



Committee: Ad hoc Health and Disability Ethics Committee

Meeting date: 11 December 2025

Time	Review Reference	Project Title	Coordinating Investigator	Lead Reviewers
10:00am-10:30am		Committee Welcome		
10:30am-11:00am	2025 EXP 24506	DECODE (Diabetes Education and CGM Or Diabetes Education alone) outcome measures pilot study.	Dr Tim Salmond	Dr Cordelia Thomas / Dr Ptries Herst
11:00am-11:30am	2025 EXP 24331	Development of an AI-based tinnitus therapy version 2	professor Grant Searchfield	Ms Sandy Gill / Dr Andrea Furuya
11:30am-12:00pm	2025 FULL 24547	A Study to assess ZE63-0302 in Participants with Type 2 Diabetes Mellitus	Dr Dean Quinn	Ms Neta Tomokino / Dr Kate Parker
12:00pm-12:30pm		<i>Break (30 mins)</i>		
12:30pm-1:00pm	2025 FULL 23142	NGT Study	Professor Stuart Dalziel	Ms Jessie Lenagh-Glue / Dr Ptries Herst
1:00pm-1:30pm	2025 FULL 24537	Can the Pūkeko posting activity help understand children's experiences?	Mrs Mona Roper	Ms Sandy Gill / Dr Rebekah Jaung
1:30pm-2:00pm	2025 FULL 24367	CFWY003A12201: A study to investigate efficacy and safety of FWY003 compared with placebo in participants with geographic atrophy secondary to age-	Prof Anthony Wells	Dr Cordelia Thomas / Dr Andrea Furuya

		related macular degeneration		
2:00pm-2:30pm	2025 FULL 24578	SRP-1005-101: A Study to Evaluate the Effect of SRP-1005 in participants with Huntington's Disease	Prof Tim Anderson	Ms Jessie Lenagh-Glue / Dr Kate Parker
2:30pm-2:45pm		<i>Break (15 mins)</i>		
2:45pm-3:15pm	2025 FULL 24615	Exploring electrical stimulation to improve visual function	Dr Divya Adhia	Ms Neta Tomokino / Dr Rebekah Jaung
3:15pm-3:45pm	2025 FULL 24588	K9531-3104: Efficacy and Safety of KAI-9531 Administered Once Weekly in Participants Living with Obesity or Overweight and Diabetes.	Dr. Claire Thurlow	Ms Sandy Gill / Dr Kate Parker
3:45pm-4:15pm	2025 FULL 24163	J5S-MC-CEAA: A Phase 1 Study of LY4088044 in Healthy Participants	Dr Chris Wynne	Ms Jessie Lenagh-Glue / Dr Andrea Furuya
4:15pm-4:45pm	2025 FULL 23900	AB-10-8011 (Aspire-201) : Phase 2 study of AHB-137 in HBeAg negative CHB participants in Asia-Pacific Region.	Professor Edward Gane	Dr Cordelia Thomas / Dr Rebekah Jaung

Welcome

The Chair opened the meeting at 10:00am and welcomed Committee members.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.



New applications

1	Ethics ref:	2025 EXP 24506
	Title:	DECODE (Diabetes Education and CGM Or Diabetes Education alone) outcome measures pilot study.
	Principal Investigator:	Dr Tim Salmond
	Sponsor:	University of Otago
	Clock Start Date:	28 November 2025

Dr Tim Salmond 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 why pregnancy is an exclusion as no medication is being given. The Researcher stated it comes from the larger study because pregnancy alters glycaemia. The exclusion is for scientific integrity and to keep the study population consistent between the two studies. The Researcher stated if a participant was pregnant it would change their glycaemia independent of the intervention and the change cannot be attributed to the pregnancy or the intervention.
2. The Researcher confirmed the study data would not be used for future research.

Summary of outstanding ethical issues

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

3. The Committee advised a control is not appropriate for this research and requested this is removed.
4. The Committee queried the fitness test on the bicycle. The Researcher stated it would be similar intensity to a person with diabetes walking uphill. The Researcher stated it would be undertaken in a safe environment with a St John's paramedic assisting with the test. The Committee queried what data the test adds to the research. The Researcher stated the test is a valid way to assess where someone is on the spectrum of aerobic fitness and whether their diabetes is improving on a mitochondrial level. The Committee requested including this information in the information sheet.
5. The Committee requested the Researcher develop a safety plan for responding to any participant distress or other adverse events during the research. Please include information about this and how participants will be cared for in the information sheet. The Committee requested the safety plan includes detail on what resources the researchers have available as some participants may not have timely access to a GP or may not be enrolled at all.

(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4).

6. The Committee requested the Researcher investigate whether the Prezy card would be taxable according to the IRD. The Committee recommended not including mention of the prezy card in the advertisements as this could potentially be seen as an inducement. Mentioning a koha is permitted.
7. The Researcher clarified there is no interview with anyone in the UK and this will be done by the New Zealand based research team. The Committee requested information about the interview is included in the information sheet and how data generated from it will be stored/used.

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

8. Please insert the cultural statement from the HDEC template.
9. Please be consistent in the information sheet and refer to participants as “you”.
10. Please revise the line about withdrawal when practicable, participants may do so at any time.
11. Please include information about the safety plan.
12. Please include information about why the fitness test on the bicycle is being done.
13. Please include information about the interview.

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 develop and include a safety plan to respond to adverse events

After receipt of the information requested by the Committee, a final decision on the application will be made by the full committee online.

2	Ethics ref:	2025 EXP 24331
	Title:	Just-in-Time Adaptive Intervention Artificial Intelligence system in tinnitus digital therapy study
	Principal Investigator:	Professor Grant Searchfield
	Sponsor:	The University of Auckland
	Clock Start Date:	28 November 2025

Professor Grant Searchfield and Mr Ke Mao 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 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 issues present in the previous decline letter have not been responded to and requested these are incorporated in the resubmission.
2. The Committee advised if the study is commercially sponsored then it requires clinical trial insurance. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1*).
3. The Committee requested the Researchers develop a safety plan to respond to participants indicating severe distress and that this is detailed in the protocol and information sheets. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4*).

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

4. Please include headers and footers with a version date.
5. Please make it clear on the first page which sheet is for controls and which is for people with tinnitus.
6. Please provide more detail on the study design, including total number of participants and numbers in the control and tinnitus groups.
7. Please clarify who is funding the study.
8. Please amend "TrueSilence provides the therapy being studied" to state they supply the product.
9. Please include more information on the financial conflict of interest the lead investigator has with TrueSilence.
10. Please review the control PIS and ensure it contains relevant information for the control group and no information only applicable to the tinnitus group.
11. Please review the people with tinnitus PIS and ensure it only contains relevant information for people with tinnitus and no information only applicable to the control group.
12. Please use the ACC statement from the HDEC template.
13. Please amend Māori health support to Māori cultural support.



14. Please include more information on the questionnaires and the safety plan to manage participant distress.
15. Please ensure all information in the consent form has been explained in the PIS
16. Please undertake a general revision to ensure correct grammar and syntax.
17. Please specify how participants will be able to keep the therapy and how it will be provided.
18. Please include more information on the use of AI generating a custom-made sound track in the tinnitus PIS.
19. Please ensure information is consistently grouped, eg information about the questionnaires and the safety plan should be together.
20. Please address the discrepancy between the PIS and CF on withdrawing data. The PIS states participants may ask data not analysed is deleted but the consent form states it will continue to be processed.

Decision

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

3	Ethics ref:	2025 FULL 24547
	Title:	An Exploratory Randomised, Double-Blind, Placebo-Controlled Study of the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ZE63-0302 in Participants with Type 2 Diabetes Mellitus
	Principal Investigator:	Dr Dean Quinn
	Sponsor:	Eilean Therapeutics
	Clock Start Date:	28 November 2025

Dr Dean Quinn, Dr Sharmin Bala, Ms Katie Kennett and Ms Erin King were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researchers confirmed formal Māori consultation was still pending and would occur in 2026.
2. The Researcher clarified participants would be recruited through a combination of database searches, advertising and potentially through GPs and other support networks.

Summary of outstanding ethical issues

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

3. The Committee noted the study appeared to be advertised on the Momentum website before approval and requested this is taken down until HDEC approval is issued.
4. The Committee requested the reimbursement rates are included.
5. The Committee requested the sentence in the advertising material to “gain early access to treatment at no cost” is removed as this may be overstating benefit.
6. The Committee queried why participants would need to have a diagnosis of at least 7 years as this did not appear to be in the protocol.
7. The Committee requested clarification on how disability data was being collected and what it would be used for.

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

8. Please undertake a general revision for typos (eg several times “necessary” is missing a y).
9. Please state if the drug will not be available to participants after the study.
10. Please refer to an investigational product or study period rather than treatment or treatment period.



11. Please amend the explanation of an RCT to include an explanation of a placebo trial like this one.
12. Please specify what drugs of abuse are eg if alcohol is included
13. Please state that GP notification is mandatory.
14. Please provide an address for where samples will be sent overseas
15. Please make tests following study withdrawal not mandatory they are optional
16. Please specify that the study may not be terminated by the Sponsor for commercial reasons
17. Please use gender neutral language when referring to pregnancy
18. Please refer to the Medical Officer of Health instead of government health authorities when discussing notifiable diseases.
19. Please ensure the sheet is specific to a New Zealand context and remove anything that only applies to an overseas site.
20. Please confirm who the primary contact person is with a phone number and email contact.

Decision

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

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

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

4	Ethics ref:	2025 FULL 23142
	Title:	RCT of interventions to reduce the pain and distress of nasogastric tube (NGT) insertion in young children
	Principal Investigator:	Professor Stuart Dalziel
	Sponsor:	Monash University
	Clock Start Date:	28 November 2025

Professor Stuart Dalziel and Ms Medha Rao 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 granted a waiver of consent to review medical records to identify eligible participants in the research.
2. The Researcher confirmed study data would be deidentified during the study and at the end an anonymised dataset would be created for future use.
3. The Researcher confirmed all participants would be recruited in the emergency department and clarified a nasogastric tube is different to intubation. The Researcher explained the time taken for a decision to insert a nasogastric tube is not time critical and can take up to three hours. The Researcher confirmed they would not need to enrol without consent or for best interests and all participants would be enrolled with parent / guardian consent.

Summary of outstanding ethical issues

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

4. The Committee requested a copy of the video that will be provided to participants. The Researchers stated they can provide the script. The Researcher stated recent studies have shown the video is useful for communicating study information and a valuable adjunct to the information sheet.
5. The Researcher confirmed the fentanyl and midazolam doses are standard and commonly used in paediatric populations. The Researcher explained there is some variation in paediatric doses of midazolam. The Committee requested information explaining these are commonly used in New Zealand are included in the information sheet, so parents are assured.
6. The Committee requested section 8.5 of the data management plan is updated to only include relevant bullet points and specify future research related to the research question. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15*).

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

7. Please amend the information on page 5 to state that parents do not need to stay in the room to do the scale and the clinicians will do this also.
8. Please update the tables on page 8 and 9 to include specific examples of identified, coded and deidentified information (eg the video recordings).
9. Please make it clear that only coded data will be sent to Australia and no other countries.
10. Please specify what the data may be used for in the future.
11. Please remove any references to caregiver consent and specify parent / legal guardian.
12. Please include cultural statement acknowledging tapu of the head.
13. Please include ACC statement from the HDEC template.
14. Please complete the last bullet point on page 3 (“and there may be risks of injury or”).
15. Please remove the reference to flipping a coin and explain randomisation.
16. Please amend ‘you’ are invited to ‘your child on page 4.
17. Please amend the sentence on page 18 to state identifiable data will be kept for 10 years after the youngest participant turns 16.
18. Please transfer the information about Māori data sovereignty and making data available from the data management plan to the information sheet.
19. Please remove the statement on the consent form that it is the child’s choice as they will be too young to assent.

Decision

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

- Please address all outstanding ethical issues, providing the information requested by the Committee.
- Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17*).
- Please update the data management plan. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15*).

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Jessie Lenagh-Glue and Dr Ptries Herst.

5	Ethics ref:	2025 FULL 24537
	Title:	Validation of a Novel Tool for Assessing Experiences of Children with Psychological Distress and / or Behavioural Challenges
	Principal Investigator:	Mrs Mona Roper
	Sponsor:	Stand Tū Māia
	Clock Start Date:	28 November 2025

Mrs Mona Roper 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 encouraged the Researcher to share results of the study with participating practitioners, wider iwi and the community in which the work is being undertaken.

Summary of outstanding ethical issues

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

2. The Committee advised that caregivers are not authorised to give legal consent for children to participate in research and this must be done by a parent / legal guardian. The Committee requested study documentation is updated to specify this. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.21-6.30*).
3. The Committee requested the protocol is updated to include more information on what Stand Tū Māia does, such as the complex needs of the children served by the organisation, what types of practitioners are working there and any specific demographics of the children served. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8*).
4. The Committee advised that informed consent must be given for research activities to comply with the National Ethical Standards and information about what participation in the study involves must be provided to participants and/or guardians to obtain their consent to participate in the research. The Committee requested the information sheet is updated to include a statement advising participants they may not like some of the questions that will be asked and they do not need to answer them if they do not wish to. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17*).
5. The Committee requested the Researcher develop a safety plan in the protocol on how to respond to participant distress or other adverse findings arising in the research. This information needs to be in the information sheet so participants understand the process and what will happen. The Researcher described current processes and the Committee requested these are explained in the safety plan. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4*).

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

6. Please adapt the [HDEC information sheet template](#) as this contains prompts for everything required under the National Ethical Standards.

Decision

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



6	Ethics ref:	2025 FULL 24367
	Title:	CFWY003A12201: A randomized, double masked, placebo-controlled, multicenter, dose-range finding study to assess the efficacy and safety of FWY003 in patients with geographic atrophy secondary to age-related macular degeneration
	Principal Investigator:	Professor Anthony Wells
	Sponsor:	Novartis Pharma AG
	Clock Start Date:	28 November 2025

Ms Rachael Dawe and Ms Jaimi Clutterbuck 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 advised that clinical trials may not be terminated solely for commercial reasons in New Zealand.
2. The Committee noted the insurance certificate was due to expire at the end of 2026 and advised this would require renewal for the whole study duration.
3. The Committee advised as scientific aspects would not be discussed and no trade secret would be disclosed the threshold for a closed meeting under the Official Information Act 1982 was not met.

Summary of outstanding ethical issues

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

4. The Committee requested any advertising material is provided for review as this requires approval before use. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.10 – 11.13*).
5. The Committee noted software packages HEYEX and PyTorch are mentioned on the information sheet but are not detailed in the data management plan. Please update the data management plan and describe how data from this software will be managed. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15*).
6. The Committee queried how long information would be stored for. Under the Health Information Privacy Code identifiable information should not be kept for longer than necessary. Coded or deidentified information may be kept for longer without the privacy risk storing identified information has. Please ensure this information is in the data management plan and information sheet.
7. The Committee advised cold calling patients from a clinical database to invite them to participate in research is not appropriate. Information about the study such as a handout may be provided to patients at clinical appointments and then if they are interested in participating they can contact the research team. The Committee requested the protocol is updated to reflect this. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8*).

8. The Committee advised payment for participation is not considered unethical in New Zealand and clinical trials commonly offer some form of koha eg a cash payment or supermarket voucher. The Committee recommended including a koha for participation in addition to reimbursement for travel/parking expenses. The Researcher agreed to consult with the Sponsor. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.20 – 11.22*).
9. The Committee expressed concern at quality-of-life questionnaires being reviewed up to 5 days later in case someone has indicated distress or suicidal ideation. The Committee requested these are reviewed on the day they are completed and the information described in question E3.2 of the HDEC application form is transferred into the information sheet. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4*).

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

10. Please include detail on the type of molecule being tested so participants can be fully informed.
11. Please rephrase or explain what “dilating drops” are.
12. s 9(2)(b)(ii)
13. [REDACTED]
14. Please remove tablespoons when referring to blood/urine collection on page 6.
15. Please avoid use of the word “treatment” and state investigational product instead.
16. Please remove the reference to the Southern HDEC.
17. Please specify what the low, medium and high doses are.
18. Please rephrase “biohazard waste” in the context of biological samples and use culturally appropriate language.
19. Please include a statement acknowledging the tapu of the head and consent will be asked before touching any part of the head.
20. Please amend the statement on page 1 telling participants not to discuss the trial with others.
21. Please explain oophorectomy and salpingectomy.
22. Please advise that positive results for hepatitis and HIV are reported to the Medical Officer of Health on page 13.
23. Please use gender neutral language when discussing pregnancy.
24. Please amend Māori health support to Māori cultural support.
25. Please include more information about genetic testing for Māori. The Committee suggested adapting the HDEC intervention sheet template prompt regarding this.
26. Please use the second paragraph regarding GP notification (i.e. that it is mandatory)
27. Please include a clause on the consent form that the GP or current health provider will be notified of their participation in the trial.
28. Please state that the study drug has not been approved anywhere.
29. Please state which countries samples will be sent to and if participants want further detail (eg city) they may request this.

Decision

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

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



- Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17*).
- Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Cordelia Thomas and Dr Andrea Furuya.

7	Ethics ref:	2025 FULL 24578
	Title:	A Dose Escalation Study to Evaluate the Effect of SRP-1005 in Subjects with Huntington's Disease (INSIGHTT)
	Principal Investigator:	Professor Tim Anderson
	Sponsor:	Sarepta Therapeutics, Inc
	Clock Start Date:	28 November 2025

Ms Laura Paementier 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 Researcher confirmed participants would be in the early stages of Huntington's and all participants would have capacity to give consent.
2. The Committee queried the study's safety plan for distressing findings in the quality-of-life questionnaires. The Researcher explained suicidality is not uncommon in Huntington's patients and there is an established clinical pathway for managing this. The Researcher confirmed the questionnaire is completed by the research team face-to-face with the participant so responses are assessed in real time.
3. The Committee advised that a clinical trial may not be terminated solely for commercial reasons in New Zealand.
4. The Committee advised that data storage does not need to be 15 years and may be 10 years instead.

Summary of outstanding ethical issues

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

5. The Committee queried how much participants would be paid and advised it cannot approve the trial without this information. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.20 – 11.22*).

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

6. Please undertake a general revision to check for any formatting issues.
7. Please remove information about home health visits and Scout Clinical if they are not relevant to the study in New Zealand.
8. Please include an option for participants to choose to receive a lay summary of the study results.
9. Please amend the statement that karakia will not be available at collection to specify the participant may do this if they wish.



10. Please remove the reference to Skyhawk Therapeutics under Ownership Rights if this is not accurate.
11. Please state what the study payments are.
12. Please adapt the language around reimbursement on page 17 to be appropriate for a New Zealand context. The HDEC template may be adapted for this.
13. Please include a comment on the cultural issues around genetic testing for Māori in the optional genetic sheet.
14. Please include more information about the questionnaire on page 8. Please state that some of the questions may be upsetting and participants do not need to answer these unless they are a mandatory component of the research. Please adapt the response to question E3.2 in the HDEC application form into the PIS so participants are informed of the safety plan.
15. Please consider changing “handle it” to “tolerate it” on page 2.
16. Please correct the typo on page 20 (through / thought).
17. Please consider simplifying the schedule of assessment table to make it more user friendly (e.g. with colours or illustrations). The Committee suggested removing it from the main sheet text and including it as an appendix

Decision

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Jessie Lenagh-Glue and Dr Kate Parker.

8	Ethics ref:	2025 FULL 24615
	Title:	Exploring infraslow pink noise stimulation (IPNS) for the treatment of visual disorders: A proof-of-concept study
	Principal Investigator:	Dr Divya Adhia
	Sponsor:	University of Otago
	Clock Start Date:	28 November 2025

Dr Divya Adhia, Dr Dr. Selassie Tagoh and Dr Fransec March de Ribot 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.

Jessie Lenagh-Glue declared a potential conflict of interest but this was deemed minor and she was permitted to participate in the discussion.

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 if a power calculation had been done. The Researchers explained a power calculation has not been done as this is a pilot study and not intended to measure efficacy. Participant numbers had been determined by a statistician to make meaningful comparisons between groups. The Committee suggested adding this information to the protocol. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8*).
2. The Researchers confirmed there is no commercial interest in the study and it is investigator-led. The Committee suggested adding this to the protocol.
3. The Committee noted travel / parking reimbursement was capped at \$200 over 23 visits. The Committee advised participants should not be out of pocket for participating in research and any expenses they incur should be reimbursed. The Committee queried what accessible parking or travel options would be available and suggested offering an uber / taxi or Driving Miss Daisy option. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.20 – 11.22*).

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

4. Please remove the reference to lower back pain if this is not relevant.
5. Please state if the device is research only or if it has any other uses as part of standard of care.
6. Please include a diagram of the device so participants understand what its use involves.
7. Please clarify if coded information will also be stored on a server overseas.
8. Please expand the description of Māori data sovereignty to be specific to this study, e.g. how it was considered in the design of the study and who the information may be shared with.
9. Please replace the reference to the New Zealand Health Authority with Medsafe.
10. Please avoid use of the word 'treatment' as this is unproven research. The Committee suggested using 'study activities'.
11. Please review the 'early withdrawal visit' heading as this does not describe a visit. Please add in information about a visit or rename the heading. The Committee advised participants withdraw they may be asked to attend an early visit but it is their choice to attend.



12. Please clarify the status of vaping.
13. Please add a statement advising participants that if they get gel in their hair they will be able to clean it after.
14. Please clarify the risk of an allergic reaction is the gel.
15. Please use the ACC statement available on the HDEC information sheet template.
16. Please include a statement advising participants of the process should they indicate distress during or in their answers to any quality-of-life questionnaires.

Decision

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

4. Please address all outstanding ethical issues, providing the information requested by the Committee.
5. 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*).
6. 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 Neta Tomokino and Dr Rebekah Jaung.

9	Ethics ref:	2025 FULL 24588
	Title:	K9531-3104: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of KAI-9531 Administered Once Weekly in Participants Living with Obesity or Overweight and Diabetes
	Principal Investigator:	Dr Claire Thurlow
	Sponsor:	Kailera Therapeutics, Inc
	Clock Start Date:	28 November 2025

Dr Claire Thurlow and Ms Charlene Botha were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researchers confirmed the open label extension protocol has not been written yet.

Summary of outstanding ethical issues

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

2. The Committee queried what identifiable information about the participant is captured in the IQVIA platform. The Researcher stated they register with an email which is then linked to their study code and an app on their phone. The Committee expressed concern at the amount of personal information captured by the platform and its future uses (eg marketing) and requested quality of life questionnaires are completed on paper instead.
3. The Committee noted questionnaires ask about mood and suicidal ideation and there did not appear to be a safety plan to manage this. The Committee noted the protocol states participants must be referred to a mental health professional to determine whether they are discontinued from treatment. The Committee noted a referral may be inadequate if participants cannot be seen a timely manner and requested the Researchers develop a formal safety plan and detail it in the information sheet. The Researchers confirmed any quality-of-life questionnaires are assessed in real time and undertaken on-site with a research doctor. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4*).
4. The Committee queried how much the participant stipend will be. The Committee requested the Sponsor provide a justification for a stipend in a Phase 3 study. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.20*).
5. The Committee advised whakamā will likely be present in study participants. The Committee requested the Researchers update the protocol to include a section on responsiveness to Māori as the study involves accessing a lot of personal information in screening and how investigators will consider this. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.1 – 3.3*).

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

6. Please include a statement advising participants that some questions in the questionnaires may be upsetting and they do not need to answer them if they do not wish to.
7. Please add more information about the safety plan and what will happen if a participant indicates distress in one of the study questionnaires.
8. Please revise the information to state questionnaires will be done on paper.
9. Please include relevant risks from question E1 in the HDEC application form (pancreatitis etc).
10. Please include a statement advising the risk of weight gain upon cessation of the drug.
11. Please remove references to StudyHub and Greenphire if these will not be used in New Zealand.
12. Please avoid use of the word 'treatment' to avoid therapeutic misconception.
13. Please be consistent as the sheet refers to both study medication and study drug.
14. Please be consistent when referring to GP and 'usual doctor'
15. Please amend 'Māori health support' to 'Māori cultural support'.
16. Please include a cultural paragraph in the optional PIS.
17. Please remove the sentence that ethnicity is sensitive personal information as this is not the case in New Zealand.
18. Please include a statement advising that the study may not be terminated solely for commercial reasons.
19. Please include the risk that the study drug may decrease the effectiveness of oral contraceptives.
20. Please consider revising "You have greater than a 7-in-10 (70%) chance of receiving the study drug and less than a 3-in-10 (30%) chance of receiving placebo" as this can appear promotional because it emphasizes the advantage of receiving the study drug rather than neutrally explaining the allocation ratio.

Decision

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

7. Please address all outstanding ethical issues, providing the information requested by the Committee.
8. 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*).
9. 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 the full committee online.



10	Ethics ref:	2025 FULL 24163
	Title:	A Phase I, Randomised, Double-Blind, Placebo-Controlled, Single- and Multiple-Ascending Dose Study to Characterise the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of LY4088044 in Healthy Participants.
	Principal Investigator:	Dr Chris Wynne
	Sponsor:	Eli Lilly and Company
	Clock Start Date:	28 November 2025

Dr Chris Wynne, Ms Samantha Nie, Ms Julia O'Sullivan and Ms Kayla Malate were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried why women of childbearing potential are excluded. The Researchers stated it was due to a complex molecule with a novel mode of action and the Sponsor does not wish to risk a pregnancy.

Summary of outstanding ethical issues

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

2. The Committee queried the necessity of a pregnancy test for participants of non-child bearing potential and requested this is not performed if it is not required.
3. The Committee requested the data management plan is updated to include information on photographs, their storage and identifiability. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15*).

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

4. Please include a description of what a neurological examination consists of on page 7.
5. Please include a clause for the photograph in the consent form.
6. Please include information about any photographs and state whether tattoos or other identifying features (eg faces) will be blurred or made non-identifiable.
7. Please amend the information on page 16 to state the Medical Officer of Health and that the participant's GP will be notified.
8. Please consider revising the sentence about not eating or drinking food other than water.
9. g

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 data management plan. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15*).



11	Ethics ref:	2025 FULL 23900
	Title:	Aspire-201: Phase 2 Multi-center, Randomized, Open-label Study to Assess the Efficacy and Safety of AHB-137 in Nucleos(t)ide Analoguetreated Participants with HBeAg Negative Chronic Hepatitis B in the Asia Pacific Region.
	Principal Investigator:	Professor Edward Gane
	Sponsor:	AusperBio Therapeutics Inc
	Clock Start Date:	28 November 2025

Professor Edward Gane, Dr Christian Schwabe, Ms Samantha Nie, Ms Julia O'Sullivan and Ms Kayla Malate were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

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

1. Please insert the missing medication name.
2. Please insert the missing word on page 3 ("long-").
3. Please review 'hereforth' on page 4.
4. Please avoid use of the word 'treatment phase' to avoid therapeutic misconception, eg 'study phase', 'medication phase'.
5. Please elaborate on page 5 when it discusses discontinuation criteria and state the study doctor will discuss with the participant.
6. Please state what a neurological examination consists of.
7. Please transfer the information on page 17 about supporting a participant who indicates distress to page 7 when the questionnaire is discussed.
8. Please clarify when the payment clause is applicable or remove the sentence is this is not required.

Decision

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

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

General business

The meeting closed at 4:30pm.

