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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 18 March 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:00pm-12:30pm |  | Committee Welcome |  |  |
| 12:30pm-1:00pm | 2025 FULL 22011 | MAV1: Endograft Treatment of Aortic Disease | Mr Manar Khashram | Catherine / Jade |
| 1:00pm-1:30pm | 2025 FULL 22031 | How different mask designs affect people's breathing in COPD and OHS patients using long-term home ventilation. | Dr William Good | Jonathan / Andrea |
| 1:30pm-2:00pm | 2025 FULL 21953 | The A.R.R.E.S.T. study (NZ) | Dr Jagrut Lallu | Kate O’Connor / Kate Parker |
| 2:00pm-2:30pm |  | Break (30 mins) |  |  |
| 2:30pm-3:00pm | 2025 FULL 22383 | The iLet BP Algorithms Study | A/Prof Martin de Bock | Jonathan / Sotera |
| 3:00pm-3:30pm | 2025 FULL 22184 | D5241C00007-JOURNEY: A study to investigate the efficacy and safety of tezepelumab in adult participants with moderate to very severe COPD (HDEC Application) | Dr Syed Hussain | Kate O’Connor / Andrea |
| 3:30pm-4:00pm | 2025 FULL 22206 | Continuous Glucose monitoring for Type 2 Diabetes in Pregnancy: a Feasibility Study | Dr Charlotte Oyston | Jonathan / Jade |
| 4:00pm-4:30pm | 2025 FULL 22237 | Exploring the use of a new testing method that looks for genietic material of microorganisms possibly present in spinal fluid samples received in a New Zealand clinical laboratory. | Miss Delphine Marjoshi | Catherine / Kate Parker |
| 4:30pm-4:45pm |  | Break (15 mins) |  |  |
| 4:45pm-5:15pm | 2025 FULL 22165 | GS-US-409-5704: Study of GS-1427 In Participants With Moderately To Severe Active Ulcerative Colitis | Dr Paul Hamilton | Kate O’Connor / Jade |
| 5:15pm-5:45pm | 2025 FULL 22303 | BJT-778-301: A Study to Evaluate BJT-778 in Participants with Chronic Hepatitis Delta Virus (HDV) Infection. | Professor Edward Gane | Catherine/ Sotera |
| 5:45pm-6:15pm | 2025 FULL 22372 | A Study to Assess KRRO-110 in Healthy Participants and in Participants with Alpha-1 Antitrypsin Deficiency (AATD) | Dr Mark O'Carroll | Catherine / Andrea |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Dr Kate Parker  | Non-lay (Observational studies)  | 11/02/2020  | 11/02/2023  | Present  |
| Dr Andrea Forde | Non-lay (Intervention studies)  | 22/12/2021 | 22/12/2024 | Present |
| Ms Catherine Garvey  | Lay (the Law) (Chair) | 19/03/2019  | 19/03/2022  | Present  |
| Dr Sotera Catapang  | Non-lay (Observational studies)  | 11/02/2020  | 11/02/2023  | Present  |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Ms Jade Scott | Non-lay (Intervention/Observational studies) | 15/08/2021 | 15/08/2024 | Present |
| Ms Kate O’Connor  | Lay (Ethical/Moral reasoning) (Chair) | 13/08/2021 | 16/08/2024 | Present |
| Dr Catriona McBean | Lay | 03/03/2025 | 02/03/2030 | Present |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that no apologies had been received.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Kate O’Connor confirmed their eligibility and were co-opted by the Chair as a member of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 18 February 2025 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2025 FULL 22011** |
|   | Title:  | MAV1: Evaluation of the Mavericks Endograft System in the Treatment of Ascending Aortic Pathology |
|   | Principal Investigator:  | Mr Manar Khashram |
|   | Sponsor:  | Mavericks Endo, Inc. |
|   | Clock Start Date:  | 06 March 2025 |

Mr Manar Khashram and Ms Gypsy Francis 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 clarity whether this is a first in human trial. The Researcher confirmed that it is, currently there is not a graft specifically designed for the ascending aorta. To date there have been operations completed successfully using grafts designed for other vessels.
2. The Committee sought clarity about explanting the device and under what circumstances this would occur. The Researcher advised that they do not expect to explant any, except for in an instance where a participant has died and requires a coronial autopsy to confirm cause of death.
3. The Committee queried whether the team conducting the surgery have sufficient experience and what training will be provided. The Researcher advised that the surgical team are very experienced in this type of procedure and that the sponsor would attend at least the first two cases.
4. The Committee sought clarity around who would be consenting potential participants to ensure some separation between the research and treating clinician and avoid conflict of interest. The Researcher advised that a cardiologist or cardiothoracic surgeon who will not be involved in the procedure will discuss the study with potential participants.
5. The Committee clarified that the researchers will commence this trial in participants who are capable of providing informed consent and will not attempt to proceed on a “best interests” basis without submitting a further amendment to the Committee, in reliance on results in participants who gave informed consent to participate.

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 there is an emergent issue with USA Federal Government funding for research. The Committee noted that studies had been suddenly terminated without regard to the welfare of participants, and that this could also impact New Zealand participants if a study was terminated without warning in breach of ethical principles and the New Zealand Ethical Standards. The Committee requested written assurances from the Sponsor’s Chief Medical Officer, Chief Financial Officer, and Chief Legal Officer, inclusive, that the USA Federal Government is not the source of any funding. If there is US Federal Government funding, this should be highlighted, and the study will require further consideration by the Committee**.**
2. The Committee request that it is protocolised that participants who can provide consent are recruited first and foremost and only recruit participants included under best interests’ criteria later in the study if necessary. Noting that you will also require an Information sheet and Consent Form for family members asked to hear about the trial and indicate their view on whether the potential participant might want to participate. The information sheet will explain what the study involves and why you believe this is in the potential participants best interests and ascertains what the family believe the participant would want. Please add to this document and to the PIS for continued participation the diagram from the main PIS, and remove some points that do not make sense, such as ‘we won’t enrol you if you are pregnant’, as they are already enrolled. Where participants are enrolled on a best interest’s basis without giving their consent then ACC will apply. Please ensure that this is reflected in the PIS for continued participation. Please prepare a document outlining potential scenarios that may occur where the participant is unable to consent, and enrolment is on a best interest’s basis including e.g. a contingency plan for when there are no family willing or available to discuss the trial with. These documents will need to be submitted as a significant amendment for review by the Committee prior to including these participants. The Committee recommended some “best interest” resources and that the researcher contact the secretariat if needed for assistance.
3. The Committee noted that ascending aortic disease has a significant fatality rate, the evidence given was 1% per hour, and queried if pregnant and lactating people would be excluded from standard of care treatment. Pregnant and lactating women should not be routinely excluded from trials, particularly where they would not be excluded from standard of care treatment.
4. The Committee noted that the participant information seet (PIS) and the Data Management Plan (DMP) need to be consistent, for example, the PIS mentions there will be blood samples taken therefore the DMP needs to include management of tissue. The PIS also mentions the possibility of future research, but this is not in the DMP. Please review and ensure these documents are aligned.
5. The Committee stated that the DMP needs to be amended to cover local governance policies.

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

1. Please add a black box first in human warning on the front page.
2. Please ensure that the serious nature of the potential participants condition is highlighted. The Committee noted that this is currently not clear in the PIS.
3. On page 2 where it states, “there may be risks of injury or illness”, this should also include death.
4. On page 4 please provide more information around the device recovery process.
5. On page 4 please provide more detail around overseas data transfer, such as where data will go, who will have access and the deidentification process.

**Decision**

This application for participants who are able to consent for themselves 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. If and when the researchers seek to enrol participants on a “best interests” basis this will be subject to an amendment and further HDEC approval.

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Catherine Garvey and Ms Jade Scott.

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| **2**   | **Ethics ref:**   | **2025 FULL 22031** |
|   | Title:  | The effect of mask design on ventilation parameters in COPD and OHS patients on long-term home non-invasive ventilation. An experimental study. |
|   | Principal Investigator:  | Dr William Good |
|   | Sponsor:  | Fisher & Paykel Healthcare Ltd |
|   | Clock Start Date:  | 06 March 2025 |

Dr Valeria Mereacre 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 sought clarity around the process of recruitment from the database and whether participants had consented to be contacted for research purposes. The Researcher advised that Middlemore Hospital would contact individuals in their database (having given consent to be contacted for research purposes) who were potential candidates for participation and seek their consent for the Researcher to contact them about the study. The Researcher would then phone them and if they were interested, send the participant information sheet (PIS), and allow them a week to consider before following up. Participants would also be given an opportunity for face-to-face discussion before providing consent.
2. The Committee queried what is meant by “suitable bed”, and what facilities are provided for participants. The Researcher advised that they have a bed which is suitable for up to 300kgs, which is why people over 300kg are excluded. The sleeping room is separate to the rest of the facility and is in close proximity to a toilet and shower room. The Researcher clarified that the room is not suitable for more than one person and therefore participants would not be able to have another person present with them for the study overnight.
3. The Committee questioned that if overnight video recording is for safety, it should be live monitored rather than recorded. The Researcher advised that two sleep technicians who are first aid trained will be onsite overnight and monitoring. A recording will also be made.

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 trial needs to be registered with a World Health Organisation approved clinical trials registry.
2. The Committee noted that disability data should be collected as severe obesity and COPD are disabling conditions.
3. The Committee request that information pertaining to how payment for study participation could impact upon participants benefit payment, and how this will be managed is included in the protocol.
4. The Committee stated that pregnant and lactating persons should not be excluded as standard and request that the sponsor review this for this device trial.
5. The Committee noted that participants should not be required to contact the sponsor to withdraw. Contacting the PI (orally or otherwise) is sufficient.
6. The Committee advise that the Data and Tissue Management Plan needs to include information on governance. Note it should also have a date and version number.
7. The Committee noted that the insurance certificate is due to expire, and an updated certificate will be required.

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

1. Please include information about the provision of transport to and from the site.
2. Please explain that the video recording is to review the quality of sleep overnight and provide assurances as necessary about participants privacy.
3. Please provide information about how payment for participation in the study could impact upon individual participants benefit payments.
4. Please add that GP notification of inclusion in the study will be mandatory.
5. Please give clear instructions about whether the participant needs to bring their own mask to wear post-intervention or if this will be provided on site. Also, please clarify the timeframe for each type of mask.
6. Please be clear that the participant will be unable to bring a support person.

**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 Mr Jonathan Darby and Dr Andrea Forde.

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| **3**  | **Ethics ref:**   | **2025 FULL 21953** |
|   | Title:  | The A.R.R.E.S.T. study: Prospective, cross-over trial to assess the short-term efficacy of novel myopia management contact lenses. |
|   | Principal Investigator:  | Dr Jagrut Lallu |
|   | Sponsor:  | nthalmic Pty Ltd |
|   | Clock Start Date:  | 06 March 2025 |

Dr Jagrut Lallu and Daniel Tilia 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 whether individuals in the database had consented to be contacted about research. The Researcher confirmed that they have.
2. The Committee queried how consenting would occur to maintain separation between research and standard clinical care. The Researcher advised that they have two separate teams in different buildings, one for standard care and another for research.
3. The Committee noted that it was great that the participant information sheet/consent form (PIS/CF) would be available in Te Reo Māori and asked if these had been produced yet. The Researcher advised that these would be produced once any changes the Committee required had been made.

Summary of outstanding ethical issues

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

1. The Committee requested the amount of insurance is reviewed, as currently it is potentially too low.
2. The Committee noted that any token of appreciation should go to the child who is the participant not their parent who is their proxy.
3. The Committee suggested that a QR code could be provided on the advertisement to link to further information about the study. The Committee also noted that the children pictured in the advertisement are all wearing glasses, so it needs to be highlighted that the study involves contact lenses, potentially through an image of a lens on a finger. Please use ‘contact lens’ rather than ‘management product’.
4. The Committee queried how the study would control for screen usage, as this is an issue for myopia.
5. Please add further information into the data management plan under governance, such as the Privacy Act and Health and Disabilities Commissioners Code of Rights, as well as any institutional policies. Also update the time the data will be kept from seven years to ten years after the last participant turns sixteen.

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

1. Please adapt the PIS/CF to create a younger child version and an older child version. The younger child version should have more pictures and less words.
2. Please provide information in the parents PIS about what to do if the participant gets conjunctivitis or any other type of infection or experiences any other adverse event. Include that the researchers will provide any treatment and cover costs involved.
3. Please state that there is free parking available for the caregivers of participants, and that travel costs will be reimbursed.
4. Please change the study description from placebo control to active control and explain what this means.
5. Please state who the sponsor is and where the sponsor is located, at the start of the PIS.
6. Please include a section that explains what happens in terms of ongoing treatment at the end of the study.
7. Please change the wording about giving the gift vouchers as recognition for the participants time, as time has tax implications.
8. Please include information in the PIS (not just the consent form) that the participants GP will be notified of their participation in the study and of any abnormal findings.
9. The Data Management Plan states that data may be shared with other groups, please include this information in the PIS and name those groups.
10. Please state where participants data will be going overseas and how it will be protected.
11. Please include a diagram/flow chart that illustrates the study design, including cross-over at six months, different lenses in each eye, etc, in both the adult and child PIS, to assist with understanding.
12. Please highlight how long the study participation goes for.
13. Please check and correct the page numbers.
14. State that Northern A have reviewed the ethical aspects of the trial.
15. Please add the option to have a text/phone call/email regular reminder to wear the contact lenses.
16. Please change the time that data will be held to ten years after the youngest participant turns sixteen.
17. Please remove reference to samples, as no samples are being taken.
18. Please reword the statement on page 4 about consent being done in one day but may be done over multiple days.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O’Connor and Dr Kate Parker.

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| **4**  | **Ethics ref:**   | **2025 FULL 22383** |
|   | Title:  | The iLet Bionic Pancreas System Alternate Insulin Algorithms Study |
|   | Principal Investigator:  | Associate Professor Prof Martin de Bock |
|   | Sponsor:  | Beta Bionics, Inc. |
|   | Clock Start Date:  | 06 March 2025 |

Tom Wilkinson, Steven Russell, and Renee Meier 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 whether there would be a test run completed in adults prior to any adolescent participants being enrolled. The Researcher confirmed this is the case and in the cross-over trial.
2. The Committee queried whether participants would be reconsented before the cross-over trial. The Researcher confirmed they would be, and before each test run.
3. The Committee queried whether there would be a wash out period during the cross-over trial. The Researcher advised that due to the short (one-two hour) half-life of insulin delivered via pump this will not be required.
4. The Committee queried whether there were any restrictions on meals or snacks. The Researcher advised that there are not, participants can eat their normal diet.
5. The Committee queried what the Researchers are doing to increase accessibility for people with visual impairment or manual dexterity impairment. The Researchers advised that individuals with these impairments will be able to participate if they have a support person who is willing and able to assist them. The sponsor advised that whilst it will not be part of this study, long term they are developing accessibility features.
6. The Committee queried the participant information sheet (PIS) stating that participants would have twenty-four-hour access to contact study staff. The Researchers confirmed that this is correct and has been made available in prior studies and advised that there is a study phone which is shared between the team, as anticipated issues should be easily resolved by the study team over the phone, rather than necessitating a hospital visit.

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 pregnant and lactating persons should not be routinely excluded in clinical trials.
2. The Committee noted that in the protocol, the exclusion criteria mention a legally authorised representative. This is not applicable to New Zealand.
3. The Committee advised that this study must be registered with a World Health Organisation approved clinical trials registry.
4. The Committee requested that the data management plan state specifically which data governance policies the study is operating under.
5. The Committee noted that locality authorisation from the University appears to be missing from the application and will need to be obtained.
6. The Committee requested that the sponsor consider licencing the device in New Zealand.
7. The Committee noted that there is an emergent issue with USA Federal Government funding for research. The Committee noted that studies had been suddenly terminated without regard to the welfare of participants, and that this could also impact New Zealand participants if a study was terminated without warning in breach of ethical principles and the New Zealand Ethical Standards. The Committee requested written assurances from the Sponsor’s Chief Medical Officer, Chief Financial Officer, and Chief Legal Officer, inclusive, that the USA Federal Government is not the source of any funding. If there is US Federal Government funding, this should be highlighted, and the study will require further consideration by the Committee**.**

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

1. Please provide information about the cross-over study design in the main PIS and advise that the participant will be invited to participate in this, but it will be consented separately.
2. Please advise participants that notification to their GP (if relevant) is mandatory.
3. In the caregiver test-run PIS under the section ‘how is the study designed’ it states that you want ten adult participants, this should be changed to say that the test-run has been completed in adult participants and you are now looking for paediatric participants.
4. Please check and correct the page numbering.
5. Please highlight information about participants needing to use the Dexcom application to use the device.

**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 Mr Jonathan Darby and Dr Sotera Catapang.

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| **5**  | **Ethics ref:**   | **2025 FULL 22184** |
|   | Title:  | A Randomised, Double-blind, Placebo-controlled, Parallel Group, Multicentre, Phase III Study to Evaluate the Efficacy and Safety of Tezepelumab in Adult Participants with Moderate to Very Severe Chronic Obstructive Pulmonary Disease (JOURNEY) |
|   | Principal Investigator:  | Dr Syed Hussain |
|   | Sponsor:  | AstraZeneca Pty Ltd |
|   | Clock Start Date:  | 06 March 2025 |

Dr Syed Hussain, Meggie Zhao, Maye Hamed, Carlos Arbulu, Lisa Riedl, Duncan Hui, and Jessica Robinson 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 thanked the sponsor for providing the minutes of the FDA and EMA trial reviews.
2. The Committee queried having some participants on a placebo for over a year and what would happen if their symptoms worsened. The Researchers advised that they would still be on their standard treatment, and if their symptoms worsened, they would still receive standard of care to address these.
3. The Committee asked whether AstraZeneca intend to license Tezepelumab in New Zealand. The representative form the Sponsor advised that it is their intention to do so.
4. The Committee queried who would be reviewing CT’s given the current restricted resources for Radiology in New Zealand. The Researcher advised that they have arranged a contract for this.
5. The Committee queried whether participants are excluded from having vaccines during the study, as it would be particularly important for this cohort to be vaccinated against respiratory illnesses. The Researchers advised that the exclusion only applies to live attenuated viruses, but other vaccines would be allowed during the study.
6. The Committee queried how timeliness of response to participant concerns would be addressed. The Researchers advised that the e-diary is monitored and anything of concern would be immediately followed up.

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 pregnant and lactating women should not be routinely excluded without justification.
2. The Committee noted that the data management plan includes reference to under sixteen-year-olds, which needs to be removed. Further information is also required in the governance section. It also states that ‘the following data management policies apply’ but then none are listed.
3. The Committee requests the sponsor consider reimbursement for the participant’s time. Reimbursement for expenses should be consistent between sites.
4. The Committee noted that the trial needs to be registered with a World Health Organisation approved clinical trials registry.

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

1. Please state that it is approved but not funded for severe Asthma in New Zealand, and which countries it is licenced in.
2. Please clarify what is meant by smoke. State whether vaping is allowed.
3. On page 3 please remove reference to flipping a coin.
4. On page 11 please change helminths to worms, for ease of understanding.
5. Page 13 should state adverse events rather than side effects.
6. On page 15 please change Northern B to Northern A.
7. On page 17 please expand genetics to include proteomics and multiomics, the optional PIS/CF also requires an expanded explanation around what testing will be carried out.
8. Please remove reference to teaspoons when referring to blood.
9. Please include on page 16 that karakia will not be available at the time of tissue disposal.
10. In the contraceptive appendix please change unborn child to less emotive terminology such as pregnancy and outcome of pregnancy, as live birth cannot be assumed.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O’Connor and Dr Andrea Forde.

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| **6**   | **Ethics ref:**   | **2025 FULL 22206** |
|   | Title:  | Continuous Glucose monitoring for Type 2 Diabetes in Pregnancy: A Feasibility Study |
|   | Principal Investigator:  | Dr Charlotte Oyston |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 06 March 2025 |

Dr Charlotte Oyston 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 sought clarity around what a waiver of consent was for. The Researcher explained that it was only for recruitment purposes, in terms of reviewing relevant information for an approach to potentially eligible participants so it was determined that a waiver of consent is not required.
2. The Committee noted that in the peer review a comment was made about the recruitment timeframe being quite tight and queried whether sufficient participants could be recruited in this timeframe. The Researcher advised that there are many patients in Counties Manukau with type two diabetes and this continues to increase. There is also significant interest in Continuous Glucose Monitoring (CGM), so they do not foresee any issues in achieving recruitment targets.
3. The Committee asked for clarification around when responses to surveys will be reviewed as there are conflicting answers in the application submission. The Researcher clarified that the surveys will be completed in the presence of research staff, who will be able to take immediate action if something is causing distress. The principal investigator will then review the survey results within twenty-four hours and follow up as required.

Summary of outstanding ethical issues

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

1. The Committee noted that in the advertisement that the HDEC application number should be recorded at the bottom.
2. The Committee noted that in the protocol the version date on the front page does not match the version date on the footer. Please correct.
3. The Committee requested that the exit interview guide is submitted for review before being utilised.
4. The Committee noted that sign off from the University of Auckland, as sponsor, is required.

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

1. Please add the Ministry of Health general enquires phone number (0800 855 066).
2. Please add a picture or diagram of the CGM.
3. Please state that at the end of the study the monitor can be placed in the general rubbish.
4. Please give participants clear information that Dexcom will have access to their data and give the option to use a receiver rather than their cell phone and/or create a pseudonym.

**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 Mr Jonathan Darby and Ms Jade Scott.

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| **7**   | **Ethics ref:**   | **2025 FULL 22237** |
|   | Title:  | Pilot study - Exploring the use of metagenomics in detecting viral/bacterial/fungal/parasite infections in cerebrospinal fluid in a New Zealand clinical laboratory. |
|   | Principal Investigator:  | Miss Delphine Marjoshi |
|   | Sponsor:  | Te Whatu Ora - Waitaha Canterbury |
|   | Clock Start Date:  | 06 March 2025 |

Miss Delphine Marjoshi and Maik Dilcher 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 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 current study design is retrospective and involves accessing stored clinical samples which have not previously been consented for use in research. If something of clinical significance is identified the person who the sample came from may be contacted. The Committee were not comfortable with this approach and recommend considering contacting individuals to gain consent for use of their samples, or alternatively changing to a prospective approach where individuals are consented prior to the samples being obtained. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.49-7.56)* Noting that a Participant Information Sheet and Consent Form (PIS/CF) will be required.
2. The Committee advised that as this study involves pathogens, it comes under the Convention for Biological Diversity, and there are treaty considerations when sending pathogens overseas, including in silico. The Researchers will need to refer to the Nagoya Protocol. The Committee recommend reaching out to ESR and MFAT.
3. The Committee noted that the study protocol appears to be more of a laboratory procedural manual and is missing a lot of the sections that would be expected in a study protocol. Please update to ensure all relevant sections are included as per *(**National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7, 9.8).*
4. The Committee questioned whether it is necessary to send the sequencing data overseas, or if there is an option in New Zealand to carry out the analysis. (Which the Researcher confirmed there is and will look further into). *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.14)*
5. The Committee advised that the Data Management plan needs to specify what are notifiable diseases. There needs to be clear information about what happens to data submitted to the Chan Zuckerberg cloud bio-hub. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*
6. The Committee noted that it was not clear that the peer reviewers’ comments had been addressed.

**Decision**

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

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| **8**   | **Ethics ref:**   | **2025 FULL 22165** |
|   | Title:  | A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multicentre, Dose-Ranging Study Evaluating the Efficacy and Safety of GS-1427 in Adult Participants With Moderately to Severely Active Ulcerative Colitis (UC) |
|   | Principal Investigator:  | Dr Paul Hamilton |
|   | Sponsor:  | Gilead Sciences |
|   | Clock Start Date:  | 06 March 2025 |

Dr Claire Thurlow, Dr Omer Eljyli Hajelssedig, Chris Ng, Aimee Clement and Charlene Botha was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried whether participants would be eligible to receive Vedolizumab which is approved and funded under special authority in New Zealand. The Researcher advised that the study is looking for participants who have not had success on other medications and it would be considered on a case-by-case basis. Also, that if they were eligible for Vedolizumab and it was working for them, then that would be the preferred option.
2. The Committee clarified if it was correct that only four participants were intended to be recruited in New Zealand but there are five participating sites. The Researcher advised that they expect it to be difficult to recruit participants as they are looking for more severe cases, hence the rationale for having five sites. The target number of participants for New Zealand has been increased to fourteen to twenty.
3. The Committee questioned how timeliness and cost of referral for ongoing issues will be handled. The Researcher advised that each site would have access to a gastroenterologist.
4. The Committee queried how conflict of interest scenarios would be handled. The Researcher advised that if a potential participant was identified by a study doctor who was also the primary clinician, then they would make a referral for a study coordinator to contact the potential participant and discuss the study and consenting process.

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 requests the sponsor consider making the product available at the end of the study for those participants who have received benefit, due to the potential for therapeutic benefit and the inclusion criteria requiring participants who have not had successful treatment with any other medications.
2. The Committee asked the researcher to consider having a courier collect the stool sample to avoid the need for it to be stored in the fridge/freezer.
3. The Committee noted that QOL questionnaires are used and requested that there is a prior arrangement for mental health support, due to the current limit on publicly available resources.
4. The Committee noted that as the drug is being trialled in New Zealand it would be appropriate that the sponsor then apply to have it licensed here.

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

1. Please review language and use lay terms where possible for ease of understanding.
2. If it is not possible for stool samples to be collected by courier and they will need to be stored in the participant’s fridge, please make this clear, as there are cultural issues with this.
3. In the optional future research form, please change the wording so that it states the Ethics Committee only approve the ethical aspects of the study.
4. On page 5 please change drugs and medicines to illegal substances and medicines.
5. Please clarify the contraception section to make it clear under which circumstances barrier contraception is required. If two forms of contraception are required due to the potential risk of teratogenicity, this needs to be explained.
6. Please provide information about what happens when the trial is over, in terms of treatment.
7. Notification of study participation to the participants GP should be mandatory.

**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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| **9**  | **Ethics ref:**   | **2025 FULL 22303** |
|   | Title:  | A Global, Randomized, Open-label, Multicentre, Phase 2b / 3 Trial Evaluating BJT-778 vs. Delayed Treatment for the Treatment of Chronic Hepatitis Delta Infection (AZURE-1) |
|   | Principal Investigator:  | Professor Edward Gane |
|   | Sponsor:  | Bluejay Therapeutics, Inc. |
|   | Clock Start Date:  | 06 March 2025 |

Dr Christian Schwabe, Kayla Malate, Julia O’Sullivan and Lucy Druzianic 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 sought clarity around recruitment, whether potential participants were already known to the researchers or if advertising would be involved. The Researcher advised that there is a relatively small group who are predominantly in Auckland, where they are already under the treatment of the PI.
2. The Committee noted that they would like to see ongoing treatment made available to participants if there is benefit, which appears to be flagged in the protocol with a reference to a registry for participants receiving ongoing investigational product. The Researcher advised that the sponsor cannot make any guarantee at this stage but are committed to ongoing hepatitis research. The registry studies will be submitted as a separate protocol if it goes ahead.
3. The Committee queried that participants may be transferred from one dose arm to another dose arm. The Researcher advised this would only be done as part of an amendment if it was determined by a safety committee that a dose was inferior.

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 phoning Lifeline is an insufficient safety plan for participants who are identified as being in distress in questionnaires administered as part of the study. Any response needs to be timely and appropriate.
2. The Committee noted that the governance section of the Data Management Plan needs to include information about NZCR’s specific privacy policies.
3. The Committee noted that the IDMC charter had not been provided and queried that if the sponsor had final sign off over decisions made by the independent data monitoring committee, then it would not be truly independent.
4. The Committee noted that there is an emergent issue with USA Federal Government funding for research. The Committee noted that studies had been suddenly terminated without regard to the welfare of participants, and that this could also impact New Zealand participants if a study was terminated without warning in breach of ethical principles and the New Zealand Ethical Standards. The Committee requested written assurances from the Sponsor’s Chief Medical Officer, Chief Financial Officer, and Chief Legal Officer, inclusive, that the USA Federal Government is not the source of any funding. If there is US Federal Government funding, this should be highlighted, and the study will require further consideration by the Committee**.**

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

1. Please highlight the importance of taking all scheduled doses and include information about how missed doses will be handled.
2. On page 17 it states that other parties may be contacted about the participants care but they will be consulted about this unless it is considered ‘contrary to their best interests’. Please remove this statement as it implies that the participant is not competent to decide what is in their own best interests.
3. On page 18 please change ‘side effects’ to ‘adverse events’.
4. Please move the benefits section from page 14 to be alongside the risks section.
5. Please clarify if barrier contraception is required if the participant is sterilised.
6. On page 26 please remove mention of ACC when explaining tax obligations.
7. Please amendment the statement about Northern A, to reflect that Ethics Committees only approve the ethical aspects of the study.

**Decision**

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

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

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| **10**   | **Ethics ref:**   | **2025 FULL 22372** |
|   | Title:  | A 2-part, Single- and Multiple-dose Escalation, Phase 1/2a Study to Investigate the Safety, Tolerability, Pharmacodynamics, and Pharmacokinetics of KRRO 110 in Healthy Adult Volunteers and in Adult Participants with Alpha-1 Antitrypsin Deficiency (AATD) |
|   | Principal Investigator:  | Dr Mark O'Carroll |
|   | Sponsor:  | Korro Bio, Inc. |
|   | Clock Start Date:  | 06 March 2025 |

Dr Mark O'Carroll, Julia O’Sullivan, Kayla Malate, Lucy Druzianic, Noosheen Ahdi and Jhoanna Abella was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried that the healthy volunteer study had not yet started. The Researcher clarified that the healthy volunteer study would be in Australia, and that no New Zealand participants would be enrolled in the healthy volunteer study. The Researcher advised that the healthy volunteer study is about to commence, and this study which they have presented to the Committee will not commence until the healthy volunteer study has concluded and the results made available.
2. The Committee queried how potential participants will be identified. The Researcher advised that there is an existing registry for people with alpha-1 antitrypsin deficiency, this includes whether they have consented to being contacted for research.
3. The Committee queried what the benefit is for individuals in the optional sub-studies involving bronchoscopy and a liver biopsy. The Researcher confirmed that there is no benefit to participants in these optional sub studies, and the benefit would only be for the sponsor.
4. The Committee queried whether the bronchoscopy involved a biopsy or only BAL. The Researcher confirmed BAL.
5. The Researcher confirmed the information sheets for these optional sub-studies would be revised to remove compensation as a benefit of participation and to clearly confirm the absence of benefits for participants, other than the possibility of incidental findings or results.

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 further information around data governance in the Data Tissue Management Plan.
2. The Committee request that the sponsor apply to have the drug licenced in New Zealand given that it is going to be trialled here.
3. The Committee request that the protocol states that the healthy volunteer phase of the study does not apply to New Zealand.
4. The Committee noted that there is an emergent issue with USA Federal Government funding for research. The Committee noted that studies had been suddenly terminated without regard to the welfare of participants, and that this could also impact New Zealand participants if a study was terminated without warning in breach of ethical principles and the New Zealand Ethical Standards. The Committee requested written assurances from the Sponsor’s Chief Medical Officer, Chief Financial Officer, and Chief Legal Officer, inclusive, that the USA Federal Government is not the source of any funding. If there is US Federal Government funding, this should be highlighted, and the study will require further consideration by the Committee**.**

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

1. Please amend the statement that this drug has been trialled in sixteen participants, to state that the first in human trial is currently underway.
2. Please submit an amendment with the updated information from the first in human trial once this is available.
3. In the optional PIS please remove reference to biopsy after BAL, this should state fluid sample.
4. Please clarify what testing will be done in the optional sub-studies, rather than just stating no genetic testing.
5. Please move reimbursement to separate section in the optional PISs rather than being a benefit.

**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).*

## General business

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

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| **Meeting date:** | 15 April 2025 |
| **Zoom details:** | To be determined |

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. **Other business**

The Committee discussed whether it would be possible to either include in the submission form or add an update to the website, regarding the emerging issue around federal funding from the US, and the Committees request for written assurances about funding being secure for New Zealand studies, to protect participants.

The meeting closed at 6.20pm.