support above standard of care. The Committee accepted this justification.
2. The Committee advised that whānau assent could not be used to enrol participants under Right 7(4) of the Code. The Code requires that the provider takes into account the views of other suitable persons interested in the welfare of the consumer who are available to advise the provider, but this cannot be taken as consent or assent to participate and the decision to include the individual rests with the provider who may only do so if they determine participation is in the participant’s best interests. The Researcher confirmed they were aware of this and the whānau assent form had been uploaded in error. The Committee advised a specific whānau information sheet would not be required and instead whānau could be provided the standard information sheet and invited to discuss the trial.

Summary of outstanding ethical issues

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

1. The Committee requested references to focus groups are removed from the data management plan. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).

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

1. Please remove references to tissue samples on page 5 as these will not be collected during the trial.
2. Please adapt the ‘What will happen to my information?’ section from the [HDEC information sheet template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) and replace the reference to ‘only those who need to know’. Please include information on identified versus deidentified data, how and where data will be stored, who may have access to it, what it will be used for, how long it will be stored and all other applicable prompts.
3. Please include information about the psychological surveys in the PIS and protocol and what will happen if a participant indicates distress in their response.
4. Please include a contact number for Māori cultural support.
5. Please remove the reference to the UK ethics committee and state that the ethical aspects of the study have been approved by the Central Health and Disability Ethics Committee.
6. Please remove the clause in the consent form that participants “understand information collected about me will be used to support other research in the future and shared with other researchers” or alternatively develop information in the sheet to explain this.
7. Please remove the statement in the guardian PIS that “in New Zealand consent can only be given by the patient” as this is incorrect.
8. Please remove the sentence on page 2 “This is accepted practice” as this refers to the law regarding emergencies.
9. Please remove any references to “continued” participation as enrolment will occur at the hospital.
10. Please include the right to access and correct information about participants. A prompt for this may be adapted from the HDEC template.
11. Please revise the statement in the child PIS that they will not be allowed to see or change the data held to align with the right to access and correct information in the HDEC template.
12. Please revise the sentence in the older child PIS that states when you had the transfusion the doctor decided you could take part in the study to reflect that study participation will not begin until the hospital.
13. Please revise the statement that before any research goes ahead it is checked by an ethics committee as not all research requires ethics approval.
14. Please remove the statement in the child consent form “I understand it is up to me to tell my parent who is signing for me whether or not I want my data to be used”. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**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 the full committee online.

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| **8**   | **Ethics ref:**   | **2024 FULL 18109** |
|   | Title:  | Colorectal Anastomosis and Bacterial Eradication (CABE) Trial: The effect of pre-operative antibiotics on Anastomotic Leaks in Colorectal Surgery |
|   | Principal Investigator:  | Dr John Woodfield |
|   | Sponsor:  | The University of Otago |
|   | Clock Start Date:  | 18 January 2024 |

Dr John Woodfield, Dr Kari Clifford and Mr Cole Melhopt 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 no psychometric questionnaires would be used during the study.

Summary of outstanding ethical issues

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

1. Please remove the ‘yes / no’ tickbox in the consent for regarding informing the participant’s GP as this should be mandatory.
2. Please include more detail regarding privacy and what happens to participant data. This may be adapted from the ‘What happens to my information?’ section of the [HDEC information sheet template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
3. Please include information advising participants of their right to access and correct information held about them. This may be adapted from the HDEC template.
4. Please correct Human Disability Ethics Committee to Health and Disability Ethics Committee and state it has approved the ethical aspects of the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**Decision**

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

* 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).*

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| **9**   | **Ethics ref:**   | **2024 FULL 19038** |
|   | Title:  | Pilot study of administration of psilocybin in healthy volunteers within a marae setting. |
|   | Principal Investigator:  | Dr Patrick McHugh |
|   | Sponsor:  | Mātai Medical Research Institute |
|   | Clock Start Date:  | 18 January 2024 |

Dr Patrick McHugh, Associate Professor Suresh Muthukumaraswamy and Dr Will Evans 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 two trained individuals would be with the participant during the psychedelic experience with additional staff in the background.
2. The Researcher confirmed participants would have 1 – 2 sessions before the psychedelic experience to discuss what to expect and what they are trying to achieve. The Researcher confirmed a debrief would take place the following day and a week after.
3. The Committee noted relevant cultural issues not discussed in the application include Māori data sovereignty and the potential for whakamā.

Summary of outstanding ethical issues

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

1. Please adapt technical terms (eg feasibility) into lay-friendly language.
2. Please remove the reference to approval in Australia and state the legal status in New Zealand.
3. Please add the right to correct information in on page 2.
4. Please change uses of amphetamine to methamphetamine.
5. Please remove references to male and female and state any participant on page 3.
6. Please clarify what is meant by substance use disorder and specify how recent in the exclusion criteria on page 3.
7. Please define what certain medical conditions and medications are on page 3.
8. Please remove the comment on adding information about distress on page 6.
9. Please correct the error stating an IUD is not a highly effective method of contraception on page 7.
10. Please correct the typo “this may feel is a bit like daydreaming” on page 7.
11. Please correct the typo on page 7 “(will affect your personally”).
12. Please remove the statement telling participants to keep receipts for reimbursement and consider a stipend instead.
13. Please revise HDEC Central to Central HDEC on page 12.
14. Please include more information on why the trial is being done in healthy volunteers in a marae setting.
15. Please revise the statement telling participants to contact the study team if they are feeling distress as appropriate follow-up should be provided as a matter of course.
16. Please include more information on questionnaires and possible triggers they may contain as well as the safety plan if a participant indicates distress.
17. Please revise the statement on future unspecified research and specify that future research will be directly related to the study question. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**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).*

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

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| **10**   | **Ethics ref:**   | **2023 FULL 19181** |
|   | Title:  | Phase 1/2 Multicenter, Open-label Study to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of NTLA-3001 in Participants with Alpha-1 Antitrypsin Deficiency (AATD)-Associated Lung Disease |
|   | Principal Investigator:  | Dr Mark O'Carroll |
|   | Sponsor:  | Intellia Therapeutics, Inc. |
|   | Clock Start Date:  | 18 January 2024 |

Dr Mark O’Carroll, Professor Ed Gane, Ms Kayla Malate and Ms Holly Thirlwall 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 arrangements for insurance and what cover participants would have after the trial. The Researcher stated a long-term follow-up study for 15 years would have insurance that would cover participants. The Committee noted this presupposes participants would sign onto the follow-up study and queried the scenario of a participant who did not or who had a child after 15 years that may have a treatment-related injury. The Researcher stated anyone who had an adverse event caused by the study drug would have compensation paid by the Sponsor and the local site would help facilitate this.

Summary of outstanding ethical issues

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

1. The Committee queried the risk of germline editing and requested a copy of the Gene Technology Advisory Committee (GTAC) report when available.

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

1. Please revise the statement on page 8 instructing participants to inform the study doctor if they decide to stop having NTLA-3001 as it is a one-time infusion.
2. Please include information advising that a lot of the research was done in macaque monkeys.
3. Please revise the technical information on page 11 to be lay-friendly. The Committee suggested a diagram illustrating the insertion process would be beneficial.
4. Please remove the information on development of antibodies from page 12 if this is not a concern.
5. Please remove the information on allergic reaction if this is not relevant to the first exposure.
6. Please remove the statement on page 16 “it is unknown whether these edited genes will be passed down to future generations”.
7. Please remove the statement on page 20 “NTLA-3001 is at an early stage of development. Therefore, after the research finishes, you will not be able to continue to receive NTLA-3001”.
8. Please review the font size throughout the document and ensure consistency.
9. Please revise the use of the term ‘male’ on page 5. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).

**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 a copy of the GTAC letter when available. The Committee will suspend the 90-day limit to respond to provisional approval so this may be supplied.

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Dr Patries Herst.

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| **11**   | **Ethics ref:**   | **2023 FULL 19233** |
|   | Title:  | A PHASE 1/2A DOSE-ESCALATING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF SINGLE AND MULTIPLE DOSES OF ARO-CFB IN ADULT HEALTHY VOLUNTEERS AND ADULT PATIENTS WITH COMPLEMENT-MEDIATED KIDNEY DISEASE |
|   | Principal Investigator:  | Dr Christian Schwabe |
|   | Sponsor:  | Arrowhead Pharmaceuticals Inc. |
|   | Clock Start Date:  | 18 January 2024 |

Dr Christian Schwabe, Ms Kayla Malate and Ms Holly Thirlwall 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 the insurance deductible would be paid by the company and not the participant.
2. The Researcher confirmed vaccination was a mandatory component of study participation and the vaccination PIS was for participants who are unvaccinated only.

**Decision**

This application was *approved* by consensus.

## General business

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

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| **Meeting date:** | 27 February 2024 |
| **Zoom details:** | To be determined |

 The following members tendered apologies for this meeting.

* Ms Jessie Lenagh-Glue
1. **Review of Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

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

The meeting closed at 6:30pm.