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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 20 May 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12.00-12.30pm |  | Committee Welcome |  |  |
| 12.30-1.00pm | 2025 FULL 21799 | A trial of the QCore tinnitus therapy system. | Professor Grant Searchfield | Ms Sandy Gill / Dr Sotera Catapang |
| 1.00-1.30pm | 2025 FULL 22231 | Visual and Academic Functions after Amblyopia Treatment | Dr Tina Gao | Mr Jonathan Darby / Dr Kate Parker |
| 1.30-2.00pm | 2025 FULL 22752 | A Study to Evaluate the Safety and Efficacy of BGB-16673 Compared to Pirtobrutinib in Patients With Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma. | Dr Rory Bennett | Dr Catriona McBean / Dr Andrea Forde |
| 2.00-2.30pm |  | *Break (30 mins)* |  |  |
| 2.30-3.00pm | 2025 FULL 22496 | Decide Trial. Dexmedetomidine to reduce post-op delirium in Cardiac Surgery. | Dr Amy Gaskell | Ms Sandy Gill / Ms Jade Scott |
| 3.00-3.30pm | 2025 FULL 22556 | Neonatal unit patient responses to oxygen therapy | Dr Daniel Mackay | Ms Catherine Garvey / Dr Sotera Catapang |
| 3.30-4.00pm | 2025 FULL 22514 | Bioengineered Animal Tissue Graft Sling Study | Clinical Associate Professor Michael Stitely | Dr Catriona McBean / Ms Jade Scott |
| 4.00-4.30pm | 2025 FULL 22131 | REPORT Study | Dr Kalpa Jayanatha | Mr Jonathan Darby / Dr Kate Parker |

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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) | 11/08/2021 | 11/08/2024 | 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 |
| Dr Catriona McBean | Lay | 03/03/2025 | 02/03/2030 | Present |
| Ms Sandy Gill | Lay (Consumer/Community perspectives) | 22/05/2020 | 22/05/2023 | 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 Sandy Gill 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 15 April 2025 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2025 FULL 21799** |
|  | Title: | The Triple T tinnitus trial: A three-arm waitlist-controlled trial of the QCore tinnitus therapy system. |
|  | Principal Investigator: | Dr Grant Searchfield |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 08 May 2025 |

Dr Grant Searchfield 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 the principal investigator’s relationship to the sponsor company and his role in the study. The Researcher advised that the company is associated with the University of Auckland, and that he is a co-director and chief medical officer. His role is to set up and oversee the study but he will not be involved in recruitment or in gathering or analysing the data. The Researcher advised that a Research Fellow will be employed to coordinate the study and undertake the data analysis. The University of Canterbury is also involved in the study, and they will be employing a Research Coordinator as well, who will be responsible for data acquisition and management.
2. The Committee queried whether the ninety-day period would be fixed, or whether it will only count the days the participant uses the intervention for one hour, and therefore be a longer period if the participant does not use the intervention every day. The Researcher advised it is a fixed ninety days, and one hour each day is an ideal scenario but is not an absolute requirement. Part of the data they are interested in gathering is whether people use the device each day and if this is viable.
3. The Committee queried whether individuals would be able to participate in the study if they do not have a phone. The Researcher advised that to participate individuals would need to have a phone capable of running the latest software for apple or android, and acknowledged this would exclude some individuals who may otherwise wish to participate.
4. The Committee queried what the outcome measures are for efficacy and safety. The Researcher advised that the only way these can be measured for Tinnitus is through self-report questionnaires, as there are no objective tests available to measure either outcome.
5. The Committee queried whether there would be any reimbursement for travel. The Researcher advised there would not be, as they feel that the provision of the headphones is sufficient.
6. The Committee queried whether any data would go overseas. The Researcher advised that it would not.
7. The Committee commended the Researcher for a well put together and easy to understand AI presentation. The Researcher noted that the AI form was helpful in some of the points it raised.

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 for travel and mobile data would be appropriate to allow for more equitable access to this study, without creating any undue inducement.
2. The Committee noted that two insurance certificates were provided and recommend clarifying which insurer has jurisdiction, as the potential exists for each to defer to the other for cover.

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

1. Please update the contact details to include the Research coordinators that will be employed.
2. Please state that when the study period ends and the participant keeps the hardware and software, it is up to the individual if and how they wish to use it, and that their data will no longer be collected.
3. Please include Māori cultural concerns regarding tapu of the head.
4. Please change Māori health support to Māori cultural support.
5. Please remove tick boxes from the consent form, unless truly optional. Notification to the GP or audiologist that the individual is participating in the trial should not be optional.
6. Please include advice that for participants on a pre-pay mobile plan if they run out of data, whilst they will still have access to the trial therapy, their data will not be shared back to the Research team and they will not receive any updates or communications via the app.
7. Please include a safety plan to address what process will be in place if any responses to the questionnaires raise concerns about a participant’s mental wellbeing.
8. Please state that participants’ deidentified data will be used to validate an AI tool.
9. Please clarify that the study is for a fixed ninety day period, not that the participants must use the device for ninety days. Please explain that although you encourage them to complete one hour per day, if they miss a day this will not affect the length of the study.
10. Please amend the retention period to ten years for data.
11. Revise the withdrawal of data dates.
12. Please update the contact details for HDEC to the Ministry of Health general enquiries line.
13. Please state what information on a participant’s phones the app would have access to and be transparent about any data mining.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Sandy Gill and Dr Sotera Catapang.

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| **2** | **Ethics ref:** | **2025 FULL 22231** |
|  | Title: | Binocular Vision and Academic Functions of Children aged 7-12 years in New Zealand who completed Anisometropic Amblyopia Treatment - A pilot observational study. |
|  | Principal Investigator: | Dr Tina Gao |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 08 May 2025 |

Dr Tina Gao and Mr Ketemaw Demilew 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 how recruitment would be undertaken for the control group and where the advertisement would be used. The Researcher advised that the advertisement would be put up in ophthalmology clinics and targeting family members of affected participants, so that they would understand the condition being studied.
2. The Committee noted that the peer reviewer had requested additional details and queried whether these had been provided. The Researchers advised that they had been provided.

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 an individual needs to be named for the sponsor sign off, rather than a department.
2. The Committee queried the use of the terms ‘visually normal’ and ‘lazy eye’ and requested that these are reworded.
3. The Committee noted that the Data Management Plan (DMP) needs to be specific about what part of a participant’s medical record will be stored. Also state what sources will be used for data linking.
4. The Committee recommend the clinicians provide potential participants with the Researchers contact information, so that it is the individual’s choice to make contact, rather than a Researcher making the initial contact with the participants.
5. The Committee recommended that when collecting information on income the Statistics New Zealand income brackets should be used, so that it can be aligned with other data sources.

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

1. As there are two PIS forms please give them different reference numbers.
2. Please include headers for each of the PIS forms.
3. The children’s PIS is quite dense for a seven-year-old. Please introduce a simplified version for younger children.
4. Please include advice around risks associated with dilatation, such as if the child should avoid riding their bike for a specific period.
5. The first time the eye drops are mentioned, please include that they may sting.
6. Please review for repetition and condense where possible, particularly in the children’s versions.
7. Please include acknowledgement of the head being tapu.
8. Please state that this study is being conducted as part of a PhD.
9. Please align with the DMP to state the data may be used for unrelated future research. However, this should specify that this will only be Ophthalmological research.
10. Please provide information about any data linking that will occur.
11. In the parent PIS please state the risk of incidental findings.
12. In the parent PIS please state that the GP will be informed of the child’s participation in the study.
13. Please add to the consent form the option for the child’s data to be used in future research.
14. Please review the use of language around ‘the person taking care of you’, this should be changed to ‘parent or guardian’ or similar.
15. Please remove the ACC statement from the parent PIS, as this would not apply for the parents who are only completing a survey.
16. Please review for grammar and typos.

**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 Kate Parker.

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| **3** | **Ethics ref:** | **2025 FULL 22752** |
|  | Title: | A Phase 3, Open-Label, Randomized Study to Evaluate the Safety and Efficacy of BGB-16673 Compared to Pirtobrutinib in Patients With Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma |
|  | Principal Investigator: | Dr Rory Bennett |
|  | Sponsor: | BeiGene NZ unlimited |
|  | Clock Start Date: | 08 May 2025 |

Dr Rory Bennett 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 extra MRI and CT scans for the study would use public or private funds. The Researcher advised that the scans would be undertaken in public hospitals but paid for by the sponsor.
2. The Committee noted that the research coordinator will provide potential participants with the Participant Information Sheet and queried whether they will provide their contact details for potential participants to discuss any questions with them. The Researcher advised that they would and that this is standard practice.

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 written confirmation that there is no US federal funding for this study.
2. The Committee noted that follow up is until death, withdrawal from the study or loss to follow up, however the study is only for three years. Please confirm which is correct and ensure documents are aligned.
3. The Committee noted that the protocol states that the sponsor will receive postmortem results for any participants that die. This is not mentioned in the Participant Information Sheet (PIS). Please note that in New Zealand family members of the participant will have the right to decide whether this happens or not, regardless of what the participant has agreed to in the consent form.
4. The Committee noted that two weekly pregnancy testing for female participants, as per the protocol, is intrusive and not clearly justified given that female participants are advised to avoid conception using effective or highly effective contraception, and that the information in the Investigators Brochure does not indicate preclinical concerns around reproductive or developmental toxicity.
5. The Committee request that the sponsor consider licencing the medicine in New Zealand should the trial be successful.
6. The Committee noted that the application mentions that quality of life (QoL) questionnaires will be done as part of the study, however these were not provided. If QoL questionnaires will be used, there needs to be a plan in place for timely review by a clinician and appropriate follow up where necessary.
7. The Committee noted that the Data Management Plan was submitted in draft version. Reference to under sixteen-year-olds needs to be removed. The Governance section requires more detail.
8. The Committee requested a current CI indemnity certificate be provided.

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

1. 32 pages is a lot for participants to take in, please review for repetition and make more concise where possible.
2. The Committee noted for future reference that the HDEC website has templates for PIS/CF forms [Participant Information Sheet templates | Health and Disability Ethics Committees](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
3. Please simplify the blood collection table, for example state that for specific cycles the following will be collected, rather than repeating the same information for every cycle.
4. Please clarify the requirements for male barrier contraception, with sexual partners , based on the information in the Investigators Brochure on page 114.
5. Please provide additional advice around contraception, such as the use of lubricant with barrier contraceptives, and that male and female condoms should not be used together.
6. Please review requirements for frequent pregnancy testing for female participants.
7. Please state that the sponsor wants to receive postmortem results should the participant die, explain why and the need for whanau discussion on this.
8. Please state for each medicine whether it has been licensed and if so by which regulator and for what indication.
9. In phase I and II there was around a five percent death rate associated with Aspergillosis, please state this specifically rather than fungi.
10. Please state that participants will be reimbursed, rather than “may be reimbursed”, and provide information about what reimbursement will be provided for, and what the process is for participants to be reimbursed. If a rate such as mileage will be used, please consider the IRD rate and state that it will be CPI adjusted due to this being a multiyear study.
11. Please change side effects to adverse events.
12. If QoL questionnaires will be carried out, please detail the safety plan should these raise any issues of concern.
13. Please clarify the purpose of the end of dosing visit and when this may occur.
14. Please remove ‘freely’, ‘fully’ and ‘willingly’ from the consent forms.
15. Please review the requirement for testing of Hepatitis B and C at the end of dosing visit, and the requirement to notify the Medical Officer of Health, as this does not make sense to occur at the end of the study.
16. Please review the requirement for the medication to be stored at between 20-25⁰C, with regard to practical advice to participants for storage at home.
17. Please state if the sponsor has agreed to the Medicine New Zealand guidelines or remove reference to these.
18. Please remove any generic statements referring to other countries, ensure everything is customised for what will happen in New Zealand.
19. Please clarify whether participants can request the return of biological samples if they have been sent overseas.
20. Please state that HDEC approve the ethical aspects of the study.
21. Please change ‘tissue destruction’ to ‘tissue disposal’.
22. Please review the optional PIS/CF for grammar.

**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 Catriona McBean and Dr Andrea Forde.

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| **4** | **Ethics ref:** | **2025 FULL 22496** |
|  | Title: | DECIDE. DExmedetomidine in Cardiac surgery; an Intraoperative Drug Evaluation. An investigator led, multicentre, triple blinded, placebo controlled RCT |
|  | Principal Investigator: | Dr Amy Gaskell |
|  | Sponsor: | University of Sydney |
|  | Clock Start Date: | 08 May 2025 |

Dr Amy Gaskell and Mr Jono Termaat were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that the protocol mentions verbal consent and queried whether this would be used in New Zealand. The Researchers advised that this is specific to Australia and would not be used in New Zealand.
2. The Committee queried whether there would be a risk of over sedation for those participants receiving Dexmedetomidine as well as Standard of Care. The Researchers advised that participants are closely monitored and it is likely those participants would have less Propofol titrated to control the level of sedation.

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 a New Zealand appendix is added to the protocol, detailing the New Zealand sites and any differences in the way the study will run in New Zealand.
2. The Committee noted that the insurance certificate provided is due to expire on 01 July 2025, so an updated certificate will be required.
3. The Committee noted that there is a statement in the Data Management Plan about samples being anonymised before being stored for future research. If future unspecified research will be conducted there needs to be separate participant information sheet and consent form.
4. The Committee noted that any specific policies should be added to the Data Management Plan.
5. The Committee noted for future reference when referring to Māori cultural issues, blood, family and whakamā should be included.

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

1. Please add the point from the protocol that if a participant requires reintubation within fourteen days, then they would need to restart the study medication.
2. Please remove the details of the Australian Principal Investigator.
3. Please remove reference to the study operating under the TGA scheme.
4. Please review to make the document specific for a New Zealand audience, such as changing wording where it refers to this being an Australian study, run in other parts of the world.
5. Please clarify that the delirium assessments will be carried out once in the morning and once in the evening.
6. Clarify if it should state central biobank or central laboratory.
7. Please state the current uses of Dexmedetomidine in New Zealand.
8. Please outline what additional procedures or assessments will occur in addition to standard of care.
9. Please use ml’s rather than teaspoons when referring to blood volume.
10. For the baseline assessments please clarify what will be included, even those things that are Standard of Care.
11. Please state that participants will receive surgery, sedation, and post operative medication as per Standard of Care.
12. Please state that participants will be under monitoring for any side effects from Dexmedetomidine.
13. Under ‘who has approved this study’ please remove reference to Australian guidelines.
14. Currently it states samples will be stored indefinitely which is inconsistent with the Data Management Plan which states ten years. Please amend accordingly.
15. Please remove the 0800 4 ETHICS phone number as this is no longer in service and replace with the Ministry of Health general enquires line, and make the same amendment on the participant brochure.
16. Please include a safety plan which outlines the process for assessing the results of Quality-of-Life questionnaires and addressing any issues arising from these. The researchers have a duty of care to act in a timely manner.
17. Please add samples being sent overseas to the consent form.
18. Please include a Māori cultural statement.
19. Please review for spelling errors.
20. Please remove ‘freely’ from the consent form.
21. Please state that karakia will not be 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 Sandy Gill and Ms Jade Scott.

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| **5** | **Ethics ref:** | **2025 FULL 22556** |
|  | Title: | Peripheral oxygen saturation responses to changes in the fraction of inspired oxygen in neonatal unit patients on non-invasive respiratory support therapies |
|  | Principal Investigator: | Dr Daniel Mackay |
|  | Sponsor: | Fisher & Paykel Healthcare Limited |
|  | Clock Start Date: | 08 May 2025 |

Dr Daniel Mackay, Mrs Elena Adaikina, Caitlin Chatfield, Malik Peiris and James Revie were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that this is a resubmission of a previous decline, where the Researchers had not been able to attend the meeting and acknowledged that most of the issues raised have been addressed. The Committee thanked the Researchers for attending this meeting.
2. The Committee queried how long parents will have to consider whether they wish to include their baby in the study. The Researchers advised that they have a conversation about the study, provide the information sheet and allow at least twenty-four hours for the family to consider the information before meeting again to sign the consent form. The Committee queried who would make the approach. The Researchers advised that a Study coordinator would do the consenting process.
3. The Committee queried the relationship between the sponsor and the site. The Researcher advised that they have worked together on a previous device study, so already had a working relationship. In terms of funding this is only to cover costs involved in doing research, such as a research nurse.

Summary of outstanding ethical issues

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

1. The Committee noted that the protocol and Data Management Plan refer to some UK legislation, please customise for New Zealand.
2. The Committee noted that the Data Management Plan needs additional information added to the governance section.

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

1. Please revise/remove the compensation section, as this is an observational study.
2. Please remove the black box warning about risks from a device, as this is an observational study, and no interventions are occurring in addition to standard of care.

**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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| **6** | **Ethics ref:** | **2025 FULL 22514** |
|  | Title: | A descriptive study to determine the feasibility of a minimally-invasive non-mesh incontinence sling procedure using a bioengineered animal tissue graft. |
|  | Principal Investigator: | Clinical Associate Professor Michael Stitely |
|  | Sponsor: | Health New Zealand Southern via Health Research South |
|  | Clock Start Date: | 08 May 2025 |

Clinical Associate Professor Michael Stitely and Elliot Mackenzie 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 where the surgeries would be conducted. The Researchers advised this would be in public and private hospitals. In some cases, participants from the public waiting list would have their surgery done in a private hospital at no cost to them.
2. The Committee queried whether there are any additional approvals required for use of the bioengineered animal tissue graft. The Researchers advised that there are not as it is already approved for use in New Zealand. The Researchers acknowledged that this is an off-label use of the graft.
3. The Committee queried why the data is being sent to Harvard University. The Researcher advised that they have a data repository, which has strict data governance protocols, which allow for deidentified data to be used for research.

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 a copy of the Investigators Brochure for the graft.
2. The Committee requested a peer review commenting on the potential suitability of this graft for this novel use. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26, 9.28)*.
3. The Committee noted that further information about what research has been done on the use of this graft to date should be included in the protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8).*
4. The Committee noted that the Data Management Plan should state that data will be kept for ten years. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.13).*
5. The Committee noted that the protocol needs additional information, such as the name of the Principal Investigator, the study sites, the name of the sponsor, page numbers and a version number. Also state how conflict of interest will be managed in the recruitment process. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7 & 9.8).*
6. The Committee noted that if any future unspecified research will be conducted then a separate PIS/CF needs to be provided. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.8, 7.57)*.

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

1. Please state at the beginning that this is the first time this tissue graft will be used for this type of surgery.
2. Please add more detail about the tissue graft.
3. Please add to the risks section the risk for an inflammatory reaction, and for risks of surgery please include the risk of perforation of the bladder.
4. Please state that the surgery will be performed under general anaesthetic and that preoperative antibiotics may be prescribed.
5. Please include a table including all the study procedures.
6. Remove repetition about questionnaires being completed.
7. Please state what will occur at the six-month assessment.
8. Please add that participants will need someone to drive them home after surgery.
9. Please update the data management section to state that data will be kept for ten years not five.
10. Currently both a data bank and a data registry are referred to, please use consistent terminology.
11. Please state that data going overseas is going to Harvard University and why and how the data will be used in the future.
12. Please remove reference to reimbursement for time when mentioning the gift voucher.
13. Please make GP notification of involvement in the trial mandatory.

**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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| **7** | **Ethics ref:** | **2025 FULL 22131** |
|  | Title: | REducing the PrOgression of diabetic kidney disease: A cluster Randomised Trial (REPORT) |
|  | Principal Investigator: | Dr Kalpa Jayanatha |
|  | Sponsor: | Aotearoa Clinical Trials |
|  | Clock Start Date: | 08 May 2025 |

Drs Kalpa Jayanatha, Sumudu Ranasinghe, Viliami Tutone, Allan Moffatt, David Symonds, and John Baker were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that in the application and Data Management Plan there is conflicting information around whether data will be identifiable or not. The Researchers advised that Primary Health Organisations (PHOs) gather identifiable data, which will be provided in deidentified form for use in this study.
2. The Committee queried whether patients are advised that their information could be used for research when they enrol with a PHO. The Researchers advised that patients are given an information sheet and a consent form, where they are advised about potential uses of their data and can chose to consent for their data to be used in research or not. The Committee queried whether those that opted out of their data being used for research would be excluded from this study. The Researchers advised that they would be excluded.
3. The Committee queried whether any research sites have been recruited for the study. The Researchers advised that they have identified all the sites that would be suitable to participate but have not reached out to [all of] them yet, however they do not envisage any issues bringing the required number of sites on board for the study.
4. The Committee queried whether site staff or members of the research team would be collating the data. The Researchers advised that this is mostly automated, from lab results and practice data which is extracted each night for use in health surveillance.
5. The Committee queried whether control sites would know that they were control sites and whether the Researchers had considered using sites as their own controls based on the previous years’ data. The Researchers advised that the control sites would be informed, and that control and intervention sites would be geographically separate from each other. The researchers advised that due to the ongoing advancements in diabetes care using historical data would not give true evidence of the efficacy of this trial intervention.

Summary of outstanding ethical issues

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

1. The Committee noted that the protocol needs to clearly identify what is standard of care and what is research. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7 & 9.8*).
2. The Committee requested further justification for a waiver of consent to collect data. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.29*).
3. The Committee noted that the protocol does not explain whether the Kai Manaaki and practice nurses are existing employees whose additional time will be funded by the study, or new employees; or how the current availability of such staff in the potential participating practices may impact randomisation. The protocol also needs to address how they will engage with participants including any additional or new requirements of participants for attendance or remote contact. The study team will also need to address what happens at the end of the study with participating practices and any altered employment arrangements that occur due to the trial. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7 & 9.8*).
4. The Committee queried whether participants give consent for email and/or text reminders and communications, noting that not all enrolled patients will wish to receive these.
5. The Committee recommend notifying patients that the site is involved in a study and providing those patients who will be involved in the intervention with a brochure about the study.
6. The Committee requested that information is provided about the impact on cost to participants enrolled at a practice randomised to the intervention. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.1*).
7. The Committee noted that further clarification is required regarding any changes to practice management systems to accommodate participation in the study.

**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:** | 17 June 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.

The meeting closed at 4.50pm.