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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 12 December 2023 |
| **Zoom details:** | 973 875 6003 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 10:30 - 11:00am | 2023 FULL 18956 | V2- Acuity 200 (fluoroxyfocon A) Orthokeratology Contact Lens Safety and Effectiveness Study | Dr. Jagrut Lallu | Maree / Barry |
| 11:00 - 11:30am | 2023 FULL 19211 | LSD microdosing in menstruating persons with and without Premenstrual Syndrome/Premenstrual Dysphoric Disorder | Associate Professor Suresh Muthukumaraswamy | Devonie / Neta |
| 11:30am - 12:00pm | 2023 FULL 19210 | Pregabalin for the Treatment of CANVAS Associated Chronic Cough | Associate Professor Richard Roxburgh | Dianne / Patries |
| 12:00 - 12:30pm | 2023 FULL 18815 | CLIN-60190-454: A Long-Term Study of Elafibranor in Adult Participants with Primary Biliary Cholangitis | Dr Jeffrey Ngu | Dominic / Amy |
| 12:30 - 1:00pm |  | BREAK (30 mins) |  |  |
| 1:00 - 1:30pm | 2023 FULL 19064 | A Phase 2/3 Study in Pediatric Subjects with Biliary Atresia, Post-hepatoportoenterostomy | Dr Helen Evans | Maree / Devonie |
| 1:30 - 2:00pm | 2023 FULL 19068 | The AttaCH Study | Prof Paul Hofman | Dominic / Barry |
| 2:00 - 2:30pm | 2023 FULL 19041 | DEEPER Coronary Pilot Study | Dr Scott Harding | Patries / Neta |
| 2:30 - 3:00pm | 2023 FULL 19340 | Effect of brain stimulation waveforms on tinnitus. | Professor Dirk De Ridder | Dianne / Amy |
| 3:00 - 3:30pm |  | BREAK (30 mins) |  |  |
| 3:30 - 4:00pm | 2023 FULL 19344 | A Mate Wareware Prevalence Study for Māori | Dr Makarena Dudley | Barry / Neta |
| 4:00 - 4:30pm | 2023 FULL 18960 | ARODM1-1001: A Study to Investigate the Safety and Tolerability of ARODM1 in Participants with Type 1 Myotonic Dystrophy with Single or Multiple Ascending Doses. | Dr Cory Sellwood | Maree / Amy |
| 4:30 - 5:00pm | 2023 FULL 18861 | RCT2100-101: A Study To Investigate the Safety, Tolerability and Bioavailability of Single Ascending Doses of RCT2100 in Healthy Participants | Dr. Rohit Katial | Dianne / Devonie |
| 5:00 - 5:30pm | 2023 FULL 19206 | SGB-9768-001: A Study to Investigate the Safety and Tolerability of SGB-9768 in Healthy Participants | Dr Alex Cole | Dominic / Patries |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Dr Devonie Waaka  | Non-lay (Intervention studies)  | 18/07/2016  | 18/07/2019  | Present  |
| Mr Dominic Fitchett  | Lay (the Law) (Chair) | 05/07/2019  | 05/07/2022  | Present  |
| Ms Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Ascc. Prof Nicola Swain | Non-lay (Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Apologies |
| Ms Dianne Glenn | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Neta Tomokino | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Apologies |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Mrs Carla Strubbia | Non-lay (Intervention Studies) | 03/07/2023 | 02/07/2026 | Apologies |
| Dr Patries Herst  | Non-lay (Intervention studies)  | 22/05/2020  | 22/05/2023  | Present  |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |

## Welcome

The Chair opened the meeting at 10:00am with a karakia and welcomed Committee members, noting that apologies had been received from, Ms Neta Tomokino, Associate Professor Nicola Swain and Mrs Carla Strubbia

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mr Barry Taylor of the Northern B HDEC and Dr Patries Herst of the Central HDEC 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 14 November 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 18956** |
|   | Title:  | Clinical Evaluation of Safety and Effectiveness for Acuity 200™ (fluoroxyfocon A) Orthokeratology Contact Lens for Overnight Wear |
|   | Principal Investigator:  | Dr. Jagrut Lallu |
|   | Sponsor:  | Acuity Polymers, Inc. |
|   | Clock Start Date:  | 30 November 2023 |

Dr Jagrut Lallu and Mr Bret Andre 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 Researcher confirmed Dr Jagrut Lallu is the study’s coordinating investigator and would be responsible for the management and conduct of the study in New Zealand.
2. The Committee advised that if a participant under 16 has sufficient capacity to provide informed consent to participate in the study (ie can understand the information sheet and the study) they are entitled to provide their own informed consent and parental consent would not be required.

Summary of outstanding ethical issues

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

1. The Committee requested the Researcher supply an additional simplified assent form for younger children. The Committee suggested this could be more pictorial and be used for children who would better understand a simplified form and did not have to be used strictly by age. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.22).*
2. The Committee requested the Researcher supply a certificate of professional indemnity. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.6).*
3. The Committee requested the Researcher reimburse participants for travel and other costs associated with visits (eg petrol voucher or taxi fare). The Committee requested the Researcher include information on this in the participant information sheet.
4. The Committee requested the Sponsor authorise the system in EthicsRM. The sponsor authorisation question can be updated when responding to the provisional approval.
5. The Committee requested the Researcher review section 9.1 of the data management plan and ensure any data generated during the study is kept for at least 10 years after the youngest participant turns 16. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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

1. Please insert headings into each information stating what they are (eg ‘Parent / Guardian sheet).
2. Please insert a clarification at the beginning of the parent / guardian sheet to state when the sheet refers to ‘you’ it refers to ‘you or your child’.
3. Please remove the researcher instruction box from page 1.
4. Please amend the statement on page 3 on participants being chosen to participate to state they are ‘invited’ to participate.
5. Please remove any ‘yes / no’ tick boxes on the consent form unless they are truly optional (ie the participant can answer ‘no’ and still participate).
6. Please insert an optional ‘yes / no’ tick box on the consent form for participants to request a copy of their individual results.
7. Please insert an optional ‘yes / no’ tick box on the consent form for participants to request a lay summary of the study results when available.

**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 obtain Sponsor authorisation of the study in the EthicsRM system.
4. Please supply evidence of professional indemnity for the coordinating investigator *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.6).*
5. Please update the data management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Barry Taylor and Dr Maree Kirk.

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| **2**   | **Ethics ref:**   | **2023 FULL**  |
|   | Title:  | Assessing the effects of LSD microdosing in menstruating persons with and without Premenstrual Syndrome/Premenstrual Dysphoric Disorder |
|   | Principal Investigator:  | Associate Professor Suresh Muthukumaraswamy |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 30 November 2023 |

Associate Professor Suresh Muthukumaraswamy was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee expressed concern at running both studies simultaneously and stated a preference to conduct them sequentially. The Committee requested the Researcher supply the SCOTT review when available.
2. The Committee requested the Researcher amend the error in the information sheet which states Ritalin is placebo. The Committee noted if participants think they may be taking Ritalin then all associated risks with it will need to be included in the information sheet.
3. The Committee requested the Researcher update the protocol to state the genotyping in the schedule of assessments is subject to an optional additional consent.
4. The Committee requested the Researcher update the protocol to include the reproductive status questionnaire during screening.
5. The Committee requested the Researcher correct the typo in section 7.1 of the data and tissue management plan which states “All tissue samples will be labelled with identifiers and considered deidentified”.
6. The Committee requested the Researcher update section 12 of the data and tissue management plan to state any assessments participants have that do not affect study blinding should be provided to participants on request.
7. The Committee requested the Researcher register the trial on a WHO-approved clinical trials registry prior to commencement.
8. The Committee requested the Researcher supply commercial clinical trial insurance for the study.
9. The Committee requested the Researcher supply evidence of professional indemnity for the coordinating investigator.
10. The Committee requested the Researcher supply responses to the following questions which were missed on the main application form. These questions can be answered by changing the response in question E10 to ‘Yes my study is commercially sponsored’ when responding to the provisional approval.
	1. Is a sponsor, manufacturer or distributor of any medicine or item being trialled receiving the study data set and/or supplying the investigational product / device?
		* Please explain your answer
	2. In the event of injury to a participant in your intervention study, will compensation potentially be available for all of the following entitlements, which would be available through ACC?
		* rehabilitation (comprising treatment, social rehabilitation, and vocational rehabilitation)
		* first week compensation
		* weekly compensation
		* lump sum compensation for permanent impairment
		* funeral grants, survivors' grants, weekly compensation for the spouse or partner, children and other dependants of a deceased claimant, and child care payments
	3. Please confirm that:
		* insurance cover will be in place for the duration of the study in New Zealand, and
		* participation in the trial does not affect the right of participants to pursue legal remedies in respect of any injury alleged to have been suffered as a result of participation.

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

1. Please include a statement advising that participant reimbursement is prorated.
2. Please include a statement in the information sheet advising that the study team believes the teratogenic risk of LSD is low but this has not been proven and participants should avoid getting pregnant by following the contraception guidance.
3. Please insert frequency data for adverse events in the information sheet and whether anyone has been withdrawn from previous studies due to adverse event. This can include comment that adverse events are decreasing as dosing is being adjusted based on previous data.
4. Please undertake a general revision to use lay-friendly language.
5. Please define LSD as lysergic acid diethylamide (LSD) the first time it is used then refer to it as LSD subsequently.
6. Please remove the repetition of “during the study” on page 2.

**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).
4. Please supply the SCOTT review.
5. Please update the data and tissue management plan *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17)*:
6. Please supply evidence of ACC-equivalent commercial clinical trial insurance*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1)*
7. Please supply evidence of professional indemnity for the coordinating investigator *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.6).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Dr Devonie Waaka.

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| **3**   | **Ethics ref:**   | **2023 FULL 19210** |
|   | Title:  | Pregabalin for the Treatment of CANVAS Associated Chronic Cough |
|   | Principal Investigator:  | Associate Professor Richard Roxburgh |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 30 November 2023 |

Associate Professor Richard Roxburgh, Ms Juno Collins and Mr Rory Burnell 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 Researcher agreed to increase travel and parking costs to $300.
2. The Researcher confirmed the study has been registered in 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 the Researcher investigate whether it is feasible to supply study participants with a unique study email address for the app used in the study so participants do not need to provide their personal email to a third-party.
2. The Committee requested the Researcher update the exclusion criteria to exclude people with a history of or current issues with drug abuse or misuse and concomitant use of opioids.
3. The Committee requested the Researcher update the protocol to include a dose reduction for participants with mild to moderate renal impairment.
4. The Committee suggested the Researcher consider whether the clinician-administered questionnaire could be gender-matched.

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

1. Please insert common, uncommon and rare side effects of pregabalin and remove the reference to the Mayo website.
2. Please amend the statement on progressive clumsiness to specify that participants are being recruited to treat a chronic cough associated with CANVAS syndrome.
3. Please correct the typo on page 2 (‘thro’).
4. Please include the blackbox warning in the Medsafe data sheet advising pregabalin is a potential drug of misuse, abuse and dependence.
5. Please include a reference to use of blood samples in the cultural statement on page 12.
6. Please define what a washout period is when it is first mentioned.
7. Please undertake a general revision to correct any spelling errors.
8. Please amend any references to Cook Island Māori to Cook Islands Māori.
9. Please include a statement advising participants their GP will receive information about their dosing so they can have continued access after the trial if they receive benefit.
10. Please amend the ‘first language’ statement in the consent form to ‘preferred language’ and include it at the beginning of the information sheet.
11. Please include a statement advising that the study drug will be withdrawn gradually at the end of the treatment period (eg up to two weeks).
12. Please include a statement advising participants at what point their data will be deidentified.
13. Please remove the optional ‘yes / no’ tickbox for notifying the participant’s GP as this should be a mandatory component of study participation.

**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 Dianne Glenn and Dr Patries Herst.

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| **4**   | **Ethics ref:**   | **2023 FULL 18815** |
|   | Title:  | A Phase III Randomised, Parallel-Group, Double-Blind, Placebo-Controlled, Two-Arm Study to Evaluate the Efficacy and Safety of Elafibranor 80 mg on Long-Term Clinical Outcomes in Adult Participants with Primary Biliary Cholangitis (PBC). |
|   | Principal Investigator:  | Dr Jeffrey Ngu |
|   | Sponsor:  | Ipsen Bioscience, Inc |
|   | Clock Start Date:  | 30 November 2023 |

Dr Jeffrey Ngu was not 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 the inclusion criteria was 18 years or over but the answer to D5 in the application form referred to parents or guardians. Please confirm that only adults 18 or over are eligible to participate.
2. The Committee requested the Researcher update the protocol so at least part of the consenting process is undertaken by research staff to allow participants the opportunity to say no to someone who is not their usual clinical provider.
3. The Committee requested the Researcher supply a researcher safety plan for home visits.
4. The Committee noted the pregnant partner information sheet has not been reviewed. If a participant or their partner becomes pregnant during the study, please submit this sheet as an amendment.
5. The Committee noted per NEAC Standard 10.15, participants who benefit from a study intervention during a clinical trial should have ongoing access to the study intervention for as long as it is clinically beneficial. Please provide a justification for not providing participants with ongoing access to IMP, particularly given the length of the clinical trial.
6. The Committee requested the Researcher ensure good quality ethnicity data relevant to the New Zealand population is collected, in addition to protocol-specified race / ethnicity data if necessary.
7. The Committee requested clarification on whether the optional banked PK samples will be used for different purposes than the optional biobanking samples. Use of the PK samples appears to be the same as the biobanked samples in the PISCF.
8. The Committee requested an explanation on the difference between the two submitted leaflets (Versioned 1a and 1b) and how they will be used.
9. The Committee requested clarification on whether Medidata responses are linked with the participant's email address (visible in the login screenshot in document 26), or whether participants will be provided with a study-specific email address.
10. The Committee requested GP notification is a mandatory component of study participation.

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

1. Please include a separation between the body of the text and the footer on all pages to aid clarity.
2. Please undertake a general revision to apply consistent formatting and line spacing throughout the sheet.
3. Please define terms the first time they are used and then use the abbreviation (eg PBC).
4. Please advise that a karakia will not be available at the time of tissue destruction on page 10.
5. Please remove the ‘yes / no’ tick boxes regarding informing the participant’s GP on the consent form as this should be mandatory.
6. Please include information on any serious side effects in animal studies (eg hepatomegaly, hepatocellular hypertrophy and liver carcinoma) and note the study will monitor liver function.
7. Please review thoroughly and delete repeated information (e.g. the statement that treatment will be for up to 7 years is included multiple times throughout the document) and acronym explanations.
8. Please delete technical names for questionnaires.
9. Please move optional sample collection and use to a separate subheading for clarity.
10. Please state that biobanked samples will not be used for unrelated research.
11. Please clarify whether genetic analyses may be performed on biobanked samples. If this is possible, genes and genetic research should be explained in lay terms, the breadth of analysis stated, and any additional risks associated with genetic analysis summarised.
12. Please state whether participants will be provided with the results of any future testing.
13. If New Zealand participants will not be asked to sign and date a separate consent for HIV testing, please delete the statement on page 8.
14. Please remove “In case you do not want to be informed about such findings, please tell the study doctor” from Section 4.1 on page 9; participant and GP notification of findings of clinical significance is mandatory.
15. Please amend the paragraph describing prohibited concomitant medications for a lay readership (e.g. hepatotoxic).
16. Please clarify whether there are any potentially serious but less common risks of elafibranor. If yes, these should be included in the PISCF.
17. Please clarify whether future use of health data generated in the study can be optional; if not, please delete the applicable tick box.
18. Please remove any references to services not available in New Zealand (eg Accellacare if this is not available).

**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 Dominic Fitchett and Ms Amy Henry.

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| **5**   | **Ethics ref:**   | **2023 FULL 19064** |
|   | Title:  | A Randomized, Double-blind, Placebo-controlled, Phase 2/3 Study to Assess the Efficacy, Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Obeticholic Acid Compared to Placebo in Pediatric Subjects with Biliary Atresia, Post-hepatoportoenterostomy |
|   | Principal Investigator:  | Dr Helen Evans |
|   | Sponsor:  | Intercept Pharmaceuticals Inc. |
|   | Clock Start Date:  | 30 November 2023 |

Dr Helen Evans and Ms Margaret Joppa 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 prevalence of the disease in Māori. The Researcher stated a study published in 2018 showed the incidence in New Zealand for Māori was about 1 in 5,000 births, 1 in 8,000 births for Pasifika and 1 in 18,000 births in New Zealand Europeans. The Researcher stated on average New Zealand had a rate of about 1 in 8,000 births making the condition more common in New Zealand than many other countries. The Committee noted this information would have been helpful to include in the application 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 requested part of the informed consent process is undertaken by research staff not involved in the usual clinical care of the participant to allow them an opportunity to say no to someone who is not their clinician.
2. The Committee requested the Researcher ensure good quality ethnicity data relevant to the New Zealand population is collected, in addition to protocol-specified race / ethnicity data if necessary.
3. The Committee requested the Sponsor authorise the form on the EthicsRM system. The sponsor authorisation question can be updated when responding to the provisional approval.
4. The Committee requested the Researcher ensure data is kept for 10 years after the youngest participant turns 16.

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

1. Please revise ‘subject’ to ‘participant’ throughout the information sheet and any other participant-facing material (including the study title).
2. Please remove spoon measurements for blood and state the amount taken in mL, rounded up to the nearest 5 or 10 value.
3. Please include the explanation of elastography contained in the mature assent form in the main PIS as well.
4. Please simplify the schedule of assessments by stating blood tests and the total volume of blood that will be drawn over the study.
5. Please remove the ‘with your consent’ regarding informing the participant’s GP on page 13 as this should be mandatory.
6. Please simplify the cultural statement in the simplified assent form.
7. Please amend ‘Māori health support’ to ‘Māori cultural support’.

**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).
4. Please update the data management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Maree Kirk and Dr Devonie Waaka.

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| **6**   | **Ethics ref:**   | **2023 FULL 19068**  |
|   | Title:  | AttaCH: A Phase 2, Multicenter, Long-Term, Open Label Extension Trial Evaluating Safety, Tolerability, and Efficacy of Subcutaneous Doses of TransCon CNP Administered Once Weekly in Children and Adolescents with Achondroplasia |
|   | Principal Investigator:  | Prof Paul Hofman |
|   | Sponsor:  | Ascendis Pharma |
|   | Clock Start Date:  | 30 November 2023 |

Professor Paul Hofman and Ms Kayla Briggs 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 it is not permissible to terminate a trial in New Zealand solely for commercial reasons.

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 the Coordinating Investigator’s certificate of indemnity is due to expire on 31 January 2024 and an updated certificate would need to be supplied via the amendment pathway.
2. The Committee noted a statement in page 10 of the PIS about pregnancy and collection of health information from an infant up to six months. The Committee noted this would require a separate consent after the birth of the infant.
3. The Committee queried whether any participants would be likely to have capacity to provide informed consent and not need parental consent and assent. The Researcher stated it was likely and participants capable of providing informed consent would do so. The Committee requested the Researcher create a new version of the information sheet for these participants.
4. The Committee noted the disability questions in the application form were answered with not applicable and requested these be appropriately answered.
5. The Committee requested the Sponsor authorise the study in the EthicsRM system. The sponsor authorisation question can be updated when responding to the provisional approval.
6. The Committee noted the Sponsor’s insurance had provision for only two participants and advised if more than two participants are intended to be recruited the insurance would need to be updated. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
7. The Committee requested the Researcher update the data management plan to specify that no future research is intended *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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

1. Please remove the explanation of what achondroplasia is as participants will be familiar with what it is.
2. Please change ‘may’ to ‘will’ when discussing reimbursement of travel expenses.
3. Please remove the statement on page 15 regarding accessing study specific information withdrawing participants as this should not be applicable in a single blind study.
4. Please amend the statement regarding access to the study drug after the study ends on page 16 to specify it is until participants stop growing.
5. Please remove the reference on page 8 regarding storage and use of blood samples for future research.
6. Please review the language in the pregnancy information on page 10 as it switches between discussing children and pregnant women to specify it is referring to the participant.
7. Please include a statement on the assent form saying the medication being tested is the same as the other study and will be given in the same way with the same frequency.
8. Please include a statement on the assent form advising that the tests will be the same as the previous study.
9. Please change ‘how do I give my consent’ to ‘how do I give my assent’ on the final page of the assent form for children who cannot read.

**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).
4. Please update the data management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Mr Barry Taylor.

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| **7**   | **Ethics ref:**   | **2023 FULL 19041** |
|   | Title:  | A Pilot study of the Drug-Eluting Coronary Spur StEnt System as a Primary trEatment for In-stent Restenosis of the CORONARY Arteries (DEEPER CORONARY). |
|   | Principal Investigator:  | Dr Scott Harding |
|   | Sponsor:  | Reflow Medical, Inc |
|   | Clock Start Date:  | 30 November 2023 |

Dr Scott Harding, Ms Di Middleditch, Ms Amanda Isula and Ms Carolyn Mascho 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 requested the Researcher collect New Zealand ethnicity data at a site level for final reporting to HDEC. The Researcher confirmed they had processes in place for this.

Summary of outstanding ethical issues

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

1. The Committee requested the Researcher update the data management plan to specify that data collected up to the point of withdrawal will continue to be used. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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

1. Please include the schedule of assessments from the protocol in the participant information sheet.
2. Please include the more detailed picture of the stent from the protocol in the participant information sheet.
3. Please amend the list of side effects on page 5 of the information sheet to move death to the endof the list.
4. Please remove ‘within stent restenosis of the coronary arteries’ from the blackbox warning to specify that this is the first time the device has been used.
5. Please include information explaining that a related version of the device has been tested previously in larger arteries.
6. Please include a statement in the sheet advising that representatives from the Sponsor will observe the first procedures.
7. Please amend the statement that the device is not available for sale to specify it is not approved for use.
8. Please include a statement advising that procedures and results from the study will be included in the participant’s medical record.
9. Please remove the statement of stigmatisation on page 9 as this is not relevant for the study.
10. Please remove the ‘yes / no’ tick boxes regarding informing the participant’s GP as this is a mandatory component of study participation.

**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).
4. Please update the data management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Dr Patries Herst.

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| **8**   | **Ethics ref:**   | **2023 FULL 19340** |
|   | Title:  | A parallel-arm comparison of three noise stimulation waveforms for modulation of tinnitus loudness and intrusiveness. |
|   | Principal Investigator:  | Professor Dirk De Ridder |
|   | Sponsor:  | The University of Otago |
|   | Clock Start Date:  | 30 November 2023 |

Professor Dirk De Ridder and Dr Divya Adhia 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 soon quality of life questionnaires would be reviewed by the research staff. The Researcher stated the data would be analysed within 2 – 3 days of collection and if there are concerns the participant and their GP will be informed. The Researcher stated a psychiatrist in the team is available to provide immediate support. The Researcher confirmed depression scores from the questionnaires would be calculated immediately.

Summary of outstanding ethical issues

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

1. The Committee requested the Researcher register the trial in a WHO-approved clinical trials registry prior to commencement.
2. The Committee requested the Researcher update the data management plan to specify that participants who fail screening will have their data destroyed. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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

1. Please remove the reference to reimbursement for ‘time’ as this may have tax implications.
2. Please insert a statement advising that deidentified data will be sent overseas.
3. Please specify that hairspray should not be used when the sheet advises participants to avoid hair products.
4. Please correct the reimbursement in the information sheet and the consent form.
5. Please include information that reimbursement will be prorated if participants withdraw from the study early.
6. Please revise the statement “If one of the two stimulation waveforms is shown to help tinnitus, you will be eligible to receive this in a follow-up study” to state “if the study suggests one may be helpful”.
7. Please revise the reference to seizures being minimal risk in the risks section to state the risk of seizure is minimal.
8. Please include a statement advising participants that their GP will be informed of any abnormal results.
9. Please review the statements regarding future use of data. The sheet states any future use is optional and the consent form has a tick box for unrelated research only.

**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, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
* please register the trial on a WHO-approved clinical trials registry.

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| **9**   | **Ethics ref:**   | **2023 FULL 19344** |
|   | Title:  | He Rapunga Hauora mō te Mate Wareware: A Prevalence Study |
|   | Principal Investigator:  | Dr Makarena Dudley |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 30 November 2023 |

Dr Makarena Dudley, Professor Ngarie Kerse and Dr Oliver Menzies were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried whether participation would be in the best interests of a participant who is not able to provide informed consent and if the intended questions regarding mental health could cause distress. The Researcher stated an assessment and conversations in a participant’s preferred language would be beneficial to that person and if issues of depression or anxiety were identified an appropriate clinical response would be organised. The Researcher confirmed interviewers will have a nursing or mental health background and have previous experience integrating with local services when required.
2. The Committee queried the scenario of a participant who did not have capacity to provide informed consent and lived alone or did not have whānau or relatives available to discuss the study with the researchers. The Researcher agreed these participants would not be included in the study. The Committee advised it is permissible to collect minimal data in an anonymised form (eg a 75-year-old male was unable to be consented).
3. The Researcher confirmed the interviews will not be recorded.

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 raised concern at the whānau agreement form as it resembles proxy consent which cannot be used to enrol an adult into research in New Zealand. The Committee stated the final page which asks would the participant wish to partake in the research to the best of their knowledge is acceptable, but the rest of the form reads as if a whānau member is providing consent on behalf of the participant. The Committee advised the Researcher that participation needs to be in the best interests of the participant and the Researcher’s duty is to ascertain their wishes as much as possible from discussion with whānau. The Committee requested the sheet is revised so it is providing information about the trial to whānau and then asks if they believe the participant would provide informed consent to participate if they were able to do so. The Committee requested statements such as “I agree” are removed from the sheet as these imply proxy consent.
2. The Committee requested the Researcher add contact information to the flyer for people to contact the study in advance to opt-out. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*
3. The Committee requested the Researcher update the data management plan to remove the HDEC template instructions. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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

1. Please undertake a general revision of the kaumātua and whānau information sheets to simplify technical terms.
2. Please include information on whether kaumātua and whānau can see each other’s responses.
3. Please include information regarding accessing health information and data linking in the sheet. There is a clause in the consent form for this but no information in the sheet.
4. Please remove ‘yes / no’ tick boxes from the consent form unless the clause is truly optional (ie the participant can answer ‘no’ and still participate).
5. Please remove the ACC statement as this is not required for an interview study.

**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 flyer, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*
4. Please update the data management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Mr Barry Taylor.

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| **10**   | **Ethics ref:**   | **2023 FULL 18960** |
|   | Title:  | A PHASE 1/2A DOSE-ESCALATING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF ARO-DM1 IN SUBJECTS WITH TYPE 1 MYOTONIC DYSTROPHY WHO ARE ≥18 TO ≤65 YEARS |
|   | Principal Investigator:  | Dr Cory Sellwood |
|   | Sponsor:  | Arrowhead Pharmaceuticals, Inc |
|   | Clock Start Date:  | 30 November 2023 |

Dr Cory Sellwood, Ms Holly Thirlwall, 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 Researcher confirmed the fee for referring neurologists would a standard rate by time spent and not the number of participants enrolled.
2. The Researcher confirmed Māori consultation was in progress parallel to the HDEC application.
3. The Researcher confirmed the timing of reimbursement was flexible given the long duration of the trial.
4. The Committee requested the Researcher collect New Zealand ethnicity data at a site level for final reporting to HDEC. The Researcher confirmed they had processes in place for this and would update the template to include this language.
5. The Researcher confirmed quality of life questionnaires would be reviewed at the time of completion to identify any concerning responses.
6. The Researcher confirmed specialist neurology input for the study was available if required.
7. The Researcher confirmed a contracted neurosurgeon would perform the muscle biopsies.

Summary of outstanding ethical issues

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

1. The Committee requested the Researcher update section 8.4 of the data and tissue management plan to specify future unrelated research will only be undertaken subject to an additional optional consent. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

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

1. Please undertake a general revision to simplify the text and remove technical terms.
2. Please remove the information explaining Type 1 Myotonic Dystrophy as participants will be familiar with it and replace it with a simple statement advising participants are being invited to take part in the study due to having MD1 and the study offers a drug to treat it.
3. Please undertake a general revision to remove any repetition.
4. Please correct the typo on the first page of the part 2 PIS to specify it is part 2 and not part 1.
5. Please include the information regarding sentinel dosing, the chances of randomisation and placebo in the PIS for part 2.
6. Please remove the repetition of voluntariness on the future unspecified research form.

**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 and tissue management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

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| **11**   | **Ethics ref:**   | **2023 FULL 18861** |
|   | Title:  | A Phase 1, Single-Center Study Evaluating the Safety, Tolerability, and Biodistribution of RCT2100 with Single-Ascending Doses in Healthy Participants |
|   | Principal Investigator:  | Dr. Rohit Katial |
|   | Sponsor:  | ReCode Therapeutics Inc. |
|   | Clock Start Date:  | 30 November 2023 |

Dr Rohit Katial, Ms Kayla Malate, Ms Julia O’Sullivan and Ms Holly Thirlwall 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 Researcher confirmed the Coordinating Investigator would travel to the Hamilton site to manage an adverse event if required.
2. The Committee requested the Researcher collect New Zealand ethnicity data at a site level for final reporting to HDEC. The Researcher confirmed they had processes in place for this.

Summary of outstanding ethical issues

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

1. The Committee requested the ‘paid clinical trials’ and ‘join a paid clinical trial at NZCR’ headlines are removed from advertising options.
2. The Committee requested Medsafe and HDEC logos are not used in any advertising material.
3. The Committee noted the insurance certificate lists cover for 32 participants and up to 48 participants are intended to be recruited. The Committee noted screen failures and reserve participants are not covered. The Committee requested this is amended to cover all participants. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
4. The Committee requested the ‘register here’ button contains information about the study and not about reimbursement. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.13).*
5. The Committee requested the Researcher update the section 9.3 of the data and tissue management plan to specify the countries data will be sent to. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

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

1. Please insert the statement regarding an interpreter on the consent form to the beginning of the information sheet.
2. Please include a link to the Medicines New Zealand industry guidelines for compensation when these are referred to.
3. Please include an explanation of mRNA on page 2 and specify the lipid nanoparticles contain the code that cells use to produce a functional CFRT transporter that produces thin slippery mucous.

**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 advertisements, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.13).*
* please update the data and tissue management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*
* please update the insurance certificate *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*

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| **12**   | **Ethics ref:**   | **2023 FULL 19206** |
|   | Title:  | A phase 1, randomized, double-blind, placebo-controlled single ascending dose study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of subcutaneously administered SGB-9768 in healthy volunteers |
|   | Principal Investigator:  | Dr Alex Cole |
|   | Sponsor:  | Suzhou Sanegene Bio Inc. |
|   | Clock Start Date:  | 30 November 2023 |

Dr Alex Cole, Ms Kayla Malate, Ms Julia O’Sullivan and Ms Holly Thirlwall 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 Researcher agreed the Wellington satellite site would not be used as doctor support would not be available at all times.

Summary of outstanding ethical issues

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

1. The Committee requested the ‘register here’ button contains information about the study and not about reimbursement. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.13).*
2. The Committee requested the Researcher update the section 8.4 of the data and tissue management plan to specify future research will be undertaken on samples subject to an additional optional consent. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

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

1. Please include information regarding the increased risk of infection due to how the drug works and how this will be managed (eg vaccination, antibiotics and monitoring of early signs).
2. Please remove the following statement from the future research PIS: “If you decide to no longer take part in the substudy or are taken off the substudy by your study doctor, future research samples will still be kept and may be used for future testing unless you request for your samples to be destroyed when asked upon your withdrawal”.

**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 advertisements, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.13).*
* please update the data and tissue management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

## General business

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

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| **Meeting date:** | 13 February 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 5:00pm with a karakia.