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| **Committee:** | CEN Health and Disability Ethics Committee |
| **Meeting date:** | 22 April 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11:30am - 12:00pm |  | **Committee Welcome** |  |  |
| 12:00 - 12:30pm | 2025 FULL 22537 | A team approach for tamariki with eating difficulties | Dr. Sarah Leadley | Dr Cordelia Thomas / Mx Albany Lucas |
| 12:30 - 1:00pm | 2025 FULL 22256 | DEXTROMETHORPHAN PLUS BUPROPION FOR TREATMENT-RESISTANT DEPRESSION – DOES ADDING BEHAVIOURAL ACTIVATION THERAPY IMPROVE OUTCOMES? | Prof Paul Glue | Ms Sandy Gill / Dr Andrea Furuya |
| 1:00 - 1:30pm | 2025 FULL 18995 | 3D printed medical device to treat precancerous cervical lesions | Dr. Adel Mekhail | Dr Catriona McBean / Dr Andrea Forde |
| 1:30 - 2:00pm | 2025 FULL 22320 | A Study to evaluate ONP-002 in adults with Mild Traumatic Brain Injury | Professor Martin Than | Dr Joy Panoho / Dr Andrea Furuya |
| 2:00 - 2:30pm |  | **BREAK (30 mins)** |  |  |
| 2:30 - 3:00pm | 2025 FULL 22285 | A Study of a Potential Disease Modifying Treatment in Individuals at Risk for or With a Type of Early Onset AD Caused by a Genetic Mutation | Dr Campbell Le Heron | Dr Joy Panoho / Dr Andrea Forde |
| 3:00 - 3:30pm | 2025 FULL 22406 | The CPS trial (Revision 1) | Dr Saad Anis | Ms Sandy Gill / Mx Albany Lucas |
| 3:30 - 4:00pm | 2025 FULL 22653 | HB0043-HV-01-01: A Study to Assess HB0043 in Healthy Participants | Dr Millie Wang | Dr Cordelia Thomas / Dr Andrea Furuya |
| 4:00 - 4:30pm | 2025 FULL 22547 | LTG-OBS-103 (Ivy): A Study to Evaluate Pain Tolerance Effects of Suzetrigine in Healthy Male Adults | Dr Hamish Prosser | Dr Catriona McBean / Mx Albany Lucas |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Ms Joan Pettit | Lay (Chair) | 08/07/2022 | 08/07/2025 | Apology |
| Mrs Sandy Gill  | Lay (Consumer/Community perspectives)  | 22/05/2020  | 22/05/2023  | Present  |
| Dr Patries Herst  | Non-lay (Intervention studies)  | 22/05/2020  | 22/05/2023  | Apology  |
| Dr Cordelia Thomas  | Lay (the Law)  | 21/12/2021  | 21/12/2024  | Present  |
| Mrs Patricia Mitchell  | Non-lay (Health/Disability service provision)  | 08/07/2022 | 08/07/2025 | Apology |
| 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 | Apology |
| Dr Andrea Furuya | Non-Lay | 03/03/2025 | 02/03/2029 | Present |
| Dr Andrea Forde | Non-lay (intervention studies) | 22/12/2021 | 22/12/2024 | Present |
| Dr Joy Panoho | Lay | 03/03/2025 | 02/02/2030 | Present |
| Dr Catriona McBean | Lay | 03/03/2025 | 02/03/2030 | Present |

## Welcome

The Chair opened the meeting at 11:30 and welcomed Committee members, noting that apologies had been received from Ms Joan Pettit, Mrs Patricia Mitchell, Ms Jessie Lenagh-Glue and Dr Patries Herst

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Andrea Forde, Dr Joy Panoho, and Dr Catriona McBean 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 25 March were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2025 FULL 22537** |
|   | Title:  | Evaluating behavioural interventions within a multi-disciplinary clinic for tamariki with eating difficulties |
|   | Principal Investigator:  | Dr Sarah Leadley |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 10 April 2025 |

Dr Sarah Leadley, Emily Jones, and Jamielee Rogers 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 were happy with the accommodations made for families that were not comfortable with taking videos at home.
2. The Researchers confirmed that if a barrier to recording a video at home was access to recording equipment, then that would be addressed as needed.
3. The Researchers confirmed that, while filming in a group session, the equipment is able to focus in on particular children and exclude any children whose guardian did not consent to the child being in 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 suggested that koha is made available for parents as well as children, for example a supermarket voucher for parents and a smaller token for children.
2. The Committee requested that the peer review be completed by someone more independent from the study.
3. The Committee queried what steps researchers would take if the videos taken at home show concerning behaviours, identifying that if concerning behaviours are seen the researchers have an responsibility to step in and notify the appropriate people. A statement outlining this this should also be provided in the PIS.
4. The Committee requested that, when videoing at home, any whānau who do not want to be captured are not filmed at the same time, along with a clear explanation that only the taped child will have data collected. This should also be clearly outlined in the PIS.
5. The Committee requested that the Data and Tissue Management Plan (DTMP) outline that data will be kept for 10 years after youngest participants turns 16.
6. The Committee requested that the governance structure be more clearly outlined in the DTMP.
7. The Committee noted that the two-week time period that the videos are being held may not be sufficient time for researcher review and analysis, especially if any complications were to arise. Any time period that is provided must be adhered to.

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

1. Please revise the wording ‘caregiver PIS’ to ‘guardian PIS’ to be in line with the Care of Children Act.
2. Please include in the PIS that the recording would only need to be about 10 mins rather than the whole meal period.
3. Please also clarify that there will be 3 recordings of meals, at the start, middle and end of study.
4. Please ensure that the PIS outlines that only consented children will be included in data collection for the study.
5. Please revise information provided in the ‘preintervention’ section for clarity.
6. Please include, alongside the description of the ‘brief’ survey, an estimation of how long the survey will take to complete, or how many questions they will be asked.
7. Please remove yes/no options from consent form if they are not truly optional.
8. Please include in the consent form a paragraph indicating that participants understand that if they do not want to record at home other options will be provided.

The Committee requested the following changes to the assent forms *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.27)*:

1. Please revise the Assent forms for ‘younger children’ and ‘older children’ as opposed to grouping by age. The use of Assent forms for preschool children may not be required.
2. Please expand wording in the Assent form under ‘what do we do?’ where it indicates that researchers might watch a video of the participant eating to also include the making of the video as well.
3. Please revise the Assent form from ‘if something goes wrong you can stop’ to say ‘you can stop at any time’.

**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 assent forms, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.27).*
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).
5. 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 Mx Albany Lucas.

## New applications

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| **2**   | **Ethics ref:**   | **2025 FULL 22256** |
|   | Title:  | DEXTROMETHORPHAN PLUS BUPROPION FOR TREATMENT-RESISTANT DEPRESSION – DOES ADDING BEHAVIOURAL ACTIVATION THERAPY IMPROVE OUTCOMES? |
|   | Principal Investigator:  | Prof Paul Glue |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 10 April 2025 |

Prof Paul Glue and Neda Nasrollahi were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researchers clarified that participants need a GP referral confirming that they have treatment resistant depression in order to enrol in the study.
2. The Committee queried the routine exclusion of pregnant and breastfeeding women from category A and B2 medicines. Both medicines are safe in pregnancy and lactating women who might be suffering severe postpartum depression. The Researchers indicated that for this treatment the medicines will be given in much higher doses than for someone with cold or flu, and so there is not enough information to support safety of higher doses in pregnancy.
3. The Researchers confirmed that references to ‘hospital number’ should be references to NHI.
4. Researchers confirmed that all participants would have had treatment and talk therapy prior to participation in the study and that this will not be the first time that any of the participants are having such therapy.

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 researchers are using tools that would have the potential to trigger people, as such the wording around discussion with community care or GP needs to be revised from ‘may discuss’ to ‘will discuss’ if there are any changes or risk factors observed in the participants.
2. The Committee noted references to ‘Hospital number’ and requested that this be revised to NHI.
3. The Committee requested more detail in the DTMP outlining governance and legal requirements.

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

1. Please outline more clearly the processes for participants who express thoughts of self-harm or high suicidality in the PIS as described during the discussion and in the submission form E.3. Outline that contact will be made with a nearby facility at the main hospital, from which an assessment will be made on the best course of action for the participant.
2. Please include in the PIS that some questions on the questionnaire may trigger people with treatment resistant depression.
3. Please describe more clearly what BAT is in the PIS so people know exactly what the therapy is.
4. Please include in the potential risks section of the PIS information around any interactions the study drug could have with over-the-counter medications or alcohol.
5. Please clarify in the PIS that this medicine is approved internationally as an antidepressant but has not been approved by Medsafe for this use.
6. Please indicate who will be providing BAT in the PIS and that the person providing this will be an appropriately trained professional.
7. Please remove ‘(women)’ after pregnancy on page 4 and refer to ‘people’ who are pregnant as opposed to ‘women’ who are pregnant.
8. Please change wording from treatment to ‘dosing’ as this is research not treatment.
9. Please change wording ‘take care of depression’ as this is still research. This could be changed to ‘overseeing’.
10. Please add ‘to resume treatment’ to wording ‘after the three-month period you will return to your regular healthcare provider’.
11. Please revise the wording in the PIS asking participants to be cautious of driving. Instead, the advice around driving could indicate that participants should not drive for ‘x’ number of hours after taking the study drug. Participants need to recognise that they may be impaired while driving.
12. Please include in the PIS that this research is looking for safer, long term, faster acting treatment for depression but is not yet available in New Zealand. However, discussion about options for continued access to the drug after the study period will be available.
13. Please provide wording in the PIS that participants can contact their GP as well as the community and mental health team to seek assessments and treatments.
14. Please revise section that indicates that ‘sponsor’ will have access to identifiable information in the event of an insurance claim. In this case ACC can be available.
15. Please revise page 6 and 7 with references to sponsor and information being sent overseas as necessary.
16. Please remove wording where promises are made about the data will be useful in informing the treatment of future patients as this is research and that is not yet determined.
17. Please revise wording in section indicating that summary of results will be provided after recruitment and data has been analysed for clarity.
18. Please clarify wording so that it is easy for participants to understand that only half of people will receive treatment.
19. Please revise the contraception section to be clear that it is not the male participants who will be consenting to the use of highly effective contraception on behalf of any female partners. This could be worded to say that contraception has been raised with the partner, and that the partner is fully aware of implications and will be involved in any discussion around contraception. This section could also include abstinence as a highly effective form of contraception.
20. Please review PIS for typos.
21. Please clarify what ‘we will monitor the therapy you will receive’ means in relation to BAT. As discussed during the meeting please outline that participants will be recorded and that the recordings may be listened to by the psychotherapist’s supervisor.
22. Please remove the mention of ovality as it will not be used in this study.

**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 Mrs Sandy Gill and Dr Andrea Furuya.

## New applications

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| **3**   | **Ethics ref:**   | **2025 FULL 18995** |
|   | Title:  | An in vivo Prospective Parallel Study to Assess Suitability, Safety, and Tolerability of a New Uterine Cervical Drug Delivery Device in Healthy Volunteers |
|   | Principal Investigator:  | Dr Adel Mekhail |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 10 April 2025 |

Dr Adel Mekhail and Jaydee Cabral were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researchers confirmed that this phase 1 study is only looking at the method of fixing a patch, there is no testing of the drug.

Summary of outstanding ethical issues

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

1. The Committee requested that the advertising wording be clarified that anyone with a disability can be included in the research as long as there is not an abnormality with the cervix or the anatomy of the cervix *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12*).
2. The Committee requested that the formatting and colouring of the advertisement be revised to allow for readability *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12*).
3. The Committee noted that this is device feasibility study for commercial use, as such this is for benefit of sponsor and there needs to be insurance in place to cover for the study *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.5*).
4. The Committee requested that more evidence of preclinical studies be provided for this type 2 device.
5. The Committee queried the contradictory nature of the request for participants to keep participation confidential but to also consult with insurance and request that these statements are revised for clarity.
6. The Committee indicated that data needs to be kept for 10 years *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*.
7. The Committee noted that the DTMP needs improvement to align with what is being done in this study. Currently there is inclusion of under 16 year olds, accessing of medical records, and notification of if notifiable diseases despite blood samples not being taken in the study *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17*).
8. The Committee requested that the references to the New Zealand health authority be revised to say Medsafe. It should be stated whether there is Medsafe approval for this device.
9. The Committee noted reference to comparison with precancerous tissue, please revise or remove as required *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7)*.
10. The Committee noted that consultation with Ngāi Tahu has taken place but no cultural issues have been outlined in the submission. The Committee requested that the questions asked of Ngāi Tahu be provided as well as their response. It is important to note that there needs to be understanding of whakamā especially in this study *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.11a)*.

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 clarify how the device may be removed, include all possibilities in the PIS.
2. Please clarify how the device will be fixed to the cervix, explaining the how gel and pins will be used. This should also include a description of what the pins are.
3. Please clearly state in the PIS that this research is a phase 1 study that is only looking at the method of fixing a patch, there is no testing of the drug.
4. Please revise wording ‘vehicle’ to be more lay friendly.
5. Please revise wording that states that this research will benefit communities, as this research may only benefit a specific cohort, people with cervixes.
6. Please provide a detailed description of how participants are expected to use diaries, how often they are expected to fill them out and how often they will be reviewed by the researchers.
7. Please remove wording ‘get your partner pregnant’ as this is not a risk in this study.
8. Please provide participants with information on exactly what they should do if the patch is naturally discharged. If necessary, provision of receptacle should be provided.
9. Please include in the PIS that a support person is allowed to come with the participant for study visits.
10. Please include a diagram of the device, the device packaging and the device in relation to the cervix in the PIS.
11. Please include a description of all of the processes that will need to take place prior to and during the attachment of the device to the cervix in the PIS.
12. Please clarify that, for this study, sexually experienced people are part of the inclusion criteria and that sexually naive people will be excluded. As the screening for this would include researchers asking participants about their sexual experience ensure that cultural consultation includes discussion specifically on this issue.
13. Please include information around risks associated with the device, this can include the possibility of dyspareunia or increased discharge, any impacts on sexual activity or infection.
14. Please include a cultural statement as female reproductive organs are sensitive in Māori and Pacific cultures.
15. Please ensure that participants are aware that Koha of $100 could be taxable and would impact people’s benefits, Could the koha be increased in light of the invasive nature of the study and the time involved.
16. Please ensure the PIS provides detail that the device follows GMP and manufacturing standards, and outlines that the device will be sterilised before use.
17. Please revise wording indicating that, since the device is approved it will pose no risk, as this is research, and it cannot be definitively said that there is no risk.
18. Please include alongside any references to FDA approval whether there is Medsafe. approval, and if not approved by Medsafe include this information as well.
19. Please remove references to Southern DHB, as this is now Health New Zealand | Te Whatu Ora (HNZ) Southern.
20. Please revise wording stating the product ‘coming to light’ as this is research and there are no assurances that this will be the case.
21. Please revise wording indicating that participants can correct their information to state that they can access their information and request corrections to their information.
22. Please ensure that yes/no tick boxes on the consent form are only available options are truly optional.
23. Please provide more detail on what ‘urgent removal’ would mean in the PIS, what processes are in place to allow for urgent removal.
24. Please ensure appropriate cultural considerations are in place, for example having participants who identify as women having the study procedures done by women also.
25. Please revise PIS for typos, repetition and clarity.

**Decision**

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

## New applications

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| **4**   | **Ethics ref:**   | **2025 FULL 22320** |
|   | Title:  | A Randomized, Double-blind, Placebo-controlled Phase IIa Study to Evaluate Feasibility, Safety, Tolerability, Blood Biomarkers, and Cognition following Intranasal Treatment of ONP-002 in Adults with Mild Traumatic Brain Injury aka Concussion |
|   | Principal Investigator:  | Dr Martin Than |
|   | Sponsor:  | Oragenics |
|   | Clock Start Date:  | 10 April 2025 |

Dr Martin Than was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researchers confirmed that Māori consultation has occurred with hospital consultation process.
2. The Committee commended the researchers on the acknowledgement of the tapu of the head in the application and recognition of cultural considerations.
3. The Researchers confirmed that the translation services available include an extensive list as opposed to a select few. Languages that do not have in person translators available will have most available via telephone.

Summary of outstanding ethical issues

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

1. The Committee noted that, in this case, the protocol and consenting process for the study is based around Right 7.4 in the Code of Health and Disability Services Consumers' Rights 1996 (the Code). Right 7.4 of the Code indicates that if the participant lacks capacity to consent, then the provider can proceed without consent if it is determined that it is in the best interest of the participant to be included in the study, and provided the person’s views if known are followed or if not that the provider takes into account the views of available suitable persons who are interested in the welfare of the consumer. The population for this study includes conscious people who may have diminished competence but are not incompetent. As such Right 7.4 is not applicable.
2. The Committee noted that potential participants for this study will be conscious but will have diminished competence. As provided by right 7.3 in the Code; if the person has diminished competence, they have the right to make choices and give consent to the extent appropriate to the level of their competence. In this case, under provisions of right 7.3, a brief conversation with patients outlining the research in broad terms and allowing participants to indicate consent at this point could be a viable alternative process. Although under right 7(6) consent must be in writing, this could be completed by the clinician who talked to the participant, indicating that the participant did indicate approval after their initial discussion about the research. This should be later followed up by a full PIS and consent process where participants can agree that data collected earlier can be used. This, in turn means that extra care needs to be taken in the consent process to ensure that participants have understood well enough what they have consented to. Any patients who are not believed to have understood what they have been asked to consent to, or are not conscious, will not be included in the study.
3. The Committee noted that, if the consenting process is to be changed to align with Right 7.3, documentation about consultation with whānau and assisted consent can be removed and a shorter script will need to be included.
4. The Committee requested assurance from the sponsor in writing that there is no reliance on US government funding for this project.
5. The Committee requested that the spelling of whānau be checked for consistency throughout documentation.
6. The Committee requested that people who can bear children who are not already on birth control be excluded, as the time period between consent to be in the study and administration of the study drug would not necessarily allow for the participant to go on birth control.
7. The Committee requested that the possible conflict of interest in having the sponsor designated safety officer, who is also chief clinical officer with sponsoring organisation, is managed for this study. Outline that the designated safety officer represents the CRO and does not have any rights to the product. Also include the role of the medical monitor as a potential third-party physician who is also independent of the sponsor.
8. The Committee noted that exclusion criteria indicated that COVID vaccination was permitted at any time, however no other vaccinations. Please revise to indicate that no vaccinations will result in exclusion from the study.

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

1. Please ensure the that the PIS introduces aspects that would be affected by study withdrawal before outlining the process for withdrawal.
2. Please revise wording in the PIS describing enrolment in the study, describing dosing of participants after their head injury. This should be sufficiently detailed and be easy for participants to understand.
3. Please revise wording that clearly states that donated blood or blood products is an exclusion rather than ‘not permitted’.
4. Please clearly outline clearly how long tissue samples will be held for and how long data will be held for in the PIS.
5. Please revise wording for disposal of ‘biohazard waste’ to ‘using established guidelines for tissue sample disposal’.
6. Please ensure that participants are aware that it can take an extended period of time to receive results if they request to receive them.
7. Please revise wording around birth control and contraception to be clear that no participants or partners of participants should become pregnant while participants are taking the study drug.
8. Please include age groups in the ‘who can take part’ section of the PIS.
9. Please include an explanation of what a placebo is for lay perspective.
10. Please clarify instructions for use of the nasal spray, where first daily administration may be in the left nostril and then the second daily administration via the right nostril.
11. Please clarify in the PIS what the compensation for participants would be and be clear that this payment for their time may be taxable and may affect any benefits they may be receiving.
12. Please remove options on the consent form if they are not truly optional. If participants withdraw indicate that data collected up to that point will still be used in the study.
13. Please ensure the wording in the consent form and the PIS are consistent when discussing whether GPs will be informed.
14. Please include in the ‘what if something goes wrong’ section clear description of what may be covered by ACC, and what will be covered by study insurance. Clarify that symptoms due to head injury may be covered by ACC, but any effects of study cannot be covered by ACC but will be covered by study insurance.

**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 Joy Panoho and Dr Andrea Furuya.

## New applications

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| **5**   | **Ethics ref:**   | **2025 FULL 22285** |
|   | Title:  | A Phase II/III Multicenter Randomized, Double-Blind, Placebo-Controlled, Two-Stage Adaptive Design, Platform Trial of Investigational Treatments for Primary Prevention of Disease Progression in Dominantly Inherited Alzheimer’s Disease |
|   | Principal Investigator:  | Dr Campbell Le Heron |
|   | Sponsor:  | Washington University in St. Louis Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU) Department of Neurology |
|   | Clock Start Date:  | 10 April 2025 |

Dr Campbell Le Heron and Nicky Slater 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. Researchers clarified that they do not require the use a locality as the study is operating independently of HNZ out of the University of Otago. Recruitment does not rely on any data or information from HNZ. Researcher contact is primarily made directly with GPs.
2. Researchers clarified that results of study participants not being made available to participants in order to protect the integrity of the blinding of the study. If participants or researchers are made aware of the results, or any changes in the brain it could introduce bias, as participants may change their lifestyle or behaviour and researchers may change how they interact or treat the participants. However, Researchers indicated that any ancillary or structural findings are shared with participants and GPs and are delt with accordingly.

Summary of outstanding ethical issues

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

1. The Committee requested clarification around the exclusion criteria of cognitive impairment. Please ensure this is described clearly in the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7)*.
2. The Committee requested assurance from the sponsor in writing that there is no reliance on US government funding for this project.
3. The Committee noted that the genetic counselling document has not been adapted to the Aotearoa New Zealand context. Please include references to New Zealand specific documents where required and an acknowledgement of data sovereignty and whakapapa *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.7)*.
4. The Committee noted that blinding would be broken in emergency situations, however there is no documented plan in place for how this would be done *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17*).
5. The Committee requested that, throughout the course of the study, the payments made to participants are adjusted for inflation and, where applicable, currency adjusted *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.21)*.
6. The Committee noted the mandatory use of a device that did not have an accompanying privacy statement. Please provide more information around this device including who is providing the device and whether the collected data is provided to the sponsor *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*.
7. The Committee requested that a comprehensive safety plan be provided to outline the processes involved in ensuring participant safety in regard to quality-of-life questionnaires. The safety plan needs to include how quickly questionnaires are assessed, who is assessing them, what will happen if any red flags are raised and give participants information on what assistance is available to them *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*

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 describe the terms ‘blinded study’ and ‘open label’ in the study partner PIS, these have been described in the participant PIS so can be adapted from there.
2. Please ensure that ‘whānau’ spelling is consistent throughout all PIS/CF documentation.
3. Please revise wording describing ‘investigational drug’ outlining that while it is not approved by Medsafe for general use, the use of the drug in this trial will go through SCOTT approval.
4. Please provide the number of anticipated New Zealand participants in the PIS.
5. Please ensure that the section in the PIS that includes payment information for participating in the research also includes information on any koha.
6. Please provide in the PIS how long participants will be observed after injection to ensure that there are no reactions or bad effects.
7. Please reformat the PIS to include the benefits of participation in the study along with the extensive requirements of being part of this study to be provided earlier in the PIS documentation.
8. Please provide contact details for Māori support, and a contact number for support if participants have concerns.
9. Please provide a description of what genetic counselling involves in the consent form. This can include information provided in the genetic counselling document.
10. Please ensure that the section on contraception and contraceptive risks refers to New Zealand brand names and is provided in New Zealand context.
11. Please ensure that the mandatory follow up of a pregnancy is changed to be optional follow up with consent.
12. Please revise the ACC statement for the New Zealand context as New Zealand has a publicly funded healthcare system.
13. Please revise PIS for typos and repetition.
14. Please replace ‘AD’ with the word Alzheimer’s to reduce use of acronyms.
15. Please revise content for stage 1 and stage 2 where information relevant to both stages can be provided in an overall statement and only differences can be provided under the different headings.
16. Please move “You are invited to participate ….” paragraph to the end of the Background section.
17. Please move the sentence “Should an emergency happen … “to the end of the section as it is a universal warning.
18. Please change ‘Part 2’ to Stage 2 as all other references are Stage 2.

The Committee requested the following changes to the optional brain donation Participant Information Sheet:

1. Please ensure that extensive Māori consultation takes place and insights are included in the optional brain donation PIS/CF.
2. Please ensure that the brain donation PIS outlines how long it may take to provide a final summary of results. This should also include a description of where the tissue is intended to be examined and stored.
3. Please revise the wording in the brain donation PIS where the ‘study’ and ‘study procedures’ are mentioned, as the donation of the brain is not any particular study.
4. Please remove the provision of advanced directive if participants should lose capacity, as they are giving consent to donate their brain.
5. Please remove the wording indicating that the donation of the brain has been approved by SCOTT.
6. Please ensure that it is clear to participants that, under the Human Tissue Act, family members may refuse for their brain to be donated despite their having given consent.

**Decision**

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

## New applications

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| **6**   | **Ethics ref:**   | **2025 FULL 22406** |
|   | Title:  | Long-Term Effects of a Cannabis-Based Medication on Sleep in Chronic Back Pain: A Randomised Crossover Trial |
|   | Principal Investigator:  | Dr Saad Anis |
|   | Sponsor:  | THE UNIVERSITY OF AUCKLAND |
|   | Clock Start Date:  | 10 April 2025 |

Dr Saad Anis and Matthew Moore was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researchers clarified that peer review comments were incorporated into the protocol and noted that they were also going through SCOTT approval.
2. The Committee queried the use of 10-point pain scales as opposed to a 5 point scale. Researchers identified that chronic pain patients are very familiar with using 10-point pain rating and pain relief scales.
3. The Researchers confirmed that the data can only be downloaded at the clinic and then directly to university servers.

Summary of outstanding ethical issues

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

1. The Committee requested that only contact details provided by the participant are used for passing on information rather than NHI, which can then be used to obtain further information.
2. The Committee requested that the safety plan be completely revised. Questionnaires about mental health and address suicidality are used in the study and the current timeframe of 14 days between questionnaire completion and assessment by someone on the team is unacceptable. The Researchers have a responsibility to take action immediately if participants have indicated on these questionnaires that they are at risk and GPs need to be informed immediately of these risks. The safety plan should outline that decisive action will be taken immediately after risk is identified, which in turn will be as soon as possible after questionnaires are completed.
3. The Committee requested that disability statements are revised, and disability consultation takes place.
4. The Committee requested that support be made available for people who have English as a second language.
5. The Committee requested that the recruitment flyer photo be replaced and be representative of New Zealand.
6. The Committee requested that the advertisement be revised where it indicates that the study has HDEC approval for 3 years. HDEC approval is ongoing as long as requirements are met.
7. The Committee requested that ‘relations with other people’ wording be clarified, indicating whether this means sexual relations or any other interactions.
8. The Committee requested that a privacy statement be provided for the app used during the study. This needs to include what data the app will be accessing, how that data will be stored, where it will be stored and who will have access to it.
9. The Committee noted that the DMP references the p\Privacy Act 1993, this can be revised to the most recent Privacy Act 2020.

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

1. Please check PIS for repetition and typos and ensure that simple language is used where possible to be more lay friendly.
2. Please use more assertive language when instructing participants not to take more than 1 mL per night.
3. Please remove section on notifiable diseases as only urine samples are being taken.
4. Please include example of what the cost can be expected instead of only indicating that it is ‘expensive’.
5. Please rephrase ‘you will have access’ to ensure that there is understanding that it will not be provided to them by the study
6. Please remove consent form tick box unless truly optional. Most studies do use participant information provided before any withdrawal.
7. Please revise instructions provided to participants for driving after taking the study product. Currently instructions indicate that participants should not drive for 10 hours after consuming the study product. Instructions should clearly indicate that participants must not drive for at least 10 hours after consuming the study product and that they may still be impaired after the 10-hour period.
8. Please ensure that participants are appropriately warned of risks involved with driving after consuming the study product, including relevant sections of the Land Transport Act and any precautions that need to take place.
9. Please ensure wording in contraception sections is clear, and that permissions and consent are not being sought and given by participants on behalf of their partners. Particularly seeking male participant consent for a female partner’s contraception.
10. Please ensure that participants understand that, while Helius THC10:CBD10 is an approved product in New Zealand, it has not been studied specifically for its long-term effects on sleep in people with chronic back pain.
11. Please ensure that potential participants are aware that use of the study product could breach terms of employment, volunteer, or sporting activities.
12. Please provide details of the activity monitor, including a picture of the device.
13. Please remove wording guaranteeing that reimbursement is not taxable as complexities around this may introduce further confusion.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).
4. Please provide Safety plan as requested by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Sandy Gill and Mx Albany Lucas.

## New applications

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| **7**   | **Ethics ref:**   | **2025 FULL 22653** |
|   | Title:  | A Phase 1a, Randomized, Double-blind, Placebo-controlled, Single Dose escalation Study to Evaluate the Safety, Tolerability and Pharmacokinetics of HB0043 in Healthy Adult Subjects |
|   | Principal Investigator:  | Dr Millie Wang |
|   | Sponsor:  | Shanghai Huaota Biopharmaceutical Co., Ltd. |
|   | Clock Start Date:  | 10 April 2025 |

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

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researchers confirmed that the costs outlined in the Advertising and the PIS are correct and the inconsistency in the submission form was incorrect.
2. The Committee noted that the protocol indicates that an effort will be made to include as many Asian subjects as possible and queried this considering the research is taking place in New Zealand and this method of recruitment would not be representative of the New Zealand population. The Researchers responded indicating that while the research is taking place in New Zealand, the sponsors are based in Asia and the product will be primarily marketed in Asia. In order to have the drug approved in Asia a certain percentage of participants need to be part of the Asian population.
3. The Researchers clarified that the use of ambiguous language such as ‘allergy to biologics’ allows for doctors to assess with participants and the sponsor on an individual bases on whether any particular allergy may be exclusionary without listing all possibilities in the PIS so as not to overwhelm participants.
4. The Researchers confirmed that identifiable data will be held on site at a secure facility.
5. Researchers clarified that active HIV and Hepatitis are exclusions for phase 1 healthy studies as there may be liver complications related to the diseases. Participants on treatment for medical conditions are also excluded from these first in human studies and for the participants there would be no benefit to participating in the study.
6. Researchers confirmed that a lay title is available in the PIS for participants to use when referencing 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 requested that the use of street language when referring to hard drugs be amended, or clarification of what the language means.
2. The Committee requested that the advertising clarify that the trial is within Auckland, and that Hamilton is the sentinel site. Indicating that screening and follow up visits can take place in Hamilton while dosing and in clinic days will be in Auckland.
3. The Committee requested that the wording in the protocol indicating that Spesolimab has been approved in New Zealand be removed, as it has not been approved.
4. The Committee requested that reference to IL-17 be consistently referred to as IL-17a as there is a large IL-17 family.
5. The Committee requested that the DMP and PIS are revised for consistency when providing information on the availability of karakia for participants. Indicate that this is an option at collection but may not be possible at tissue destruction if samples are sent overseas.
6. The Committee noted that the IB uses past tense when referring to the use of HB4003 in infertile women or on contraception and requests that this be changed as it is a first in human trial.
7. The Committee requested that the reimbursement per km in the advertisement pack be revised to match the current rate provided by IRD at 35c per km.
8. The Committee requested that the digital media pack reference to Auckland/Christchurch be removed.
9. The Committee requested that the imagery provided in the advertisements be revised to be more representative of the New Zealand population.
10. The Committee noted that the insurance certificate provided is in $AUD, clarification of the amount in $NZD expected equivalent can be provided in a cover letter.

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

1. Please include in the PIS that participants cannot be involved in any other clinical trials.
2. Please move wording that this is a first in human trial to the beginning of the PIS.
3. Please refer to Medsafe instead of the New Zealand Health Authority.
4. Please revise wording for final health checks following withdrawal from ‘if possible’ to ‘if willing’
5. Please change wording when providing activities that participants are not supposed to do from ‘should not’ to ‘must not’.
6. Please confirm, when referencing tuberculosis (TB), that this is reactivation of TB not contraction of TB.
7. Please change mentions of ‘side effects’ to ‘adverse events’ in relation to the investigational product.
8. Please revise the contraception section as previously discussed with Researcher to be clear that it is not the male participants who will be consenting to the use of highly effective contraception on behalf of any female partners. This could be worded to say that contraception has been raised with the partner, and that the partner is fully aware of implications and will be involved in any discussion around contraception.
9. Please remove payments to ACC as an example of tax obligations in appendix 3, this can remain as ‘tax obligations’ only.
10. Please provide a description of what ‘study status’ means and indicate that this can be found on the website.
11. Please clarify that meals provided will only be for in clinic days, not for whole period of trial.
12. Please revise for typos and clarity.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

## New applications

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| **8**   | **Ethics ref:**   | **2025 FULL 22547** |
|   | Title:  | A Randomized, Double-Blind, Placebo-Controlled Crossover Study to Evaluate the Pharmacodynamic Effects of Suzetrigine in Healthy Male Adults |
|   | Principal Investigator:  | Dr Hamish Prosser |
|   | Sponsor:  | Latigo Biotherapeutics, Inc. |
|   | Clock Start Date:  | 10 April 2025 |

Dr Chris Wynne, Lucy Druzianic, Julia O’Sullivan and Kayla Malate 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 identified with the researchers previously raised issues for other applications that can be addressed in this application as well.
2. Researchers confirmed that this drug is approved by the FDA in females and males. The aim of this study is to assess the pain relief capability of this drug, and in an effort to remove all known variables in order to get clean data this trial is only including males. The Researchers clarified that there are no females being harmed by not participating in the phase one study.
3. Researchers clarified that active HIV and Hepatitis are exclusions for this study as the participants would have no benefit to participating in the study and the study does not include people currently taking any other medication.
4. Researchers clarified that the appendix usually listing forms of contraception was removed for this particular study as the only applicable form of contraception was use of condoms.
5. Researchers confirmed that notification of GP wording is included in the PIS indicating that GPs will be notified of participation in the study.
6. Researchers clarified that participants will be tested for COVID if appropriate, this testing is not mandatory.
7. Researchers confirmed that many of the listed exclusion criteria are self reported, and that the importance of these exclusion criteria and why things are excluded are clearly explained to participants during the screening process. Additionally, drug tests are conducted and GPs are contacted where applicable.

Summary of outstanding ethical issues

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

1. The Committee requested that Te Tiriti o Waitangi be referenced in full where mentioned.
2. The Committee requested that the reimbursement per km in the advertisement pack be revised to match the current rate provided by IRD at 35c per km.
3. The Committee requested assurance from the sponsor in writing that there is no reliance on US government funding for this project.

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

1. Please revise wording under Contraception heading if partner or ‘myself’ becomes pregnant. As this study is only in people who cannot become pregnant
2. Please clarify throughout the document lengths of time for consistency. Currently includes ‘six weeks’, ’43 days’, ‘5 and a half weeks’, ’39 days’.
3. Please ensure consistent messaging in the prevalence of side effects throughout the document. Explanation that the prevalence of nausea and vomiting for those who took the medication were similar to the placebo group.
4. Please refer to Medsafe instead of the New Zealand Health Authority.
5. Please revise wording requesting participants complete end of study assessments. Change ‘…ask if you could complete end of study assessments’ to language requesting if they are willing to or agree to competing these assessments.
6. Please change mentions of ‘side effects’ to ‘adverse events’ in relation to the investigational product.

**Decision Approval NSC**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 27 May 2025 |
| **Zoom details:** | https://mohnz.zoom.us/j/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.