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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 17 September 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12.30-1.00pm | 2024 FULL 21079 | 218309 B-United: A study of sequential therapy with daplusiran/tomligisiran followed by bepirovirsen in people living with chronic hepatitis B. | Dr Ed Gane | Ms Catherine Garvey & Dr Kate Parker |
| 1.00-1.30pm |  | **Break 30 minutes** |  |  |
| 1.30-2.00pm | 2024 FULL 20966 | Study to Evaluate the Efficacy, Safety, and Tolerability of Fexlamose (AER-01) in Adults with Chronic Obstructive Pulmonary Disease. | Dr Michael Epton | Ms Jade Scott & Ms Maakere Marr |
| 2.00-2.30pm | 2024 FULL 21181 | DR-0201-AIM-001: A Study to Evaluate DR-0201 in Patients with Select Autoimmune Rheumatic Diseases | Dr Paul Hamilton | Mr Jonathan Darby & Dr Andrea Forde |
| 2.30-3.00pm |  | **Break 30 minutes** |  |  |
| 3.00-3.30pm | 2024 FULL 21086 | Phase 1/2 Basket Study of HER3-DXd in GI Cancers | Dr Sanjeev Deva | Ms Catherine Garvey & Dr Sotera Catapang |
| 3.30-4.00pm | 2024 FULL 20673 | A Randomized Study of XEN1101 Versus Placebo in Focal-Onset Seizures | Dr Beatriz Romero Ferrando | Ms Jessie Lenagh- Glue & Ms Jade Scott |
| 4.00-4.30pm | 2024 FULL 21219 | Comparison of two Iron polymaltose tablets under fed conditions | Dr Noelyn Hung | Mr Jonathan Darby & Dr Kate Parker |
| 4.30-5.00pm | 2024 FULL 21282 | Vagus nerve stimulation for tinnitus. | Dr Dirk De Ridder | Ms Maakere Marr & Dr Andrea Forde |

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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 | Apologies |
| 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 Maarkere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Jessie Lenagh-Glue | Lay (Consumer/Community perspectives) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 10am 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 Jessie Lenagh-Glue and Ms Maakere Marr confirmed their eligibility and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2024 FULL 21079** |
|   | Title:  | A Phase 2b, multi-centre, randomized, partially placebo-controlled, double-blind study to investigate the safety and efficacy of sequential therapy with daplusiran/tomligisiran followed by bepirovirsen in participants with chronic hepatitis B virus on background nucleos(t)ide analogue therapy (B-United)  |
|   | Principal Investigator:  | Prof Ed Gane |
|   | Sponsor:  | GlaxoSmithKline |
|   | Clock Start Date:  | 5 September 2024 |

Professor Ed Gane, and other members of the research and sponsor team 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.

Dr Andrea Forde declared a potential conflict of interest and the Committee decided to include them in the conversation as the potential conflict was not considered relevant to the Committee’s consideration of this application.

Summary of resolved ethical issues

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

1. The Committee queried the recruitment process. The researcher noted that there are currently a large pool of individuals attending hepatitis clinics and who are established on oral standard of care treatment who would potentially be eligible for recruitment. The treating clinician will make the first approach to request if their patient would be interested in participation. This might be in person at clinic or by telephone.
2. The Committee clarified that all the study medicines will be reviewed by SCOTT.
3. The Committee clarified the blinding of the study medicines using syringe taping to act as a visual guard between the patient and the dose. The person providing the dose is unblinded.
4. The Committee queried why there was no response to the cultural questions specifically relating to Māori and Pasifika risks and benefits.
5. The Committee clarified the antiviral statements referring to Covid-19.
6. Please note that the statement in C18 mentioning legally authorised representative and legal witnesses is not consistent with New Zealand law. Please note this for 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 it is necessary to record ethnicity data at the sites and this should be detailed across the study documentation.
2. The Committee sought confirmation that the deductible sum would be paid by the sponsor for the insurance in the event of a claim.
3. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP):
	1. Please include the data policies relevant to the study site.
	2. Please provide the details of the biobank mentioned in the appendix.

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

1. Please include specifics around drug abuse as an exclusion criterion, particularly for the sake of recovering addicts, and investigator discretion. This needs to be clarified in the PISCF.
2. Please ensure that it is clear that participants may stay on their standard of care medication per the protocol.
3. Please remove reference to cups in the PISCF in relation to blood amounts, please detail this in millilitres.
4. Please clarify what the length of data storage will be so that it is consistent with the DTMP.
5. Please clarify whether a third-party service for travel arrangements and reimbursement will be used and please provide the data privacy information associated with this. Please note that this should be made as easy as possible for the participants, and should not require retention of receipts for reimbursement.
6. Please remove the COVID information from the back of the PISCF as it is not necessary.
7. Please review for gendered language in terms of any pregnancy information and please remove mention of an “unborn child” as this wording is not correct.
8. Please ensure that the notification to the General Practitioner (GP) is mandatory in the CF by removing the tick boxes.
9. Please ensure that mention of pregnancy follow up states that this will require separate consent.
10. Please remove the stacked coin icon from the benefits section.
11. Please use “medicines” instead of “drugs”.
12. Please include “whānau” where mentioning family and friends.
13. Please clearly explain the NA only arm where it first appears in the PIS.
14. Please note that the FUR information could be condensed in the Main PIS.
15. Please make it clearer that this is the first time that these study medicines have been used together in this combination. This may not warrant a black box, but it should be very clear at the top of the PISCF.
16. Please replace the word “destruction” with “disposal” in terms of the disposal of tissue.
17. Please state that the study has been reviewed and the ethical aspects of the study approved by Northern A HDEC.

**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 Catherine Garvey and Dr Kate Parker.

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| **2**   | **Ethics ref:**   | **2024 FULL 20966** |
|   | Title:  | A Phase 2a, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Fexlamose (AER-01) Inhalation Solution in the Treatment of Adults with Moderate to Severe Chronic Obstructive Pulmonary Disease  |
|   | Principal Investigator:  | Dr Michael Epton |
|   | Sponsor:  | PPD – Part of Thermo Fisher Scientific |
|   | Clock Start Date:  | 5 September 2024 |

Dr Malina Storer and Dr Michael Epton were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the study would be registered with a clinical trials registry per requirements.
2. The Committee clarified the exclusion for under 40-year-olds.
3. The Committee clarified that spirometry would occur where possible before midday but would be done with the convenience of the participants in mind.
4. The Committee suggested that the researchers refer to the Māori dictionary online to take care when using te reo Māori across study documents.
5. The Committee clarified with the researchers that the potential for unblinding due to the taste of the study medicine has been considered and will be managed.

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 an explanation as to why the pharmacovigilance is being done in China. If this is occurring, it must be carefully outlined in the Data and Tissue Management Plan (DTMP).
2. The Committee requested that the protocol be amended to state that follow up would only occur for pregnancy where the participant consents.
3. The Committee noted that there is potential that there may be other health issues identified through the process of the full physical exam in the study. If there are incidental findings there must be clear mechanisms by which follow up will occur.
4. The Committee clarified that there would be devices provided for the eDiary where participants did not have their own device for use in the study.
5. The Committee requested a different system for reimbursement such as offering a stipend as the request for participants to carry receipts is overly burdensome.

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

1. Please include a black box warning at the top of the PISCF noting this is a FIH study.
2. Please ensure that there is clear information about the possibility of adverse events not previously detected in human participants.
3. Please align all mention of the study intervention or study medicine and avoid the term “drug” in the participant-facing study documentation.
4. Please ensure that it is clear that participants “will be reimbursed” rather than “may be reimbursed” and please explain when this will occur.
5. Please amend all spellings of the word whānau to ensure that the macron is included.
6. Please make it clear that there is an optional FUR PISCF and that consent for this is not handled in the main PISCF.
7. Please refer to specific data governance policies at least for the lead centre.
8. Please clarify if the participants will have to return the nebuliser at the end of the study.
9. Please provide a diagram to show what a nebuliser is.
10. Please specify how long the study visits would last.
11. Please state that karakia is not available at tissue disposal.
12. Please remove the tick box next to Ggneral practitioner notification as this should be mandatory.

**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 Jade Scott and Ms Maakere Marr.

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| **3**   | **Ethics ref:**   | **2024 FULL 21181** |
|   | Title:  | DR-0201-AIM-001: A Phase 1, Open-label, Multiple Ascending Dose Basket Study to Evaluate the Safety and Activity of DR-0201 in Patients with Select Autoimmune Rheumatic Diseases  |
|   | Principal Investigator:  | Dr Paul Hamilton |
|   | Sponsor:  | Novotech (New Zealand) Limited |
|   | Clock Start Date:  | 5 September 2024 |

Dr Paul Hamilton, Ms Kim Huljich, Mr Michael Rothenberg, Ms Meaghan Smith, Ms Angela Walker, Ms Jennifer Zeitler, and Ms Adeeba Aziz 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 the option selected in S4 of the submission form was incorrect. Please ensure in future that this is correctly answered.
2. The Committee clarified the gender inclusion in this study given the pre-clinical proportion of female samples and that autoimmune issues are typically in females. The sponsor noted that the breakdown in humans is to reduce variability.
3. The Committee clarified that there was not yet data on development and reproductive toxicity from the preclinical studies and that there would be ongoing work into this.
4. The Committee queried the location of the primary site ensuring that there was sufficient access to an Emergency Department (ED) per the protocol recommendations. The nearby ED would be made fully aware of dosing and other procedures once underway.

Summary of outstanding ethical issues

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

1. The Committee clarified the sentinel dosing and any additional monitoring and observation requirements for sentinel participants. The Sponsor clarified that the protocol did not require an overnight stay.

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

1. Please state how exclusion based on a history of drug or alcohol abuse will take into account people in recovery/no longer using.
2. Please state the exclusion of use of Chinese traditional and herbal medicines per the protocol.
3. Please refer to the study medicine as such rather than a study drug.
4. Please note that the tick box for the notification of the General Practitioner should be removed as this should be mandatory.
5. Please state that the study has been reviewed and the ethical aspects of the study approved by Northern A HDEC.
6. Please ensure that the amounts of blood are listed in millilitres (not teaspoons or cups).
7. Please clarify how the use of the travel vendor will work for participants and whether there is an option for site-based reimbursement should the participants not want to go through the third party. Please provide a privacy policy for review and for assurance that the data and privacy of participants using those services would be up to standard.
8. Please include the sentinel dosing requirements.
9. Please include more diversity in the imaging used.
10. Please use gender neutral language for the reproductive risks per the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc).
11. Please include “that will include tattoos” where referring to the blurring of images for deidentification.
12. Please provide a quantification to the risks such as numbers out of 100 as possible. If this is not practicable please refer to them on a scale such as ”likely, unlikely, very unlikely.”

**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 Andrea Forde and Mr Jonathan Darby.

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| **4**   | **Ethics ref:**   | **2024 FULL 21086** |
|   | Title:  | A Phase 1/2 Study to Evaluate the Safety and Efficacy of Patritumab Deruxtecan in Gastrointestinal Cancers  |
|   | Principal Investigator:  | Dr Sanjeev Deva |
|   | Sponsor:  | Merck Sharp & Dohme |
|   | Clock Start Date:  | 5 September 2024 |

Dr Sanjeev Deva and Ms Nivi Sinha were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that Harbour Cancer would be the only site for the study.
2. The Committee clarified that the recruitment would be open across the Auckland region and wider as possible with Sponsor reimbursement for travel. No recruitment adverts will be used for this, and it would be via clinician-based referrals conducted by email within groups of oncologists in Auckland.
3. The Committee clarified that referrals from the public sector would not require further locality approval or public/personal funding to be able to be part of the study despite the site being a private clinic.
4. The Committee noted that for future applications it would be beneficial to include more data as to incidence and benefit for Māori.
5. The Committee clarified dosing and end points of the study.

Summary of outstanding ethical issues

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

1. The Committee noted that reimbursement receipts should not have to be provided and that there should be a stipend for reimbursement to reduce burden. Please clarify this in the PISCF.
2. The Committee queried if there was intention to go for licensure in New Zealand after the trial.
3. The Committee noted that in New Zealand a trial may not be stopped for purely commercial reasons where participants are potentially receiving therapeutic benefit. Please ensure that this is clear to the sponsor and in the PISCF as that is the ethical standard in New Zealand (NEAC Standards Ch 11.37).
4. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP):
	1. Please include the organisation data governance policies that the site will comply with.
	2. Please ensure that the privacy breach section is thorough and please refer to the HDEC template to ensure that this is up to standard.

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

1. Please include the right to an interpreter at the top of the PIS.
2. Please state whether the investigational product is approved anywhere else.
3. Please refer to the study medicine or trial medicine not “study drug”.
4. Please include the statement per access to identifiable data specifically for audit under the heading “What will happen to my Information”.
5. Please combine the egg and sperm risk sections and please ensure the language for this section is gender neutral.
6. Please ensure that the notification to the General Practitioner is mandatory by removing the tick box in the consent form.
7. Please make it clear who will be paying for transport and how this will be arranged.
8. Please clarify that the approval from HDEC is only for the ethical aspects of the study.
9. Please clarify that karakia is not available at the time of tissue disposal.

**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 Catherine Garvey and Dr Sotera Catapang.

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| **5**   | **Ethics ref:**   | **2024 FULL 20673** |
|   | Title:  | A Randomized, Double-blind, Placebo-Controlled, Multicenter Phase 3 Study to Evaluate the Safety, Tolerability, and Efficacy of XEN1101 as Adjunctive Therapy in Focal Onset Seizures  |
|   | Principal Investigator:  | Dr Beatriz Romero Ferrando |
|   | Sponsor:  | Worldwide Clinical Trials Pty Ltd (on behalf of Xenon Pharmaceuticals, Inc.) |
|   | Clock Start Date:  | 5 September 2024 |

Dr Beatriz Romero Ferrando and Ms Kate Ives were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that someone who is not the treating clinician would be available to recruit and discuss participation with the potential participants.

Summary of outstanding ethical issues

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

1. The Committee queried what the “Patient Wing” service is. The researcher explained it is an online recruiting tool commonly used overseas but that the site does not intend to use it. Please submit this as an amendment if this will be used by a future site.
2. The Committee noted that the pregnancy PIS/CF would not be reviewed at this time and that this should be provided as an amendment to the study should a pregnancy occur.
3. The Committee requested that the patient letter be amended to refer to the “treatment option” as “a potential treatment option”.
4. The Committee noted that Ethnicity Data must be collected at the site level.
5. The Committee noted that the study must have a New Zealand sponsor. Please contact the research office at the Waikato Hospital for this purpose and ensure the application is signed.
6. The Committee requested that mention of under 16-year-olds in the data and tissue management plan (DTMP) can be removed as no one of this age group will be participating in this study.

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

1. Please amend measurements of blood to be in millilitres not teaspoons.
2. Please include the QoL questionnaire safety plan in place in the submission, for participants to understand what may occur if they indicate mental distress. Please be specific about the timeliness of this follow-up.
3. Please refrain from using the word “treatment” and instead refer to this as the study intervention or intervention or study.
4. Please ensure that General Practitioner (GP) notification is mandatory. Please remove the tick box for this option in the consent form.
5. Please state whether the participants will be provided a device for use.
6. Please review the PISCF for error where cutting and pasting has occurred such as reference to condoms with diaphragms etc.
7. Please clarify statements around constipation.
8. Please amend wording referring to an “unborn child” and instead refer as a “pregnancy”.
9. Please clarify that there is risk of exposure through ejaculate to sexual partners separate to that relating to pregnancy risks.
10. Under “who can take part in the study” please remove the word “may” from “your responsibilities may include”.
11. Please be clear whether karakia will be available at time of tissue disposal.
12. Please state that the study has been reviewed and the ethical aspects of the study approved by Northern A HDEC. This should also be included in the advertising.

**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 Jade Scott and Ms Jessie Lenagh-Glue.

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| **6**   | **Ethics ref:**   | **2024 FULL 21219** |
|   | Title:  | A single dose, double-blind, balanced, randomised, two-treatment, two period, two sequence, two-way crossover bioavailability study comparing 1 x 370 mg Iron Polymaltose tablet (equivalent to 100 mg of elemental iron) with 1 x 370 mg Maltofer® tablet (equivalent to 100 mg of elemental iron) in iron deficient participants under fed conditions with diet control.  |
|   | Principal Investigator:  | Dr Noelyn Hung |
|   | Sponsor:  | Zenith Technology Corporation Limited |
|   | Clock Start Date:  | 5 September 2024 |

Dr Noelyn Hung and Mrs Linda Zenith 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.

Mrs Jessie Lenagh-Glue declared a conflict of interest and the Committee decided that it would be appropriate for the member to recuse themselves from the conversation during this application.

Summary of resolved ethical issues

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

1. The Committee clarified the process for tracking compliance around the food requirements and ensuring that there is ongoing compliance and how participants who do not follow the required diet will be managed.
2. The Committee clarified the mixed gender rooms in the study site. The researcher clarified that these have been used without complaint or problem in previous studies and there is also another room available should a participant be unwilling to share a mixed gender room, and partitions are available should there ever be the need to have a separate space.
3. The Committee clarified that 1:1 consultations with the study doctor were mandatory following the small group discussions of the study during the informed consent process.

Summary of outstanding ethical issues

1. Please reword the word “drug” in the advertisement and instead replace it with “medicine”.

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

1. Please ensure that General Practitioner (GP) notification is mandatory. Please remove the tick box for this option in the consent form.
2. Please ensure that Northern A being the approver of the ethical aspects of the study is in PISCF.

**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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| **7**   | **Ethics ref:**   | **2024 FULL 21282** |
|   | Title:  | Paired vagus nerve and auditory stimulation for the treatment of tinnitus: a proof-of-concept study. |
|   | Principal Investigator:  | Dr Dirk de Ridder |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 5 September 2024. |

Dr Divya Adhia and Mr Boen Deng 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.

Mrs Jessie Lenagh-Glue declared a potential conflict of interest and the Committee decided that the member could remain for the conversation as there was no actual conflict.

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 the supplier of the device is an external manufacturer but they would not receive study data and had no input into the study design.
2. The Committee clarified that the data safety and monitoring committee was sufficiently qualified. The researcher clarified the committee’s previous involvement with similar research and data use in other populations.
3. The Committee clarified that the researcher does intend to register the study with a WHO-approved clinical trials registry.

Summary of outstanding ethical issues

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

1. The Committee requested clarification of the exclusion criteria, particularly pregnant women and recently pregnant women as the explanations given did not appear to justify this. Please clarify the basis for exclusion, and whether pain is also an exclusion criterion. *National Ethical Standards* para *9.7a & 9.8*
2. The Committee requested more information as to the safety of the device, how it has been used before in people and what training would be needed to use the device. This needs to be detailed in the protocol. This also needs to be described in length to the participants, especially as this device is novel. *National Ethical Standards* para *9.7a & 9.8*
3. The Committee queried who in the team or externally has commercial ownership and interest in the device as this is not clear and must be clarified in the protocol, and the participant information sheet/consent form (PIS/CF) for the sake of transparency. *National Ethical Standards* para *11.23*
4. The Committee requested a clear plan outlined in the protocol and the PIS as to what will occur to screening data where potential participants are either not eligible or choose not to participate. There should be a written version of this provided to potential participants prior to the screening. *National Ethical Standards* para *9.7a & 9.8*
5. The Committee noted that the peer review was not complete, and the Committee requested that the whole form was completed once the protocol was finalised as requested as part of this review. *National Ethical Standards* para *9.25-9.32*
6. The Committee requested that relevant data governance policies referred to in the application be provided as part of the data tissue management plan (DTMP).
7. Please include the HDEC reference and approving Committee in the advertising.
8. Section 8.4 of the DTMP states that data may be sent overseas. Please include this in the PICF if it is correct.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF): *National Ethical Standards* para *7.15*- *7.19*

1. Please clarify that the scores of the questionnaires are analysed immediately and detail what follow up plans are in place for individuals who indicate mental distress as part of this study.
2. Please clarify how reimbursement vouchers will be given out and how participants may state preference for parking or grocery vouchers.
3. Please clarify under Future Use of Information whether this may be consented or not consented to as part of the study.
4. Please note that the word ‘whānau’ is spelled without the macron. This is a typo, please ensure this is corrected.
5. Please amend the wording around the consent for future use statement to ask for consent not whether the participant understands.
6. Please be clear that future use of data will specifically be related to tinnitus research.
7. Please clarify if participants may withdraw data, if they cannot express this clearly.
8. Please amend the date that participants may request results from the study as the one listed has already passed.
9. Please clarify that anyone with a history of substance abuse will be excluded.
10. Please clarify who will pay for the driving service offered.
11. Please remove the 0800 4 ETHIC number and replace with the MoH general advocacy number per the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc).

**Decision**

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

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 15 October 2024 |
| **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. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 5pm.