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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 04 February 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11.30am-12.00pm | 2024 FULL 21758 | An Open-Label Extension Study of Subjects who Received an Avalyn Inhaled Antifibrotic Agent | Dr Margaret Wilsher | Mr Jonathan Darby & Leesa Russell |
| 12.00-12.30pm | 2024 FULL 19786 | EASi-KIDNEY (Studies of Heart & Kidney Protection with BI 690517 in combination with empagliflozin) | Associate Professor Janak de Zoysa | Ms Maakere Marr & Mr Barry Taylor |
| 12.30-1.00pm | 2024 FULL 20135 | Latte Dosage Early School-Age Outcomes Study | Dr Elizabeth Oliphant | Ms Alice McCarthy & Dr Amber Parry Strong |
| 1.00-1.30pm | 2024 FULL 21243 | CHAPTER-3: A randomised trial of deucrictibant prophylactic treatment against HAE attacks in adults and adolescents. | Associate Professor Hilary Longhurst | Ms Kate O'Connor & Ms Joan Pettit |
|  | *Break (10)* |  |  |  |
| 1.40-2.10pm | 2024 FULL 21768 | CHAPTER-4: A long term trial of deucrictibant treatment in prophylaxis against HAE attacks in adults and adolescents. | Associate Professor Hilary Longhurst | Ms Kate O'Connor & Ms Joan Pettit |
| 2.10-2.40pm | 2024 FULL 21716 | A Long-term Extension Study of Dazodalibep in Participants with Sjögren’s Syndrome | Dr Sunil  Kumar | Mr Jonathan Darby & Leesa Russell |
| 2.40-3.10pm | 2024 FULL 21891 | Brain network stimulation for chronic low back pain. | Dr Divya Adhia | Ms Maakere Marr & Mr Barry Taylor |
|  | *Break (10)* |  |  |  |
| 3.20-3.50pm | 2024 FULL 21770 | A study to assess Zasocitinib in subjects with active Psoriatic Arthritis | Dr Nigel Gilchrist | Ms Alice McCarthy and Dr Amber Parry Strong |
| 3.50-4.20pm | 2024 FULL 21885 | A Phase Ib, Randomized, Placebo-Controlled Study to evaluate the Safety and Tolerability of Solexan™ when Administered Topically to Shingles Lesions | Dr Jackie Kamerbeek | Ms Kate O'Connor & Ms Joan Pettit |
| 4.20-4.50pm | 2025 FULL 22086 | CBC006A1101: A Study to Evaluate BC-006 in Adult Volunteers with Obesity | Dr Jane Kerr | Mr Jonathan Darby & Leesa Russell |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Ms Kate O’Connor  | Lay (Ethical/Moral reasoning) (Chair) | 13/08/2021 | 16/08/2024 | Present |
| Mrs Leesa Russell | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Apologies  |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Ms Alice McCarthy | Lay (the Law) | 22/12/2021 | 22/12/2024 | Present |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Present |
| Dr Amber Parry-Strong | Non-Lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning)  | 13/08/2021 | 13/08/2024 | Present |
| Ms Catherine Garvey | Lay (the Law)  | 19/03/2019 | 19/03/2022 | Present |

## Welcome

The Chair opened the meeting at 11am and welcomed Committee members, noting that apologies had been received from Mrs Leesa Russell.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Catherine Garvey and Mr Jonathan Darby 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 03 December 2024 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2024 FULL 21758** |
|   | Title:  | A Multinational, Long-Term, Open-Label Extension Study of Subjects Who Have Participated in Avalyn Pharma Studies of Inhaled Antifibrotic Agents (AP-LTE-008 [SAIL]) |
|   | Principal Investigator:  | Dr Margaret Wilsher |
|   | Sponsor:  | Avalyn Pharma Inc |
|   | Clock Start Date:  | 23 January 2025 |
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Stephanie Pollard, Amy Sugalski and Schola Edwards 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 confirmed with the Researchers that the study participants are quite familiar with this device and study procedures, and the device itself is not the subject of the study, although it is still investigational.
2. The Committee confirmed that this application has also gone through SCOTT and has been treated as a new application.
3. The Committee noted conflicting statements about continued access, and the Researcher clarified that there is no definitive end to the trial and that participants will be able to have continued access until there is another avenue of access available.
4. The Committee clarified with the Researcher that termination ‘for any reason’ cannot be for purely 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 requested the Investigator Brochure (IB)-equivalent for this device being used, and further information of what other contexts it’s been used.
2. The Committee noted that study staff had signed off as part of the locality process, and confirmed with the Researcher that correct locality sign-off will occur.
3. The Committee requested review around the process for checking life-vital status. The Committee suggested that checking mortality registers rather than contacting the family would be more appropriate.
4. The Committee noted the insurance in place expires in March and will need to be extended.
5. Given the length of the study, please consider allowing participants the option to temporarily leave the study to reproduce and then rejoin later. Most participants will be older, but in the event that someone may be of reproductive age, this should be investigated as an option, or made clear to participants what their options are.
6. The Committee requested confirmation that participants needing disability support services will have these made available to them.

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

1. The Committee noted that there are statements in the PIS and CF that are unique and don’t match up to expectations here in New Zealand, with statements that don’t belong in this context. Please review wording in the sheets, paying particular attention to the items below.
2. Please include a statement that explains that some were on placebo in previous studies, and that everyone now is getting the same access and same dose.
3. Please alter wording around the statement “I will tell the study doctor if I have any physical or psychiatric (mental health) symptoms or problems”, as this is placing too much responsibility on the participant.
4. Please change wording from ‘treatment’ to ‘investigational product’ or similar to avoid therapeutic misconception.
5. Please use gender neutral language throughout, i.e. ‘if you can become pregnant’ instead of ‘if you are female who can become pregnant’.
6. GP notification is mandatory, so the consent form needs to be altered to make it clear this is not optional.
7. Include a statement that the ethical aspects of the study have been approved by the Northern B HDEC. An example of this can be found in the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates).
8. Please update the number of New Zealand participants taking part.
9. Please remove the statement around the safety of the study being monitored by the HDEC, as this is not correct.
10. Replace ‘destroy’ with ‘dispose’ when discussing the discarding of samples. Please also indicate whether karakia will be available at time of disposal.
11. Under the compensation section, there is a paragraph around ‘some sponsors may commit to the Medicines NZ guidelines’. Please be firm whether this is the case.
12. Please indicate that if there are any concern raised by answers in the questionnaires on page 10, this will be followed up by the research team.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Jonathan Darby and Ms Joan Pettit.

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| **2**   | **Ethics ref:**   | **2024 FULL 19786** |
|   | Title:  | Studies of Heart & Kidney Protection with BI 690517 in combination with empagliflozin: A multicentre, international, randomised, double-blind, placebo-controlled clinical trial of the aldosterone synthase inhibitor BI 690517 in combination with empagliflozin in patients with chronic kidney disease |
|   | Principal Investigator:  | A/Professor Janak de Zoysa |
|   | Sponsor:  | Boehringer Ingelheim International |
|   | Clock Start Date:  | 23 January 2025 |

Associate Professor Janak de Zoysa 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 clarified that participants would continue to be able to access empagliflozin on completion of the study.
2. The Committee confirmed with the Researcher that participants are first approached by clinicians independent of the study to refer to the study, and will be able to discuss the study with them further if they have questions.

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 following changes to the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8):*
	1. The Committee requested that the wording on page 12 and 13 is reviewed, as it currently appears that participants may be excluded during the run-in period based on the medication they are taking, but this is not the case.
	2. The protocol mentions that participants will self-report diabetes, however participants will be recruited from a diabetes clinic, so this would be clear from the records. Please clarify the process of referral and their standard of care.
	3. As this is a global study, please create a New Zealand specific appendix to the protocol.
	4. Please clarify what happens to participants who are Type 2 diabetic and on SGLT2 inhibitors and GLP-1 receptor agonists that excludes them from the diabetic arm if this ever is an issue.
2. The Committee stated more information around data and tissue management is required than what is available in the study documentation to satisfy the Committee that participant’s tissue and data are protected and that Standards 12.15a ,*14.16&14.17* are met. Use of the HDEC template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/) is not mandatory but is encouraged to be adapted or used as a guide/starting point. Given the international nature of the study, use of the template will ensure New Zealand-specific practices are covered.
3. The Committee requested a separate document for future research on samples, which needs to be separately consented from the main participant information sheet (PIS) with its own PIS and consent form (CF).
4. The Committee noted that the study was not framed as a commercial study but is a commercially sponsored study. Although evidence of ACC-equivalent insurance has been submitted, the Committee also requires proof of indemnity for the New Zealand Principal Investigator, along with any reference to participant access to ACC compensation removed from documentation and amended to reflect the commercial nature.
5. Point C18.1 of the application form excludes people with cognitive impairment. The Committee requested the study please consider assessing this on an individual basis, rather than making it a blanket exclusion. Participants could be included with the right support, and this can be folded into the New Zealand-specific appendix.
6. On the poster, please include New Zealand study team contact details and a statement saying that the study has ethical approval by the HDECs.

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

1. Please provide a revised version which is specific to a New Zealand audience. The Committee recommend using the [templates available on the HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates). A new intervention study-specific template is available.
2. Data linkage and access for participant information should be clarified in the main PIS and not as its own document.
3. Please make clear what “extra pills” refers to.
4. There should be a New Zealand contact for complaints and not an Australian contact.
5. Please check for spelling on Māori words, paying particular attention to macron usage.
6. When mentioning the number of participants, please state the number for New Zealand, as well as the number internationally.
7. The diagram contained on page 17 is very helpful and could be moved forward and then detail provided after.

**Decision**

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

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| **3** | **Ethics ref:**   | **2024 FULL 20135** |
|   | Title:  | Latte Dosage Early School-Age Outcomes Study: 6-year follow-up of children born late preterm who participated in a dose-finding trial of caffeine citrate for the improvement of intermittent hypoxaemia |
|   | Principal Investigator:  | Dr Elizabeth Oliphant |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 23 January 2025 |

Dr Elizabeth Oliphant and Jane Alsweiler 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 questioned whether the participants were still blinded to their treatment allocation from the original study. The Researchers noted that they are still blinded and have only received a summary of results.
2. The Committee sought clarity around how the assent process is carried out and the researcher explained that they would have spoken to the parents, who will have talked to their child about the study, ahead of the assent being sought at school.
3. It was clarified by the Researcher that analysis would be done on both caffeine dose and drops of oxygen levels.

Summary of outstanding ethical issues

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

1. The Committee noted that teachers are involved in the study and providing study data, so would need their own participant information sheet/consent form (PIS/CF).
2. When sending a letter or email to initially invite participation, please provide an option to request no further contact. Please provide this communication to the Committee for review.
3. The Committee noted that carrying out the study at school may lead to stigmatisation of the child. It is noted in the protocol that there is an option to be seen elsewhere, such as in home or in clinic but this is not mentioned in the PIS/CF. Please ensure this option is made available.
4. The Committee requested removal from the protocol the statement around following up children who have moved overseas as this will not be happening.

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

1. Please provide the option for parents to opt out of the teacher’s involvement in the study, and provide further information surrounding informing the school of the pre-term birth and risks associated with this.
2. For assent, please add a yes or no traffic light system in addition to asking the child to write their name as a second check for assent.
3. Please add commentary around the exploratory nature of this study and that child development is complex so no one factor can be isolated to determine impact. Make it clear that this won’t provide a definitive answer but may guide future studies.
4. Please provide warning that questions could be triggering add a step for parents to access support for themselves or the child if the questionnaires are triggering.

**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 Alice McCarthy and Dr Amber Parry-Strong.

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| **4**   | **Ethics ref:**   | **2024 FULL 21243** |
|   | Title:  | PHA022121-C305 (CHAPTER-3) - A Phase 3, Randomized, Double-blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Orally Administered Deucrictibant Extended-release Tablet for Prophylaxis Against Angioedema Attacks in Adolescents and Adults with Hereditary Angioedema |
|   | Principal Investigator:  | A/Prof Hilary Longhurst |
|   | Sponsor:  | Pharvaris Netherlands B.V.  |
|   | Clock Start Date:  | 23 January 2025 |

Associate Professor Hilary Longhurst and Keri-Anne Cowdrey 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 clarified with the Researcher that recruitment will be almost exclusively through clinic.
2. The Committee questioned the rationale for not providing potential participants the number of Hereditary angioedema (HAE) attacks for eligibility. The researchers explained that this is because they rely on self-report of HAE’s from the patients.

Summary of outstanding ethical issues

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

1. The Committee noted that the age of consent is 16. Participants aged 16-18 will sign the adult consent form and not need a parent to consent. Participants under 16 will need parental consent and participant assent forms.
2. The Committee recommended considering adding a paper option for a fall-back option and to avoid excluding participants should someone not be able to navigate technology.
3. The Committee noted that a lot of unnecessary documents were uploaded, specifically screen shots. In future, please only upload documents required for review for ease of assessment.
4. The data management plan is data-only and should be made into a data and tissue management plan.
5. The Committee noted that a pregnant participant/partner participant information sheet/consent form should only be submitted as an amendment in the event that a pregnancy occurs so it can be fit-for-purpose. As such, these have not approved for use with the current submission.
6. Please remove “important” from the patient engagement flyer. Also add that the screening phase will determine if they eligible to participate.

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

1. Please rename the ‘inconvenience fee’ to a ‘Koha’ and update to reflect that this would be given to participants aged 16 and above, rather than the parent. This could be a gift voucher rather than deposited into a bank account, in case some participants don’t have a bank account.
2. Please outline the risks of coming off existing prophylactics to enter the study.
3. Take out the statement regarding adolescents who are happy on their existing medication being excluded.
4. Legally authorised representative should be removed as it is not relevant to New Zealand.
5. Please state that you may or may not receive health benefit from the study, rather than ‘won’t’.
6. Please remove the point about potential participants who lack capacity to consent, as this is not relevant to this study.
7. Please highlight that the interventional product is a pill, which would be a benefit compared to the current standard of care which is IV/SC.
8. Please change the statement on page 3 that you should not take part in any other studies to clinical trials.
9. Please use lay language and define terms such as prophylaxis.
10. Please use gender neutral language, for example when referring to ‘if you can become pregnant’ rather than ‘a female who can become pregnant’.
11. Please avoid using the term ‘treatment’. Study drug or investigational product is more appropriate to avoid therapeutic misconception.
12. Please use millilitres rather than teaspoons, as teaspoons could draw comparisons to food.
13. If the sponsor has not committed to the Medicine New Zealand Guidelines, then remove this statement.
14. Please remove the yes/no option in the CF for notifying the GP, as this should be mandatory.
15. It should not be an option to withdraw data if the participant withdraws from the study, to maintain study quality.
16. On the assent form, the question about the optional PK study should be separated, to avoid confusion when stating that if any answers are no, they should not sign their name.

**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 a tissue management component to the data management plan to ensure the safety and integrity of participant tissue *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 14.16&14.17).*

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

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| **5** | **Ethics ref:**   | **2024 FULL 21768** |
|   | Title:  | PHA022121-C307 (CHAPTER-4) - A Long-term, Open-label Study to Evaluate the Safety and Efficacy of Orally Administered Deucrictibant Extended-Release Tablet for Prophylaxis Against Angioedema Attacks in Adolescents and Adults with Hereditary Angioedema |
|   | Principal Investigator:  | A/Prof Hilary Longhurst |
|   | Sponsor:  | Pharvaris Netherlands B.V. |
|   | Clock Start Date:  | 23 January 2025 |

Hilary Longhurst and Keri-Anne Cowdrey 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 clarified that all participants from CHAPTER 3 of the study would have the opportunity to join this study, which the Researcher confirmed unless there were any specific concerns.
2. It was noted that any new individuals who had not completed CHAPTER 3 but were otherwise eligible could join this study. This would not place any limits on participants from CHAPTER 3 being able to join this study.

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

1. Please rename the ‘inconvenience fee’ to a ‘Koha’ and update to reflect that this would be given to participants aged 16 and above, rather than the parent. This could be a gift voucher rather than deposited into a bank account, in case some participants don’t have a bank account.
2. Please outline the risks of coming off existing prophylactics to enter the study.
3. Take out the statement regarding adolescents who are happy on their existing medication being excluded.
4. Legally authorised representative should be removed as it is not relevant to New Zealand.
5. Please state that you may or may not receive health benefit from the study, rather than ‘won’t’.
6. Please remove the point about potential participants who lack capacity to consent, as this is not relevant to this study.
7. Please highlight that the interventional product is a pill, which would be a benefit compared to the current standard of care which is IV/SC.
8. Please change the statement on page 3 that you should not take part in any other studies to clinical trials.
9. Please use lay language and define terms such as prophylaxis.
10. Please use gender neutral language, for example when referring to if you can become pregnant rather than ‘a female who can become pregnant’.
11. Please avoid using the term treatment, study drug or investigational product is more appropriate to avoid therapeutic misconception.
12. Please use millilitres rather than teaspoons, as teaspoons could draw comparisons to food.
13. If the sponsor has not committed to the Medicine New Zealand Guidelines, then remove this statement.
14. Please remove the yes/no option in the CF for notifying the GP, as this should be mandatory.
15. It should not be an option to withdraw data if the participant withdraws from the study.
16. On the assent form, the question about the optional PK study should be separated, to avoid confusion when stating that if any answers are no, they should not sign their name.

**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 a tissue management component to the data management plan to ensure the safety and integrity of participant tissue *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 14.16&14.17).*

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

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| **6** | **Ethics ref:**   | **2024 FULL 21716** |
|   | Title:  | A Multicentre, Long-term, Randomized, Extension Study to Evaluate the Safety and Tolerability of Dazodalibep in Participants with Sjögren’s Syndrome (SS) |
|   | Principal Investigator:  | Dr Sunil Kumar |
|   | Sponsor:  | Amgen Inc. |
|   | Clock Start Date:  | 23 January 2025 |

Dr Sunil Kumar and Tanya Poppe were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified with the Researcher that this is an extension study, so participants will have the option to roll over from the other study. The Researcher confirmed those on a placebo would now receive the study drug.

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 felt the number of sham transfusions for the lower dose arm was excessive and asked if these could be removed as they create a more unfair burden on participants. If they remain, please provide sufficient justification.
2. Given the length of the study, it would be appropriate to offer a Koha on top of reimbursement for expenses.
3. The Committee noted for future reference that the Committee only require the CV for the CI and not other investigators.
4. The Committee requested confirmation that insurance is ACC equivalent.

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

1. Please note that once the analysis for the previous phase is completed, there may be a change to the recommended dose.
2. On page 3, there appear to be some paragraphs under the heading ‘study design’, which would belong in the section ‘what does my participation involve’.
3. Please use gender neutral language in the contraception section where possible, as it can be redundant to mention “if you are a female who can become pregnant” when “if you can become pregnant” will suffice.
4. Please refrain from using the term treatment, rather it is investigational medicine or study drug
5. If the New Zealand sites aren’t doing the optional assessments, then please remove these.
6. Please ensure the section regarding prohibited medication is very clear, and ensure the participant understands what remedy they can use in case of a flare.
7. Please rephrase the statement ‘you may not have to take any other drug’ and what this means.
8. Clarify if the sponsor has agreed to the Medicines New Zealand guidelines for compensation. If not, then please remove this statement.
9. Please alter the wording to correct that compensation will be ACC equivalent.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Jonathan Darby and Ms Joan Pettit.

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| **7**   | **Ethics ref:**   | **2024 FULL 21891** |
|   | Title:  | High-definition transcranial infraslow gray noise stimulation for treatment of chronic low back pain: A double-blinded randomised controlled clinical trial. |
|   | Principal Investigator:  | Dr Divya Adhia |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 23 January 2025 |

Dr Divya Adhia was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried whether nearly 2,000 visits was feasible. The Researcher reassured the Committee that there is a team dedicated to conducting these visits and based on what was achieved in the feasibility study, this is reasonable.
2. The Committee sought clarity around the consenting process, to ensure that there would be an opportunity to ask questions. The Researcher advised that the consent form would be emailed or posted but followed up with a phone call, and the option to meet in person is also offered.
3. The Committee queried why following up at 3 and 6 months. The Researcher noted that it is currently unknown how long the effectiveness lasts for, and this could help guide when a booster dose could be given for future studies.
4. The Committee noted that the participant information sheet was well laid out, with good use of diagrams and easy for a lay person to understand.
5. It was clarified that the cancer exclusion is for the reason of causing specific pain, but the study is investigating non-specific pain.

Summary of outstanding ethical issues

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

1. The Committee noted that the CI’s institution’s Research Office needs to sign off on HDEC applications as Local Sponsor. Please ensure this is done.
2. If possible, condense the questions participants have to answer and avoid repetition.

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

1. Please avoid using the word ‘treatment’, rather use investigational product.
2. Please clarify on the advertisement what the Koha is. It is important to distinguish between reimbursement for ensuring the participant isn’t out of pocket for participating but a Koha is to show appreciation.
3. Please change wording where it states that the study intervention will provide benefit, as this is not known yet.
4. Please note that those on the sham arm will only be given access to the intervention after the 6 month follow up.
5. Please offer Driving Miss Daisy as a transport option for participants.
6. On page 13 it should be changed to note that only the ethical aspects of the study have been approved by the HDEC.

**Decision**

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

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

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| **8**   | **Ethics ref:**   | **2024 FULL 21770** |
|   | Title:  | A Multi-Center, Randomized, Double-Blind, Placebo- and Active-Controlled Phase 3 Study to Evaluate the Efficacy and Safety of Zasocitinib (TAK-279) in Subjects With Active Psoriatic Arthritis Who Are Naïve to Biologic Disease-Modifying Antirheumatic Drugs (LATITUDE-PsA-3001) |
|   | Principal Investigator:  | Dr Nigel Gilchrist |
|   | Sponsor:  | Takeda Pharmaceutical Company Limited |
|   | Clock Start Date:  | 23 January 2025 |

Dr Nigel Gilchrist was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee sought assurances that participants would be equally recruited from private and public services to ensure equity of access to the interventional product, given the high cost of the currently available medication. The Researchers noted that the Doctors referring work in both public and private practice and have their patients’ best interests as priority.
2. The Committee asked if there was a safety plan in place for participants completing the questionnaire about suicide. The Researcher explained this would be completed with the researcher and referral to GP or specialist services would be made if necessary.
3. The Committee queried whether participants would have access to the study medication after the study ends. The Researcher has noted that compassionate access would be available.

Summary of outstanding ethical issues

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

1. The Committee requested a current practicing certificate for Dr Gilchrist.
2. The Committee noted that the CI of the study cannot sign as the locality authorisation. Please have someone other than the CI sign the locality authorisation, such as the director of the trust or someone else on the board.
3. In the advertisement, please mention that this is an interventional study.
4. The Committee requested clarification what the policy on reimbursement/Koha will be and ensure this is consistent between sites and everyone gets a fair level of compensation no matter what site they access.
5. Future unconsented research is only for data, not tissue, so can be included in the main participant information sheet/consent form (PIS/CF) and does not require a separate document. Please ensure this is also made as an optional item in the CF.

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

1. On page 3 please use the full name for MEDSAFE and either remove reference to FDA or explain what that is.
2. On page 4 there is a paragraph detailing the medicines and foods the participants can’t take while on the study, it would be clearer to have these bullet pointed.
3. Please clarify that any notifiable diseases will be reported to the Medical Officer of Health, rather than stating relevant authority.
4. If Greenphire are not used for travel reimbursement, then ensure mention of them is removed.
5. Please remove reference to a legal representative, as this is not relevant to New Zealand.
6. Please warn of the kind of physical assessments being undertaken and offer a support person for any physical examination.
7. Please change the ethics committee approval to Northern B, rather than Central.
8. If the sponsor hasn’t agreed to the Medicines New Zealand guidelines for compensation, then please remove this statement.
9. Please clarify the statement around a participant being removed from the study if they are not responding.
10. Please ensure that the alternatives listed are applicable to New Zealand.
11. Please include the risk of suicidal ideation and be more specific around this instead of just referring to depression, and what follow-up a participant could expect.
12. Please highlight that the comparator medication is approved for use in New Zealand but is not funded by Pharmac.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Amber Parry Strong and Ms Alice McCarthy.

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| **9** | **Ethics ref:**   | **2024 FULL 21885** |
|   | Title:  | ZOSTER EASE: A Phase Ib, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Tolerability of Solexan™ when Administered Topically to Acute Varicella Zoster Virus (Shingles) Lesions. |
|   | Principal Investigator:  | Dr Jackie Kamerbeek |
|   | Sponsor:  | Wintermute Biomedical Australia Pty Ltd  |
|   | Clock Start Date:  | 23 January 2025 |

Dr Jackie Kamerbeek and Richard Stubbs 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 questioned whether photos would mean the data was deidentified. The Researchers explained that the photos would only be of the lesions, and they have instructions to help take photos that won’t be identifiable. Also, tattoos in the lesion area are an exclusion criterion.

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 for future submissions that uploading duplicate documents bloats a submission and makes it more difficult to review.
2. The Committee noted that the insurance certificate will expire in April and an updated one will need to be submitted through the post approval pathway.
3. The Committee asked that participants be advised that there is a Shingles vaccine available.
4. The Committee raised the following regarding the advertising material *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12):*
	1. Please remove reference to sites such as John Hopkins who are not involved in the study, from the advertising material.
	2. Please remove the statement “help us do this study” from the Momentum poster, as this is unduly influential.
	3. The Committee requested removal “receive study related care at no cost” from the advertisement, as this is a minimum expectation and shouldn’t be presented as a benefit.
5. Ensure the protocol and participant information sheet are consistent when advising whether the participant can stay on an existing treatment or if they need to switch treatments.
6. All participant facing material should remove reference to the intervention as ‘treatment’, as this implies known benefit.

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

1. Please explain what an antiviral does versus what it is proposed that the investigational product does and clarify this in the New Zealand context.
2. Please add the option to the consent form for participants to choose if they want their photos to be included in publications.
3. Please clarify that the participant does not have to be on an antiviral to participate in the study.
4. Rather than stating ‘your doctor’, use ‘study doctor’.
5. Please use gender neutral language throughout in the contraception section, i.e. ‘ a woman who can get pregnant’ can just be ‘if you can get pregnant’.
6. Please make tax requirements clear with regards to reimbursements and distinguish these from the visit payment.
7. Remove refence to not receiving benefit from samples, as that does not apply to the type of samples taken in this 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 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 advertisements, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*

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

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| **10**   | **Ethics ref:**   | **2025 FULL 22086** |
|   | Title:  | A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single-Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of a Subcutaneous Injection of BC-006 in Adults with Obesity |
|   | Principal Investigator:  | Dr Jane Kerr |
|   | Sponsor:  | BaseCure Therapeutics Inc. |
|   | Clock Start Date:  | 23 January 2025 |

Dr Jane Kerr, Lucy Druzianic, Dr Chris Wynne, and Julia O’Sullivan 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 questioned at the age cut off at 65. The Researcher noted that for healthy volunteers the cut off is often 55, and for this study it is due to the fact that renal function has generally slowed down.
2. The Researchers explained their response to suicidality measures that could provide concerning responses, and the Committee was satisfied of the procedures in place.
3. The Committee sought assurance that the participants would have it made clear to them that there may not be benefit and that they may feel worse coming off medication. The Researchers stated that there was much discussion about potential side effects as part of the consent process.

Summary of outstanding ethical issues

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

1. The Committee noted that the poster should state that it has had ethical approval from the HDECs.
2. There is a typo on the advertisement stating a BMI of 30-30, please correct.

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

1. Please reword to make the timeframes clearer, including in the table.

**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

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

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| **Meeting date:** | 04 March 2025 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 4.50pm.