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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 22 July 2025 |
| **Zoom details:** | 812 7953 3520 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11:30am-12:00pm |  | Committee Welcome |  |  |
| 12:00pm-12:30pm | 2025 EXP 23259 | The ASTRA II Study | Professor Peter Gilling | Dr Cordelia Thomas / Mx Albany Lucas |
| 12:30pm-1:00pm | 2025 EXP 23071 | Reducing cardiac risk in outpatients with serious mental illness: Feasibility of cardiovascular risk assessment in outpatients with serious mental illness | Dr Mayanna Lund | Ms Sandy Gill / Dr Patries Herst |
| 1:00pm-1:30pm | 2025 FULL 224292025 FULL 23161 | A Phase 3 Study to Evaluate the Efficacy and Safety of KarXT for the Treatment of Manic Episodes in Bipolar-I DisorderA Phase 3 Open-label Extension Study to Assess the Long-term Safety of KarXT for the Treatment of Manic Episodes in Bipolar-I Disorder | Ass Prof Wayne Miles | Ms Jessie Lenagh-Glue / Dr Andrea Furuya |
| 1:30pm-2:00pm |  | *Break (30 mins)* |  |  |
| 2:00pm-2:30pm | 2025 FULL 22926 | C4551002 - A Study of PF-07248144 in Combination with Fulvestrant in People with HR-positive, HER2-negative Advanced or Metastatic Breast Cancer who Progressed After a Prior Line of Treatment | Dr Sheridan Wilson | Dr Cordelia Thomas / Mx Albany Lucas |
| 2:30pm-3:00pm | 2025 FULL 23398 | NSI-8226-205 A study to assess Solrikitug in participants with Chronic Obstructive Pulmonary Disease | Dr Paul Hamilton | Ms Sandy Gill / Mx Albany Lucas |
| 3:00pm-3:30pm | 2025 FULL 22763 | J2S-MC-GZMM: A Study of Safety and Tolerability of LY3537031 in Participants with Normal Renal  Function and Participants with Renal Impairment | Dr Nick Cross | Ms Joan Pettit / Dr Andrea Furuya |
| 3:30pm-4:00pm | 2025 FULL 22762 | J2S-MC-GZML: A Study of the Safety and Tolerability of LY3537031 in Participants with Normal Liver Function and Participants with Liver Impairment | Professor Edward Gane  | Ms Joan Pettit / Dr Andrea Furuya |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Ms Joan Pettit | Non-Lay (Intervention Studies) (Chair) | 08/07/2022 | 08/07/2025 | Present |
| Mrs Sandy Gill  | Lay (Consumer/Community perspectives)  | 22/05/2020  | 22/05/2023  | Present  |
| Dr Patries Herst  | Non-lay (Intervention studies)  | 22/05/2020  | 22/05/2023  | Present  |
| Dr Cordelia Thomas  | Lay (the Law)  | 20/05/2017  | 20/05/2024  | Present  |
| Dr Rebekah Jaung | Non-lay  | 13/07/2025 | 12/07/2028 | Present  |
| Mx Albany Lucas | Non-lay (Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Present |
| Dr Andrea Furuya | Non-Lay | 03/03/2025 | 02/03/2029 | Present |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members, noting that no apologies had been received.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 24 June 2025 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2025 EXP 23259** |
|   | Title:  | A Pilot, Prospective, Multi-center, Open-label Study of the Beacon Platform for Holmium Laser Enucleation of the Prostate (HoLEP) |
|   | Principal Investigator:  | Professor Peter Gilling |
|   | Sponsor:  | Andromeda Surgical |
|   | Clock Start Date:  | 10 July 2025 |

Dr Wikus Vermeulen, Cherie Mason, and Tony Mann 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 acknowledged that this application is related to another study that this committee has reviewed, and that the application has been greatly improved.
2. The Committee queried whether there is any possibility of this procedure causing the cancer to spread. The Researcher advised that as this is an adenocarcinoma there is no risk of the cancer seeding elsewhere.
3. The Committee noted for future reference, that in response to Māori cultural issues information should have been provided about the prevalence in Māori and that the potential for participants to feel whakamā should be highlighted.
4. The Committee queried whether the ultrasound is part of standard of care or an additional procedure unique to the study. The Researchers advised that it is part of standard of care to assess the size of the prostate.

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 protocol references a ‘legal representative’. In New Zealand legal representatives cannot consent for adults to participate in research.
2. The Committee queried having a mandatory cut off for individuals with a BMI of 35 or over. The Researchers advised that the size of the patients’ thighs can interfere with the ability to perform the procedure. The Committee noted that individuals body shape varies and some individuals with lower BMI may have larger thighs and vice versa. Therefore, please consider individuals on a case-by-case basis rather than having a mandatory BMI cut off.
3. The Researchers clarified that the eligibility criteria for the HoLEP procedure as SOC is the same as for the study. The Committee noted that all individuals requiring HoLEP surgery in the relevant period, should be offered the opportunity to participate in the study, rather than selecting individuals.

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

1. The Committee noted that while the PIS is initially written to say “you” but on page 3 changes to say, “the subject”, please amend to state “you” throughout.
2. On page 3 please use ‘current’ rather than 'concomitant’ medication, for ease of understanding for participants.
3. On page 3 please review and revise the ultrasound section as currently it has some grammatical errors and appears incomplete.
4. Please add to the PIS that the participant will be introduced to the sponsor representatives who will be observing the procedure and amend the consent form to state that the participant consents to the observers watching the procedure.
5. Please provide an explanation that there is no risk of the cancer spreading due to this procedure, to provide reassurance to potential participants.
6. Please provide an explanation that whilst the surgeon will be very experienced in performing a HoLEP procedure, the robotic arm is a novel tool, which the surgeon will have had practice using but not with humans. Outline exactly what training the surgeon will have had using the robotic arm. Also outline that using the robot arm may make the surgery take longer and that if it is taking too long (specify the acceptable time period) the surgeon will switch back to conducting the surgery manually.
7. On page 8 please remove the statement regarding the payment not being to compensate for risk or loss of earnings.
8. Please add a contact number for Māori cultural support.
9. On page 4 please use an alternative phrase to ‘water pipe’, as this could be confusing.
10. Please clarify that all pre- and post-surgery requirements will be the same regardless of whether an individual chose to join the study or have a standard HoLEP procedure.
11. Please rephrase the paragraph about pre-surgery scans, as currently it reads as though participants would have all three, when it should be one of these options.

**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 Cordelia Thomas and Mx Albany Lucas.

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| **2**   | **Ethics ref:**   | **2025 EXP 23071** |
|   | Title:  | Reducing cardiac risk in outpatients with serious mental illness: Feasibility of cardiovascular risk assessment in outpatients with serious mental illness |
|   | Principal Investigator:  | Dr Mayanna Lund |
|   | Sponsor:  | Health New Zealand Counties Manukau/ Aotearoa Clinical Trials Trust |
|   | Clock Start Date:  | 10 July 2025 |

Dr Mayanna Lund, Denisse Sanchez, Dr Ian Soosay, and Dr Sumudu Ranasinghe 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 noted that this is a resubmission of a previous decline and acknowledged that most of the previous issues have been addressed.
2. The Committee commented that the brochure is very helpful.
3. The Committee noted that the Data Management Plan states that personal information will not be used for future research and queried as this is a feasibility study whether there would be a possibility of wanting to use this data in future studies. The Researchers advised that they were comfortable that coded data would be sufficient for future studies.
4. The Committee noted for future reference when addressing Māori cultural issues, that consideration of whakamā should be stated.
5. The Committee queried how the adapted web-based PREDICT-CVD tool differs from the standard PREDICT-CVD tool. The Researchers noted that this has been adapted by the same developers and validated on a New Zealand population who access specialist mental health services to adjust for relevant risk factors.
6. The Committee queried that on page 2 of the participant information sheet it mentions that participants will be asked about their medication, but this is not included in the questionnaires. The Researchers advised that they have visibility of the participants prescribed and dispensed medications and that a conversation may be had about them, as per standard of care.

**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 some of the questionnaire questions are reframed so that they come across as less judgemental or confronting, for example instead of asking “how often do you find you do not have enough money to buy healthy foods”, you could ask “how often do you find healthy foods (e.g. fresh fruit and vegetables, unprocessed meats, whole grain foods) are too expensive to purchase”.

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

1. Please simplify and make shorter by removing or summarising the standard of care aspects, for example, the risks of medications they would receive outside of the study.
2. Please clarify that the research is about making it easier for people to access care for their hearts. All the care provided in the study is the standard recommended care that people can get from cardiologists, but appointments with them is often hard to get. This study aims to provide heart health care with mental health services.
3. Please explain that the ECG is part of standard of care to monitor for risks associated with the medication that participants are taking.
4. On page 2 please include information that this study could also result in changes to the participants medication.
5. On page 3 please state where the information will be stored for ten years.
6. On page 3 please state that any data gathered to the point a participant withdraws from the study will continue to be used.
7. On page 4 please use the ACC statement from the HDEC template. [Participant Information Sheet templates | Health and Disability Ethics Committees](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)

**Decision**

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

Please address all outstanding ethical issues, providing the information requested by the Committee.

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 Ms Sandy Gill and Dr Patries Herst.

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| **3**   | **Ethics ref:**   | **2025 FULL 22429** |
|   | Title:  | A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of KarXT for the Treatment of Manic Episodes in Bipolar-I Disorder (BALSAM-1) |
|   | Principal Investigator:  | Associate Prof Wayne Miles |
|   | Sponsor:  | Bristol Myers Squibb |
|   | Clock Start Date:  | 10 July 2025 |

Associate Prof Wayne Miles, Sachin Jauhari, and Deborah Campbell 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 sought clarification around whether participants would be supervised when taking medication, as answers in the submission form were contradictory. The Researchers confirmed that participants would be supervised while taking medication.

**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 rationale for using a placebo in this vulnerable study population. The Researchers advised that using a placebo control allows for scientific validity that there is evidence the medication is having an effect. The Committee questioned why it could not be a non-inferiority or superiority study, and whether there is a gold standard medicine it could be compared against. The Researchers appreciated the question and clarified that the target population have found that existing medicines are either non-effective or intolerable. Also, if they required treatment they would be removed from the study and treated. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 10.23 and 10.24)*
2. The protocol does not clearly identify as the target population a subset of the bipolar 1 population who do not have effective medication. If they are the objective, the study must clarify if and how they are currently medicated and what the effect would be if they were assigned to the placebo group.
3. On a related note, the Committee noted that the risk of the wash out period for people who have recently experienced an episode requiring hospitalization has not appropriately been addressed or justified. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.1, 8.2 and 8.3)
4. The Committee noted the protocol states that an investigator will determine whether it is safe for a potential participant to discontinue psychoactive drugs. Please explain how this determination will be made.
5. The study does not clarify for participants that their stay in the hospital will extend up to 5 weeks if they join the study. It might be helpful to compare that to what the typical hospital stay is for a person experiencing a severe episode.
6. The Committee noted that this study will be done in the public health system and queried whether there are sufficient resources available. Particularly if participants are required to stay in an inpatient facility during the 2-week washout period plus the 3-week study period, when mental health beds are in such high demand. Please explain how you will manage this issue.
7. The Committee queried how informed consent could be obtained from individuals experiencing a manic episode. The Researchers advised that the intent is to pre-screen individuals whilst they are well and inform them of the study, so that when they believe they may be beginning a manic episode they can contact the study team in that early phase and consent whilst still well enough to do so. The Committee noted that this is not well described in the study documentation. There also needs to be an explanation for how capacity to consent will be assessed. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.3, 7.4, 7.7 and 7.8)*
8. The Committee noted that not all manic episodes require hospitalization and how it will be determined if an individual who has consented to join the study is experiencing an episode that meets enrolment criteria.
9. The Committee stated that it would not be appropriate to use electronic records without consent to identify potential participants, rather case workers should be informed of the trial and discuss it with potential participants to gain their consent to be contacted by the study team about pre-screening. The Committee did not accept the justification that participants should be screened for eligibility before being spoken to about the study in case they get their hopes up about being able to participate and then being ineligible. The Committee felt these expectations could be managed as part of the discussion. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.6 and 11.7c)*
10. The Committee noted that on page 40 of the protocol it states that the investigator will titrate the study drug up to participant tolerability. Please explain what you are looking for to make the tolerability determination and clarify whether that will reveal study arm.
11. The Committee noted that page 40 also states that there will be no study drug taper at the end of the 3-week intervention period. Please provide more information about that, including whether there are any risks associated with a sudden stop of the study drug.
12. The Committee noted that the Data Management Plan states Syneos Health will be doing pre-screening, this would not be appropriate, as it would require identifiable data to be sent offshore, so should be amended. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.6)*
13. The Committee queried whether participants would be given the results of any biomarker or genetic analysis that they participate in. The Committee noted that both these aspects should be optional parts of the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.49)*
14. The Committee queried why there is not a Data Safety Monitoring Committee and noted that one should be required given use of this drug for treatment of bipolar disease is not approved for anywhere. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.27)*
15. The Committee felt the placebo letter was inappropriate and should not be used.
16. The Committee suggested that an interim analysis be considered after the first one-hundred participants. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.3)*

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

1. Please state where overseas, i.e. which countries, data may be sent to.
2. Please state that the questionnaires involve sensitive issues and could be upsetting and include a safety plan that outlines how any distress caused will be handled, as per the information provided in the submission form.
3. If there will be a wash out period, please include detailed information about how the participant will be monitored during this period, outlining exactly what the participant can expect to happen.
4. Please state that the GP will be notified of the participant's involvement in the study and that this is not optional.
5. On page 6 please state what support will be provided if a participant tests positive for Hepatitis or HIV. It should also be stated that this is an exclusion criterion.
6. In the optional biomarker PIS please provide more information such as which biomarkers will be investigated, and the purpose of investigating these biomarkers. Please include a diagram of the wrist device and include a section on risks associated with the device, as per the user guide.
7. Please state that HDEC have approved the ethical aspects of the study, rather than the study.
8. Please include information about the optional future research which is on the consent form.
9. Please remove the statement on page 10 about being pregnant or breast feeding, as these individuals are excluded from the study.
10. Please amend the statement about being unable to drive or operate machinery, as the participants will be in hospital and therefore is unlikely to be operating heavy machinery.
11. Please rephrase the statement on page 12 about a “pharmacological intervention” to lay language.
12. Please rephrase the term “treatment” to “study drug”, “investigational product” or similar. As this is research you cannot describe it as treatment.
13. Please remove the statement that “if you withdraw from the study, the doctor will continue to gather information about you if the law allows”. If the participant withdraws then no further information can be gathered about them. It should be also stated that information gathered up until the time of withdrawal will be used for analysis to maintain research integrity.
14. On page 17 the acronym BMS is used. Please use the full name on the first use.
15. Please explain what will happen in terms of medication for those who do not go onto the extension study.
16. Please state that karakia will not be available at the time of sample disposal if samples are being sent overseas.
17. Please provide more information about who is reviewing the audio recordings for the Young Mania Rating Scale in the personally identifiable information section on page 14.

**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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| **4**   | **Ethics ref:**   | **2025 FULL 23161** |
|   | Title:  | A Phase 3, Open-label Extension Study to Assess the Long-term Safety of KarXT for the Treatment of Mania or Mania with Mixed Features in Bipolar-I Disorder (BALSAM-3) |
|   | Principal Investigator:  | Associate Prof Wayne Miles |
|   | Sponsor:  | Bristol Myers Squibb |
|   | Clock Start Date:  | 10 July 2025 |

Associate Prof Wayne Miles and Deborah Campbell 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.

**Decision**

As this application is an open label extension study of the previous application and given that study was declined, the committee felt the most appropriate course of action is for this application to be withdrawn and amended in line with the previous application to be submitted for review at a later date.

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| **5**  | **Ethics ref:**   | **2025 FULL 22926** |
|   | Title:  | An Interventional, Open-Label, Randomized, Multicenter, Phase 3 Study of PF-07248144 Plus Fulvestrant Compared to Investigator’s Choice of Therapy in Adult Participants with Hormone Receptor-Positive, HER2-Negative Advanced/Metastatic Breast Cancer Whose Disease Progressed After Prior CDK4/6 Inhibitor-based Therapy |
|   | Principal Investigator:  | Dr Sheridan Wilson |
|   | Sponsor:  | Pfizer Inc. |
|   | Clock Start Date:  | 10 July 2025 |

Dr Sheridan Wilson, Azmeena Sajid, and Ruta P. 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 that Fulvestrant is injected into the gluteal area and queried whether participants would be able to have a clinician of the same gender if requested.
2. The Committee noted that the appendices are very helpful.
3. The Committee acknowledged the excellent answer the Researchers gave in response to C4 of the submission form.

**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 information provided states that quality-of-life questionnaires won’t be reviewed until the sponsor reviews them, months after completion, and that is inconsistent with New Zealand’s expectations around duty of care.
2. The Committee noted that it would be helpful for participants to be given a copy of the main PIS to read at the time of pre-screening, so that potential participants have all the information required to make an informed decision about whether they would like to be considered for the study.
3. The Committee noted that any identifying features in photographs will need to be blurred out.
4. The Committee noted that the insurance certificate will expire before the study ends and that an updated insurance certificate will need to be provided.
5. The Committee requested that if New Zealand will not be participating in the Arm A QTc sub study this should be removed from the protocol.

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

1. Please use the lay study title rather than the full study title.
2. Please include a warning on page 6, that the questionnaires used in the study may be upsetting (as per the statement in E1 of your submission form), along with a safety plan that advises the participant what action would be taken should the participant exhibit distress.
3. Please add a statement that participants may request a clinician of the same gender and that they can bring a support person. Also state whether the participant will need to remove any clothing at any of the visits.
4. Please include references to the appendices where appropriate throughout the PIS.
5. Please ensure that lay language is used throughout, terms such as ‘lost to follow up’ may be confusing for participants. All acronyms should be defined the first time they are used.
6. Please use gender neutral language, for example on page 5 in the statement about menopausal participants.
7. Please remove the statement about the study potentially being ended for the commercial interests of the sponsor, as this is not a permitted reason to stop a study in New Zealand.
8. Please remove the statement “any payments you may be responsible for”, as this is not applicable.
9. Please remove or rephrase the statement “the study doctor assumes your continued participation”, as this cannot be assumed.
10. Appendix A and B could be combined.
11. In the optional sample PIS, the statement under the heading ‘what is the purpose of the study’ does not answer the question.
12. On page 3 please reword the sentence about tissue samples as currently it does not read as though it is directed at the participant.
13. Please remove the statement in the optional future unspecified research (FUR) form about reimbursement for additional visits as this is not applicable.
14. On page 4 of the FUR information sheet, please remove the statement about samples not being destroyed if the law does not allow it, as this is not applicable to New Zealand.
15. On the FUR consent form please remove the check boxes that say, ‘I agree’, as the statement already says, ‘I agree’, doubling up on this wording makes it confusing.
16. In the optional sample PIS please remove one of the “if there is any” from the about left over tissue, as this phrase is repeated.
17. Please remove the check boxes from the optional sample consent form. Also remove reference to Auckland, as the same points should apply to all sites.
18. On page 5 it states that participants will be given ‘luteinising hormone releasing hormone’, please provide an explanation for what this is and why participants will be given it.
19. Please rephrase to say that if you withdraw you will be asked to, rather than ‘required to’ continue follow up.
20. On page 21 where it refers to notifiable diseases, please specify what these are. Information should also be provided that these tests will be carried out and what will happen if a participant has a positive test result.
21. On page 25 it indicates that unless participants advise that they opt out their consent to continue is assumed. Consent is opt in, not opt out in New Zealand, so this needs to be rephrased.
22. Please clearly state which drugs are the investigational arm and which are the control arm, once these are defined refer to them in a consistent way throughout the document, as currently it is unclear which arm everolimus belongs to.
23. Please include an explanation that as part of pre-screening their tumour has been identified as having the biomarkers which may respond to the study drug.
24. On page 4 please state that if the participant is taking everolimus that this should be taken with food.
25. On page 25 it states that the study drug will only be given during the study but else where it is indicated that if the drug is working for the participant the study will continue. Please clarify this, that if the participant is receiving benefit from the drug, they will continue to receive it.

**Decision**

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

Please address all outstanding ethical issues, providing the information requested by the Committee.

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).*

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 Cordelia Thomas and Mx Albany Lucas.

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| **6**   | **Ethics ref:**   | **2025 FULL 23398** |
|   | Title:  | NSI-8226-205: A Phase 2, Randomized, Double-blind, Placebo-controlled, Multiple Dose-Ranging Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Solrikitug in Participants with Chronic Obstructive Pulmonary Disease (ZION) |
|   | Principal Investigator:  | Dr Paul Hamilton |
|   | Sponsor:  | NI One Inc. (trading as Uniquity One) |
|   | Clock Start Date:  | 10 July 2025 |

Dr Paul Hamilton, Charlene Botha, Andrew Lee, Jiten Rana, Hema Balasubramanian, and Daniel Miconi 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 when quality of life questionnaires would be reviewed. The Researchers noted that this would be done on site and would be looked at straight away, and any concerns would be assessed and triaged appropriately for the individual.

**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 for future reference in the submission form the questions about responsiveness to Māori and Pacific people, were not answered correctly, they should include specific information related to the disease setting.
2. The Committee noted that a separate PIS/CF will need to be supplied to the Committee for review for future unspecified research.
3. The Committee noted that the PIS for discontinuation of the study drug should not be used, rather information should be included in the main PIS that if a participant withdraws, they will be asked to attend a final study visit.
4. The Committee noted that the data Management Plan needs to be made consistent with the intent to retain samples for future research.
5. The Committee suggested considering paying a Stipend rather than requiring participants to produce receipts for reimbursement, as this can be burdensome for participants.
6. The Committee noted that they have not reviewed the pregnancy form, and this should be submitted as an amendment if it is required.
7. Please provide a justification for the exclusion of individuals with Hepatitis B and C.

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

1. Please clarify the statement around withholding at home treatment, in line with the advertising that states that participants may continue daily maintenance medications.
2. Please use gender neutral language throughout.
3. On page 2 please state how many participants are expected to be recruited in New Zealand.
4. On page 2 add ‘only’ to the statement about having a one in three chance of being on placebo.
5. On page 5 when referring to the study questionnaire please provide some information about the type of questions that will be asked.
6. Please include a safety plan that explains what will happen should a participant experience distress because of completing the questionnaires. The answers to E3.1 and E3.2 in the submission form would be appropriate to use for this.
7. Under “If you participate”, the language about continuing Standard of Care (SOC) medications is a bit confusing. Please revise to say, “Continue with your SOC medications as usual, except when the study requires you to withhold them.”
8. Please be more specific about the amount of alcohol participants can consume, and what is meant by illicit drugs or drugs of abuse.
9. Please change the wording in the contraceptive section to only include information that is specific to what is required in New Zealand, rather than stating what is required in certain regions.
10. Please use ‘withdraw’ rather than ‘drop out’ on page 4.
11. Please state whether the participant will be required to undress for the physical examination, and if they can bring a support person or have a clinician of the same gender.
12. Please state that testing for Hepatitis B and C is because it is an exclusion criterion.
13. Please state that karakia will not be available at the time of tissue disposal as the samples are going overseas.
14. Please use the terminology ‘study drug’ or ‘intervention’ rather than ‘treatment’
15. Please remove the tick boxes from the consent form regarding data staying in the study if the person withdraws from the study.
16. Please present the study visit information in tabular form.
17. Please state where in the US study samples will be sent.

**Decision**

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

Please address all outstanding ethical issues, providing the information requested by the Committee.

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 Ms Sandy Gill and Mx Albany Lucas.

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| **7**   | **Ethics ref:**   | **2025 FULL 22763** |
|   | Title:  | A Phase 1, Multicenter, Parallel-Design, Single-Dose, Open-Label Study to Evaluate the Pharmacokinetics and Safety of LY3537031 in Participants with Normal Renal Function and Participants with Renal Impairment |
|   | Principal Investigator:  | Dr Nick Cross |
|   | Sponsor:  | Eli Lilly & Co. |
|   | Clock Start Date:  | 10 July 2025 |

Dr Nick Cross, Dr Kody Shaw, Kayla Malate, Samantha Nie, and Julia O’Sullivan 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 noted that there are three different cohorts in this study but only ten participants for New Zealand, so queried how they would be allocated into the different cohorts. The Researchers noted that it would be competitive recruitment and there could be potential for additional participants in New Zealand if the target here is reached quickly. Those with renal impairment and on dialysis would be recruited first.
2. The Committee queried whether participating in this study would disqualify an individual from being able to be on a transplant list. The Researcher advised that it would not. Individuals would be excluded from participation if they had a transplant scheduled in the next few months, or it would otherwise interfere with their clinical care.
3. The Committee noted that suicidal ideation has been experienced by individuals on these weight loss drugs and queried how much of a risk this is for participants and also when they stop taking these drugs. The Researcher noted that there is some confounding information around the treatment and the underlying conditions. Given the length of the study this would not be expected to be an issue, as this tends to be a longer-term issue. The Committee noted that so long as participants are being monitored that would negate this concern.
4. The Committee queried that participants may be excluded based on mental health grounds and how this would be assessed. The Researcher stated that for some individuals with high levels of anxiety being required to stay in an inpatient facility may be overly distressing. This would be discussed with individuals, and at the discretion of the clinical investigator.

**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 insurance certificate will expire before the end of the study and requested that evidence of on-going insurance is provided.

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

1. Please provide some more context around the exclusion of individuals with a history of mental health conditions.

**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).*

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| **8**  | **Ethics ref:**   | **2025 FULL 22762** |
|   | Title:  | A Phase 1, Multicenter, Parallel-Design, Single-Dose, Open-Label Study to Evaluate the Pharmacokinetics and Safety of LY3537031 in Participants with Normal Hepatic Function and Participants with Mild, Moderate, or Severe Hepatic Impairment |
|   | Principal Investigator:  | Professor Edward Gane |
|   | Sponsor:  | Eli Lilly & Co. |
|   | Clock Start Date:  | 10 July 2025 |

Professor Edward Gane, Kayla Malate, Samantha Nie, and Julia O’Sullivan 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 noted that there are three different cohorts in this study but only ten participants for New Zealand, so queried how they would be allocated into the different cohorts. The Researchers noted that it would be competitive recruitment and there could be potential for additional participants in New Zealand if the target is reached here quickly.
2. The Committee queried whether participating in this study would disqualify an individual from being able to be on a transplant list. The Researcher advised that it would not. Individuals would be excluded from participation if they had a transplant scheduled in the next few months, or it would otherwise interfere with their clinical care.
3. The Committee noted that suicidal ideation has been experienced by individuals on these weight loss drugs and queried how much of a risk this is for participants and equally when they stop taking these drugs if there is an increased risk at this time. The Researcher noted that there is some confounding information around the treatment and the underlying conditions. Given the length of the study this would not be expected to be an issue, as this tends to be a longer-term issue. The Committee noted that so long as participants are being monitored that would negate this concern.
4. The Committee queried that participants may be excluded based on mental health grounds and how this would be assessed. The Researcher stated that for some individuals with high levels of anxiety being required to stay in an inpatient facility may be overly distressing. This would be discussed with individuals, and at the discretion of the clinical investigator.

**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 insurance certificate will expire before the end of the study and requested that evidence of on-going insurance is provided.

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

1. Please avoid using gendered language, e.g. if you are a female that could get pregnant.
2. Please revisit the wording around barrier contraception, as presumably male and female barrier are not being suggested to be used together.
3. Please provide some more context around the exclusion of individuals with a history of mental health conditions.

**Decision**

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

please address all outstanding ethical issues raised by the Committee

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

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 26 August 2025 |
| **Zoom details:** | To be determined |

 The following members tendered apologies for this meeting.

* Sandy Gill
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.

The meeting closed at 3.30pm.