|  |  |
| --- | --- |
| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 14 November 2023 |
| **Zoom details:** | https://mohnz.zoom.us/j/9738756003 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 10:30 - 11:00am | 2023 FULL 19076 | LASN01-CL-1101: A Ph 1 study to determine the safety, tolerability, immunogenicity and pharmacokinetic properties of LASN01 in healthy subjects and in patients with PF or TED (HDEC) | Dr Jeremy Krebs | Dominic / Devonie |
| 11:00 - 11:30am | 2023 FULL 18887 | Can eye movements help identify early changes associated with Alzheimer’s Disease? | Professor Steven Dakin | Amy / Neta |
| 11:30am - 12:00pm | 2023 EXP 18561 | Anti-inflammatories and Physiotherapy for people with Knee Osteoarthritis: The AP-KO randomised controlled trial. | Dr Cathy Chapple | Maree / Nicola |
| 12:00 - 12:30pm | 2023 FULL 19042 | A Phase 2 Study to Evaluate Patient Reported Preference for SC Pembrolizumab Coformulated with Hyaluronidase Over IV Pembrolizumab Formulation in Participants With Multiple Tumor Types (MK-3475A-F11) | Dr Peter Fong | Dianne / Amy |
| 12:30 - 1:00pm | 2023 FULL 13734 | The Tairāwhiti pilot study: a pediatric imaging study | Dr Haribalan Kumar | Nicola / Neta |
| 1:00 - 1:30pm |  | BREAK (30 mins) |  |  |
| 1:30 - 2:00pm | 2023 FULL 18665 | Phase 3 Efficacy and Durability of Ampreloxetine for the Treatment of Symptomatic nOH in Participants with Multiple System Atrophy (CYPRESS Study) | Prof Tim Anderson | Maree / Devonie |
| 2:00 - 2:30pm | 2023 FULL 18502 | Oxygen delivery devices in bronchoscopy procedures and the effect on oxygenation (OXYBRONCH) | Dr Georgia Burton | Dianne / Nicola |
| 2:30 - 3:00pm | 2023 FULL 18780 | FAST study | Dr Annie Wong | Maree / Devonie |
| 3:00 - 3:30pm | 2023 FULL 18622 | Comparison of betamethasone ointment applied to the skin | Dr Noelyn Hung | Dominic / Amy |
| 3:30 - 4:00pm | 2023 FULL 18624 | Comparison of betamethasone OV ointment applied to the skin | Dr Noelyn Hung | Dominic / Amy |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 | Present |
| 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 | Present |
| 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 | Present |

## Welcome

The Chair opened the meeting at 10:15am with a karakia and welcomed Committee members, noting that no apologies had been received.

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 12 September 2023 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **2023 FULL 19076** |
|  | Title: | A Phase 1, randomized, double-blind, placebo-controlled, single and multiple ascending dose study to determine the safety, tolerability, immunogenicity and pharmacokinetic properties of LASN01 in healthy subjects and in patients with pulmonary fibrosis or thyroid eye disease |
|  | Principal Investigator: | Professor Jeremy Krebs |
|  | Sponsor: | Lassen Therapeutics; Novotech (New Zealand) Limited |
|  | Clock Start Date: | 27 October 2023 |

Professor Jeremy Krebs, Ms Cecilia Ross, and Dr Kenneth Chan 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 a research team member who is not directly involved in the clinical care of a participant undertake part of the informed consent process, to allow participants the opportunity to say no to someone who is not their clinical provider. The Researcher stated the anticipated way of recruiting is that doctors would identify potential participants from the clinic list and provide them with the information sheet and then another research team member would follow up at a later time.
2. The Researcher confirmed New Zealand census ethnicity data would be collected at a site level.
3. The Committee noted the pregnancy PIS was not reviewed. If a pregnancy in the study occurs the sheet can be submitted via the amendment pathway.
4. The Researcher confirmed no future unspecified research was planned.

Summary of outstanding ethical issues

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

1. The Committee requested an update to the data management plan to include all known overseas labs tissue will be sent to. *(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 review of technical terms followed by brackets and remove instances where the technical term is not necessary or has already been explained. The Committee noted the lay term by itself would be sufficient in most cases.
2. Please undertake a general proofread to correct any typos and ensure the content is relevant to New Zealand (eg remove references to ‘state government’).
3. Please simplify the second sentence on page 1 (“This project is testing..”) as much of this information is explained later in the document.
4. Please remove the paragraph regarding pulmonary fibrosis on page 2 and simplify the information by stating the drug has been developed for several indications including scarring of the lungs and thyroid eye disease.
5. Please simplify the description of ‘Part A’ on page 3.
6. Please remove the duplicated information on blinding on page 3.
7. Please correct the randomisation chance on page 3 that refers to ‘the same chance’. The Committee noted the randomisation ratio is 3:1 so this statement is inaccurate.
8. Please simplify the exclusion criteria on pages 4-5 as most participants will be excluded during clinician screening and the detail provided is unnecessary.
9. Please remove the reference to counselling following a positive COVID-19 result on page 6.
10. Please remove duplicated explanations of assessments from page 6 onward.
11. Please simplify the assessment table for a lay audience. For example, a line for eye assessments and one for blood tests is sufficient.
12. Please include information on how long each study visit will take (eg two hours, four hours).
13. Please explain what mRNA is in lay language, that it is a marker of gene expression, what genes are and make it clear that the participant’s whole genetic code will not be analysed.
14. Please remove cup measurements on page 11 and the explanation of 2 mL discards. The Committee noted if the discard is considered worth informing participants of it can be included in the total blood volume instead.
15. Please specify which city and country the overseas labs are located in on page 11.
16. Please advise that no karakia will be available at the time of tissue destruction on page 11.
17. Please simplify the discussion of risks in the second and third paragraphs of the ‘risks of study drug section’ on page 12.
18. Please include the risk of allergic reaction and reproductive risks in the study drug section and not with the minor risks of study assessments.
19. Please correct the contraception information. The Committee noted it currently reads as if participants must choose two forms of contraception from the bullet list and in addition use condoms.
20. Please make it clear that study MRIs will be included in the participant’s clinical record and cannot be withdrawn if the participant withdraws from the study.
21. Please delete the optional ‘yes / no’ tickboxes from the GP notification clause as this is a mandatory component of study participation.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**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 data management plan to specify any overseas labs tissue will be sent to. *(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 Devonie Waaka.

|  |  |  |
| --- | --- | --- |
| **2** | **Ethics ref:** | **2023 FULL 18887** |
|  | Title: | Effect of Mild Cognitive Impairment and Alzheimer's Disease on oculomotor response, perception, and cognition |
|  | Principal Investigator: | Professor Steven Dakin |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 27 October 2023 |

Professor Steven Dakin was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researcher confirmed all participants would be competent to provide informed consent and would be recruited from a parent study which involves competency assessments. The Committee advised the Researcher that the informed consent process for this study would need to involve someone that has the ability to ensure participants have retained capacity to consent. The Researcher confirmed the person who will undertake the informed consent process will be able to make this assessment.
2. The Researcher confirmed a participant’s GP will be notified if incidental findings are discovered.
3. The Researcher confirmed the site is accessible for disabled participants.

Summary of outstanding ethical issues

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

1. The Committee requested the Researcher include a researcher safety plan for home visits in the protocol. The Committee suggested checking if the parent study has one which could be used for the sub-study. *(National Ethical Standards for Health and Disability Research and Quality Improvement 11.62).*
2. The Committee requested the Researcher check whether the reimbursement for travel and parking costs can be increased, as $40 may be insufficient for some participants. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.21).*
3. The Committee requested the Researcher review the advertisement to correct any typos. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*

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

1. Please undertake a revision to correct any typos.
2. Please remove any ‘yes / no’ tick boxes on the consent form unless the clause is truly optional (ie the participant can answer ‘no’ and still participate).

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**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 include a researcher safety plan for home visits *(National Ethical Standards for Health and Disability Research and Quality Improvement 11.62).*
* please update the advertisement *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*
* please investigate whether increasing the koha for travel and parking expenses can be increased *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.21).*

|  |  |  |
| --- | --- | --- |
| **3** | **Ethics ref:** | **2023 EXP 18561** |
|  | Title: | Anti-inflammatories and Physiotherapy for people with Knee Osteoarthritis: The AP-KO randomised controlled trial |
|  | Principal Investigator: | Dr Cathy Chapple |
|  | Sponsor: | The University of Otago |
|  | Clock Start Date: | 30 October 2023 |

Dr Cathy Chapple 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.

Associate Professor Nicola Swain declared a potential conflict of interest. The Committee determined there was no conflict and Associate Professor Swain was permitted to contribute to the discussion and decision of the application.

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 study has been submitted for Māori consultation and this is in progress.
2. The Researcher confirmed the study has been registered in the ANZCTR.
3. The Researcher confirmed the locality approval process is underway.

Summary of outstanding ethical issues

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

1. The Researcher confirmed the medicine would be dispensed by a pharmacist with appropriate labelling. The Committee requested the Researcher update the protocol to include this process. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
2. The Committee requested the Researcher update the protocol to clarify that an unblinded pharmacist will be involved in the study to ensure the correct medicine or placebo is dispensed. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
3. The Committee requested the Researcher update the protocol to specify that sustained release naproxen will be used. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
4. The Committee requested the Researcher update the letter to GPs to state that participants should not be prescribed NSAIDs or PPIs during the study period.
5. The Committee requested the Researcher update the data and tissue management plan to remove references to using a contract research organisation. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*
6. The Committee requested the Researcher complete the missing sections in the data and tissue management plan and remove the ‘Note to researchers’ on page 3. *(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 review for medical terms (eg cardiovascular, renal, haemoglobin) and simplify for a lay audience.
2. Please include instructions and directions for participants to obtain the study medicine from the pharmacist.
3. Please make it clear that participants should not take any other NSAIDs, PPIs or any other major groups of medicines that interact with the study drugs.
4. Please include a more detailed description of what NSAIDs are. The Committee suggested examples of NSAIDs available in pharmacies and supermarkets, including combination products (eg “Nuromol”).
5. Please include a statement advising that contraception is required for the duration of study participation. An example can be found in the [HDEC template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
6. Please include a statement advising that blood test results will be included in the participant’s clinical record and cannot be removed if the participant withdraws from the study.
7. Please insert the word ‘related’ into the clause on future research.
8. Please provide the Medsafe Consumer Medicine Information sheet for all medications used in the study with the participant information sheet.
9. Please remove the 0800 4 ETHIC phone number as this is no longer in use.
10. Please remove the fax number for the Advocacy service.
11. Please include a number for Māori cultural support.
12. Please remove the ‘yes / no’ tickbox on the clause for informing the GP of study participation and abnormal results as this should be mandatory.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
* please update the data and tissue management plan, incorporating feedback raised by the Committee (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

|  |  |  |
| --- | --- | --- |
| **4** | **Ethics ref:** | **2023 FULL 19042** |
|  | Title: | A Phase 2 Study to Evaluate Patient Reported Preference for Subcutaneous Pembrolizumab Coformulated with Hyaluronidase (MK-3475A) Over Intravenous Pembrolizumab Formulation in Participants With Multiple Tumor Types (MK-3475A-F11) |
|  | Principal Investigator: | Dr Peter Fong |
|  | Sponsor: | Merck Sharp & Dohme LLC |
|  | Clock Start Date: | 02 November 2023 |

Dr Peter Fong, Ms Sophie Goodger and Ms Azmeena Sajid 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 no tissue would be sent overseas.
2. The Committee requested a research team member who is not directly involved in the clinical care of a participant undertakes part of the informed consent process, to allow participants the opportunity to say no to someone who is not their clinical provider. The Researcher stated participants are encouraged to discuss the study with their GP, oncologist or referring surgeon regarding the benefits and risks of participation.
3. The Committee requested the study collect New Zealand ethnicity data at a site level for final reporting to HDEC. The Researcher confirmed this is collected in an internal database.

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 10.1 of the data and tissue management plan which states tissue will be sent to the overseas Sponsor. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*
2. The Committee noted section 12 of the data and tissue management plan states screening results will not be returned to participants as they are anonymised. The Committee noted screening results must be re-identifiable in order to enrol participants and monitor safety and so should be accessible if requested. The Committee requested an update to section 12 to address this. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*
3. The Committee queried the anonymous data collection in section 7.3 of the data and tissue management plan. The Researcher stated questionnaires for patients are deidentified and the healthcare professional questionnaire is anonymous with only the provider’s role captured in the form. The Researcher agreed to confirm with the Sponsor and update 7.3 to clarify. *(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 a statement at the beginning of the sheet to advise that a translator is available if required.
2. Please simplify some of the technical language for a lay audience (eg the sentence “It is expected that pembrolizumab delivered subcutaneously will maintain a risk/benefit profile comparable to that of intravenous administration” on page 8).
3. Please include an estimated duration for how long the screening visit is expected to take and how long it will take to complete the questionnaire.
4. Please review any duplicated information regarding data (access and withdrawal). It appears statements from the HDEC template and the Sponsor are both included.
5. Please correct ‘less’ to ‘fewer’ where applicable.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**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).*

|  |  |  |
| --- | --- | --- |
| **5** | **Ethics ref:** | **2023 FULL 13734** |
|  | Title: | The Tairāwhiti pilot study: a whole-body imaging-based pediatric study |
|  | Principal Investigator: | Dr Haribalan Kumar |
|  | Sponsor: | Matai Medical Research Institute |
|  | Clock Start Date: | 02 November 2023 |

Dr Haribalan Kumar and Dr Eryn Kwon 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 MRIs will be reviewed by a radiologist.
2. The Committee recommended collecting additional contact information and/or a secondary contact to assist with the one-year follow-up.
3. The Researcher agreed to provide a koha to the children.

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 Researchers confirmed participants would be re-screened after one year. The Committee requested information explaining this is added to the information sheet. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
2. The Committee requested the Researcher supply the text for any social media or newsletter advertisements as these require HDEC approval before use. (*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 specify that no future unspecified research is planned. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
4. The Committee noted the questionnaire contained technical medical language and disorders which would generally not be present in a paediatric population. The Committee recommended the Researcher determine what information they want to capture from the questionnaire and put it in a lay-friendly manner that parents will be able to complete. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.1).*
5. The Committee noted the questionnaire asks about medications and headaches in the first-person (“Do you...”) and if the parent is completing it on behalf of the child it should state “Does your child...”).
6. The Committee requested a revision to the questionnaire to remove any irrelevant information (eg “5th rugby participant = 5”).
7. The Committee requested the Researcher update the study advertisement to state an MRI is low risk and remove the comparison with taking a photograph. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*
8. The Committee queried whether only actionable findings would be reported to participants or whether they could choose to receive non-actionable incidental findings. The Researcher stated important findings would be reported. The Researcher stated they would consult with the radiologist and review Matai’s incidental findings policy. The Committee requested the information sheet is updated to include information regarding this. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.45 - 11.49).*

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

1. Please undertake a general revision for syntax and grammar to correct any errors (eg “This understanding will help understand what typical development.” on page 2).
2. Please state how many people will participate in the study and the age range (7 – 13).
3. Please state that scans will be repeated in a year.
4. Please include a description of GE Healthcare and explain what data will be shared with the company.
5. Please explain that the images will undergo medical review by a radiologist and include more information on what incidental findings will be reported.
6. Please specify that data will be kept for 10 years after the youngest participant turns 16.
7. Please remove the sentence regarding competency of children from the parents PIS as parental consent will be obtained.
8. Please specify that ECG leads will be applied to all participants.
9. Please state that all participants will have muscle, bone, hearts, lungs and brains studied.
10. Please include information explaining that a lay summary will be provided to all participants at the conclusion of the study.
11. Please include a statement acknowledging the risk of privacy breach.
12. Please include information regarding withdrawal of data and state this will not include the MRI scan as it will be entered into the participant’s clinical record.
13. Please clarify the period participants may withdraw data (the consent form states 12 months and the data management plan states two weeks).
14. Please clarify the consent clauses on who can access the images. One states images will only be available to study investigators and another states images will be used for teaching, presentations, demonstrations and research. Please clarify whether these are identifiable or not.
15. Please include a statement advising that New Zealand privacy law will not apply to images sent overseas.
16. Please include a statement advising participants that a taxi is available if they do not have private transport and free parking is available.
17. Please include a statement in the children’s form advising that the MRI machine is large and can be loud.
18. Please include a statement in the children’s form advising that they will have another scan in a year.
19. Please include a statement in the children’s form advising the age of participants (eg “other kids like you who are 7 – 13 years old”).
20. Please include footers and page numbers in all information sheets.
21. Please include a statement advising whether participants can wear an underwire bra for the MRI.
22. Please include information on whether the MRI technicians can be gender-matched and how the participant’s privacy will be protected.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**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 questionnaire, taking into account feedback provided by the Committee.
3. 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).*
4. 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).*
5. Please supply any study advertisements *(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 Neta Tomokino and Associate Professor Nicola Swain.

|  |  |  |
| --- | --- | --- |
| **6** | **Ethics ref:** | **2023 FULL 18665** |
|  | Title: | A Phase 3, Multi-centre, Randomized Withdrawal and Long-Term Extension Study of Ampreloxetine for the Treatment of Symptomatic Neurogenic Orthostatic Hypotension in Participants with Multiple System Atrophy |
|  | Principal Investigator: | Prof Tim Anderson |
|  | Sponsor: | Theravance Biopharma Ireland Limited; Calyx Bioconsulting Limited |
|  | Clock Start Date: | 02 November 2023 |

Ms Laura Paementier was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researcher confirmed the Coordinating Investigator has a renewed MPS Certificate.

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 answer to B8 in the application form which indicated there would not be ongoing access to the study drug. The Committee noted this is inconsistent with [Standard 10.15 of the National Ethical Standards](https://neac.health.govt.nz/national-ethical-standards/part-two/10-ethical-features-of-studies/) which states participants who benefit from a study intervention should have ongoing access for as long as it is clinically beneficial. The Committee requested a justification for why ongoing access would not be available. The Researcher stated there would be an open label extension for two years but were uncertain of future access. The Committee requested the Researcher consult with the Sponsor on ongoing access for participants who benefit from ampreloxetine (eg access to another clinical trial or compassionate supply) and provide an update. This can be submitted as an amendment form via the post-approval pathway. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 10.15).*

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

1. Please include a lay title on page 1.
2. Please amend the data storage information to state “at least 15 years” for simplicity.
3. Please move or remove the following sentence from the bullet list under deidentified information on page 17 as identifiable information would need to be shared in such a situation: “Other individuals and entities as required by law, regulation or ethics, such as to other health care professionals if you talk about harming yourself or the Investigator believes there may be a risk that you might harm yourself.”
4. Please delete duplicated information under the ‘purposes of use’ list on page 18.
5. Please delete duplicated information regarding use of data post-withdrawal on page 19.
6. Please amend the bullet point on page 20 to remove “Decisions made in the commercial interests of the Sponsor” as terminating a therapeutic trial for commercial reasons is not permitted in New Zealand.
7. Please remove repeated information on ownership and financial benefit on page 21 (this is already covered on page 19).
8. Please amend the paragraph on page 21 regarding access to results, as participants should be able to access screening and safety results, particularly during open-label access.
9. Please include an optional ‘yes / no’ clause in the consent form for participants to receive a lay-summary of results.
10. Please include a statement advising that karakia will not be available at the time of tissue destruction.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**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 provide an update regarding ongoing access for participants who benefit from the study intervention via the amendment pathway *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 10.15).*

|  |  |  |
| --- | --- | --- |
| **7** | **Ethics ref:** | **2023 FULL 18502** |
|  | Title: | High flow nasal oxygen therapy versus conventional oxygen therapy in patients undergoing bronchoscopy and the effect on oxygenation: a randomised controlled trial |
|  | Principal Investigator: | Dr Georgia Burton |
|  | Sponsor: | Te Whatu Ora – Waitaha Canterbury |
|  | Clock Start Date: | 02 November 2023 |

Dr Georgia Burton 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 noted the request to translate the information sheet into Te Reo Māori and encouraged the researcher to undertake this.
2. The Researcher confirmed Fisher & Paykel Healthcare will not get access to the study dataset.
3. The Researcher confirmed the study has been registered in a clinical trial 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 noted a bronchoscopy may cause anxiety for patients and introducing the study within an hour of the procedure may not be appropriate. The Committee requested an update to the protocol to allow for a mechanism of informing potential participants of the study ahead of time. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.7).*
2. The Committee requested the Researcher update the data management plan to comply with [Chapter 12 of the National Ethical Standards](https://neac.health.govt.nz/national-ethical-standards/part-two/12-health-data/). The Committee requested the Researcher include information on applicable institutional data governance policies, named accountability for compliance, what will happen in the event of a privacy breach, future use of data and whether it may occur, access to and storage of identifiable information (consent forms, contact lists), return of results and withdrawal of data. The Committee recommended the Researcher adapt the [HDEC Data Management Plan template](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/) as this contains prompts for all the required information. *(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 state how many participants are expected to join the study.
2. Please better explain what the two devices / treatment arms are and the differences between them. A diagram or photo would be useful (p2).
3. Please include a statement advising that both treatment arms involve devices approved for use in New Zealand.
4. Please include an explanation of whether a person in the high-flow group would get the same or more oxygen in total than the standard care group.
5. Please state the chances of being randomised to each treatment arm. .
6. Please include a statement advising participants that they will be told which treatment arm they are randomised to.
7. Please include information on the alternatives of taking part in the study (ie standard treatment).
8. Please explain what the extra monitoring equipment consists of and how it will be attached. A diagram would be useful.
9. Please include a statement in the use of data section on the rights of participants to access and request corrections to information held about them and future uses of data.
10. Please acknowledge the risk of privacy breach.
11. Please include a statement on the involvement of Fisher & Paykel Healthcare (eg that the device and attachments have been donated but the company, but the company did not design the study and will not receive the dataset).

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**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 Ms Dianne Glenn and Associate Professor Nicola Swain.

|  |  |  |
| --- | --- | --- |
| **8** | **Ethics ref:** | **2023 FULL 18780** |
|  | Title: | FAST study: Feasibility ASessment of circulating Tumour DNA (ctDNA) in the diagnosis of advanced lung cancer |
|  | Principal Investigator: | Dr Annie Wong |
|  | Sponsor: | The University of Otago |
|  | Clock Start Date: | 02 November 2023 |

Dr Annie Wong was not present 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 requested information on the process of the return of results indicating hereditary genetic abnormalities to blood relatives. It is noted in the application that the participant may give permission for results to be provided to blood relatives but there is nothing regarding how, where and when blood relatives would be approached regarding options for notification. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.46 – 11.49).*
2. The Committee noted it is unclear whether face to face interviews may take place at private residences. If this is intended please ensure a formal researcher safety plan is in place. *(National Ethical Standards for Health and Disability Research and Quality Improvement 11.62).*
3. The Committee requested an update to the data and tissue management plan to include the name and address of the overseas lab in section 2. Please delete references to imaging and biomedical monitoring in section 5. Please remove references to tissue from surgical resection of the tumour, mastectomy and oophorectomy in section 5. Please include the process for the return of incidental genetic findings to the participant or blood relatives in section 11. Please update the contents page. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*
4. The Committee noted Section 11 of the data and tissue management plan states “If a study assessment returns a result of potential clinical significance, the participant will be informed as per the study protocol” but could not locate information regarding this in the protocol. Please update the protocol to include this process. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
5. The Committee noted the information sheet states data collected prior to participant withdrawal will continue to be used but the DTMP states it is optional. Please clarify what is intended and amend documents for consistency. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*
6. The Committee noted data retention time is stated to be up to 10 years in Section 9 of the data and tissue management plan, and a minimum of 15 years in the information sheet. Please clarify what is intended and amend documents for consistency. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*
7. The Committee noted it is unclear whether interviews will be recorded. If they will be, please describe access to, storage and retention of the raw recordings in the identifiable data sections of the data and tissue management plan. *(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):

**PISCF PATIENTS**

1. The PISCF states up to 50 participants will be invited to take part in an interview; the protocol states 10-15 will be invited. Please clarify what is intended and amend study documents for consistency.
2. The PISCF states that all generated data will be de-identified, but then states that 'Information about your participation in this study will be recorded in your health records'. Please clarify what information this pertains to, and explicitly state whether it includes the participant's genomic data.
3. Please state whether the interview will be recorded / transcribed. As recordings are identifiable, please state how long recordings will be retained for, how they will be stored, and who will have access to them. State also whether participants are able to access the transcript summary and make any corrections if required; and whether any potentially identifiable information in the recording will be deleted from the transcript.
4. Please correct formatting issues.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**PISCF CLINICIAN SURVEY**

1. Insufficient information is provided regarding data management. Please state how the survey will be completed (eg online or paper); the form in which data will be collected (with identified / de-identified / anonymous); whether participants can request withdrawal of data prior to its analysis; whether data may be used for future research; and whether data may be shared with other researchers.
2. Please include the possibility of privacy breach if data is collected in any form other than anonymously.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**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 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).*
5. Please include a researcher safety plan for home visits if these are planned *(National Ethical Standards for Health and Disability Research and Quality Improvement 11.62).*

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.

|  |  |  |
| --- | --- | --- |
| **9** | **Ethics ref:** | **2023 FULL 18622** |
|  | Title: | A pivotal in vivo bioequivalence study comparing betamethasone ointment (Nova Chem, Australia) to Diprosone® ointment (Organon, Australia), using the ED50 for Diprosone® ointment calculated from the pilot dose duration-response study and using 90 responders with the expectation to have 40-60 participants who meet the responder and detector criteria (“evaluable”). |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Nova Chem Australasia Pty Ltd |
|  | Clock Start Date: | 27 October 2023 |

Dr Noelyn Hung was not present 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 requested the study advertisement is updated to state the non-branded ointment is investigational. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*
2. The Committee requested the trial is registered in a WHO-approved clinical trial registry. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.2).*

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

1. Please include a statement regarding financial rights / commercial rights as per the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
2. Please refer to the Southern HDEC on page 15.
3. Please make it clear the non-branded ointment is investigational and has not been approved for use in New Zealand.
4. Please update the contraception section using the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
5. Please state clearly that whether contraception is required for participants who are able to father a child.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**Decision**

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

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

|  |  |  |
| --- | --- | --- |
| **10** | **Ethics ref:** | **2023 FULL 18624** |
|  | Title: | A pivotal in vivo bioequivalence study comparing betamethasone OV ointment (Nova Chem, Australia) to Diprosone® OV ointment (Organon, Australia), using the ED50 for Diprosone® OV ointment calculated from the pilot dose duration-response study and using 90 responders with the expectation to have 40-60 subjects who meet the responder and detector criteria (“evaluable”). |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Nova Chem Australasia Pty Ltd |
|  | Clock Start Date: | 27 October 2023 |

Dr Noelyn Hung was not present 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 requested the study advertisement is updated to state the non-branded ointment is investigational. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*
2. The Committee requested the trial is registered in a WHO-approved clinical trial registry. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.2).*

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

1. Please include a statement regarding financial rights / commercial rights as per the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
2. Please refer to the Southern HDEC on page 15.
3. Please make it clear the non-branded ointment is investigational and has not been approved for use in New Zealand.
4. Please update the contraception section using the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
5. Please state clearly that whether contraception is required for participants who are able to father a child.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**Decision**

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

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

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 12 December 2023. |
| **Zoom details:** | To be determined |

The following members tendered apologies for this meeting.

* Associate Professor Nicola Swain

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 2:50pm with a karakia.