|  |  |
| --- | --- |
| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 18 February 2025 |
| **Zoom details:** | 965 0758 9841 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 12:00 - 12:30pm |  | Committee welcome |  |  |
| 12:30 - 1:00pm | 2024 FULL 21764 | Australia and New ZealandLung Transplant Registry (ANZLUNG) | Dr Sasiharan Sitamparanathan | Catherine / Kate |
| 1:00 - 1:30pm | 2024 FULL 21223 | Evidencing the causal mechanisms of Kaupapa Māori health transformation | Associate Professor SachaMcMeeking | Maakere / Jade |
| 1:30 - 2:00pm | 2024 FULL 21735 | OD-07656-201: A Phase 2a Study of OD-07656 and Vedolizumab Therapy inModerately to Severely ActiveUlcerative Colitis | Dr Paul Hamilton | Dianne / Sotera |
| 2:00 - 2:30pm | 2024 FULL 21756 | ELITE-BTK Trial | Dr Andrew Holden | Jessie / Andrea |
| 2:30 - 2:50pm |  | Break (20 mins) |  |  |
| 2:50 - 3:20pm | 2024 FULL 21551 | A Phase 2/3 Study of Ficerafusp Alfa (BCA101) or Placebo in Combination with Pembrolizumab in First LinePD-L1-pos, R or M HNSCC | Dr David Gibbs | Dianne / Jade |
| 3:20 - 3:50pm | 2024 FULL 18376 | The Dragon 2 Trial | Doctor Rukshan Fernando | Catherine / Sotera |
| 3:50 - 4:20pm | 2024 FULL 22079 | COBRA - COrticosteroids forBiphasic Reactions in Anaphylaxis | Dr Adrian Owen | Jessie / Kate |
| 4:20 - 4:30pm |  | Break (10 mins) |  |  |
| 4:30 - 5:00pm | 2024 FULL 21521 | GBP560\_001: A Phase I/II Study to Assess the Safety, Reactogenicity, andImmunogenicity of SK Japanese Encephalitis mRNA Vaccines (GBP560) in Healthy Adults. | Dr Cory Sellwood | Maakere / Andrea |
| 5:00 - 5:30pm | 2024 FULL 21748 | AROALK7-1001: A Study to Evaluate ARO-ALK7 in Adult Volunteers with Obesity With and Without Type 2 Diabetes. | Dr Christian Schwabe | Catherine / Jade |
| 5:30 - 6:00pm | 2024 FULL 21892 | PX578-001: A Study to Evaluate PX578 in Healthy Adults | Dr Chris Wynne | Jessie / Kate |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Dr Kate Parker  | Non-lay (Observational studies)  | 11/02/2020  | 11/02/2023  | Present  |
| Dr Andrea Forde | Non-lay (Intervention studies)  | 22/12/2021 | 22/12/2024 | Present |
| Ms Catherine Garvey  | Lay (the Law) (Chair) | 19/03/2019  | 19/03/2022  | Present  |
| Dr Sotera Catapang  | Non-lay (Observational studies)  | 11/02/2020  | 11/02/2023  | Present  |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Apologies |
| Ms Jade Scott | Non-lay (Intervention/Observational studies) | 15/08/2021 | 15/08/2024 | Present |
| Ms Dianne Glenn | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting with a karakia at 12.00pm and welcomed Committee members, noting that apologies had been received from Mr Jonathan Darby.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Diane Glenn, Ms Maakere Marr and Ms Jessie Lenagh-Glue 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 19 November 2024 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1**   | **Ethics ref:**   | **2024 FULL 21764** |
|   | Title:  | Australia and New Zealand Lung Transplant Registry |
|   | Principal Investigator:  | Dr Sasiharan Sitamparanathan |
|   | Sponsor:  | Te Whatu Ora Te Toka Tumai Auckland |
|   | Clock Start Date:  | 06 February 2025 |

Dr Sasiharan Sitamparanathan and Kelly Marshall 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 was satisfied that potential participants have adequate time to consider participation after discussion with the Researcher.
2. It was noted that some children in New Zealand may go to Australia for surgery. There is an Australian arm of the study, which has received Australian ethical approval.
3. The Committee queried if community consultation has been performed regarding this registry. The Researcher clarified they had not in New Zealand, but in Australia part of the registry development had consumer input. With the registry growth, further consultation will occur.
4. The Committee noted the data linkage policies detailed in the application is too vague. The only planned data linkage is mortality data at this stage and this is still being established – any additional data collection will be dealt with as an amendment.

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 children under 16 should sign the assent form and then be reconsented when they turn 16. This process should be noted in the assent form.
2. The Committee queried why future unspecified research was mandatory according to the participant information. After discussion, the Committee requested it is clarified where mentioned that it will be restricted to the organ donation and transplant sector, and to ensure the consent form is explicit that they are consenting to their data being shared overseas.
3. Please consent surviving individuals who have had a lung transplant, since the closure of the previous cardiothoracic surgical registry, between 2000 and 2024. An appropriate information sheet should be provided for these participants.
4. The Committee noted the waiver of consent applied for is justified, however the Committee queried whether the researchers have explored the feasibility of consenting people who are still alive to be in the registry. The Researcher responded that this could be done and considered and the Committee requested to see this back.

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

1. Please review for duplicate sentences.
2. Please remove the yes/no option for items that are not truly optional in the CF.
3. Please review all references to Australia e.g., Medicare, and ensure that the CF is New Zealand specific.
4. Please update the Australian and regional ethics committees to be Northern A HDEC and the reference number. Also state that only ethical aspects of the study are reviewed by HDEC.

**Decision**

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

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

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

|  |  |  |
| --- | --- | --- |
| **2**   | **Ethics ref:**   | **2024 FULL 21223** |
|   | Title:  | Evidencing the causal mechanisms of Kaupapa Māori health transformation |
|   | Principal Investigator:  | Associate Professor Sacha McMeeking |
|   | Sponsor:  | University of Canterbury |
|   | Clock Start Date:  | 06 February 2025 |

Associate Professor Sacha McMeeking and Dr Annabel Ahuriri-Driscoll 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 commended the Researchers on the quality and thoughtfulness of the application.
2. The Committee discussed with the Researcher what 25 Kaupapa Māori organisations were broadly referred to in the application, and it was clarified it was difficult to strictly define at this stage due to limitations on diversity if these are pre-selected.
3. The Researchers clarified that they are not advertising the study.

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 separate document for the questions that will be asked across the focus groups.
2. The Committee noted that there was reference in the application to developing study documentation further if including those under 16 or needing supported consent. The Committee highlighted to the Researchers that any additional participant facing materials (recruitment, information sheets, assent forms) will be required to be submitted as an amendment in the post-approval pathway to the HDEC for review. Assent forms will be required to be developed if there are any participants under 16.
3. The question being asked for staff members regarding if they had a magic wand that could be used to help uplift was noted to be a good question to also ask non-staff participants.
4. The Committee requested further clarity around how identifiable data will be used in the Data Management Plan.

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

1. Please remind participants of confidentiality of what is discussed in the focus groups, including a statement advising them that what is shared within these discussions should not be shared outside of it.
2. Please clarify that the Koha goes to the organisation and make a statement about it being taxable. The Committee commended the researchers for their intention to seek advice on payment of koha, vouchers and so on.
3. Please put the full name of the ethics committee and note that HDEC reviews the ethical aspects of the study.
4. Please put the full name of the Health Research Council before the acronym HRC.
5. Please note that participants can request a review of their interview recording.
6. Please add a version number and page numbers.
7. Please indicate in the Staff PIS what kinds of questions they will be asked.
8. The Committee noted that some participants may not wish to have their organisation de-identified. If there is an option of publishing identifiable information, please include this in the PIS.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Maakere Marr and Ms Jade Scott.

|  |  |  |
| --- | --- | --- |
| **3**   | **Ethics ref:**   | **2024 FULL 21735** |
|   | Title:  | OD-07656-201: A Phase 2a, Two-Part, Open-Label and Randomized Study to Evaluate the Safety and Efficacy of OD-07656 and of Subsequent Vedolizumab Therapy in Patients with Moderately to Severely Active Ulcerative Colitis |
|   | Principal Investigator:  | Dr Paul Hamilton |
|   | Sponsor:  | Odyssey Therapeutics, Inc. |
|   | Clock Start Date:  | 06 February 2025 |

Dr Paul Hamilton, Dr Anthony Opipari, Dean Tasker, Charlene Botha, Kristi Viliagonzalo and James Stanley were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researchers clarified that all participants in part 1 will be eligible to participate in part 2.
2. The Researchers clarified that all the doses given are below maximum validated safe dosing levels.
3. The Researchers noted that the medication would not be available on compassionate grounds after the conclusion of the study.

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 provision of the updated indemnity certificate for the CI.
2. The Committee noted that there is an emergent issue with USA Federal Government funding for research. The Committee noted that studies had been suddenly terminated without regard to the welfare of participants, and that this would also impact New Zealand participants if a study was terminated without warning in breach of ethical principles and the New Zealand Ethical Standards. The Committee was assured by the Sponsor that this study is wholly privately funded and that the Sponsor will provide written confirmation of this, and, as requested by the Committee, this will be from the Chief Medical Officer, Chief Financial Officer and Chief Legal Officer inclusive.
3. The Committee noted a New Zealand-specific data and tissue management plan needs to be provided.
4. The Committee noted the e-diaries in use are a third party with poor privacy standards from a New Zealand perspective, especially with data going overseas. The Committee queried if there is a possibility this could be done in-house. The Researcher responded that would be difficult, however could be done through paper versions and would investigate further.

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

1. Please include information about how missed doses will be handled.
2. Please proofread for repeated statements.
3. The black-box warning should be on the first page.
4. Please note for participants that it is advisable to rest the day after an infusion.
5. Please consider the cultural implications (such as whakamā) of storing a stool sample in the fridge.
6. Please make it clear that if a participant with a disability needs a support person, then the support person’s costs will be covered.
7. Offer of interpreters should be made clearer earlier in the PIS and not in the consent form. Alternatively, ensure that this will be verbally highlighted.
8. In the risk section, please use lay language and use ratios as well as percentages. Please also include the risk of blood draw.
9. The Committee noted that side effects should be reframed as adverse events as that is more accurate.
10. Please be consistent in the use of language i.e. both ‘drug’ and ‘medicine’ are used to describe the investigational product,
11. Use ‘outcome of pregnancy’ rather than assuming that the outcome is a live infant.
12. Please review the statement regarding compensation with respect to whether the Sponsor is in fact a member of Medicines NZ .The HDECs have a [new intervention-specific template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates) that has different wording for use.

**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 supply a tissue 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 Dianne Glenn and Dr Sotera Catapang.

|  |  |  |
| --- | --- | --- |
| **4**   | **Ethics ref:**   | **2024 FULL 21756** |
|   | Title:  | A PHASE 1/2A DOSE-ESCALATING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF ARO-ALK7 IN ADULT VOLUNTEERS WITH OBESITY WITH AND WITHOUT TYPE 2 DIABETES MELLITUS |
|   | Principal Investigator:  | Dr Andrew Holden |
|   | Sponsor:  | Arrowhead Pharmaceuticals, Inc. |
|   | Clock Start Date:  | 06 February 2025 |

Dr Andrew Holden, Helen Knight, Davina Ofren and Cindy Corne 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. After discussion, the Researcher clarified that blinding of the Sponsor is not impacted by a a medical representative of the Sponsor who may be present for training on use of the device.
2. The Researchers clarified that the quality-of-life questionnaires will be done with a member of staff present and evaluated immediately, and the clinical team would step in if concerns were flagged.

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 there is an emergent issue with USA Federal Government funding for research. The Committee noted that studies had been suddenly terminated without regard to the welfare of participants, and that this would also impact New Zealand participants if a study was terminated without warning in breach of ethical principles and the New Zealand Ethical Standards. The Committee was assured by the Investigator that the Sponsor will be approached to determine if the USA Government is the source of any funding. The Committee requested that the Sponsor provide written confirmation that the US Government is not the source of any funding and, as requested by the Committee, that this will be from the Chief Medical Officer, Chief Financial Officer and Chief Legal Officer inclusive.
2. The Committee queried the exclusion around people who are pregnant or are breastfeeding. The Researcher clarified that the FDA has imposed this requirement. The Committee queried if a breastfeeding/pregnant person would be excluded from treatment – and therefore asked the Investigator to provide justification for this routine exclusion from the trial if their pregnant or breastfeeding status would not exclude them from treatment according to the current standard of care.

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

1. Please change ‘unborn child’ to ‘pregnancy outcome’, as a live infant cannot be assumed.
2. Please change the wording from ‘loss of benefit or without penalties’ to ‘without change to standard of care’.
3. Please note that triggering questions may be asked and advise how emotional distress will be handled.
4. Please remove reference to flipping of a coin for randomisation.
5. Please reword the section explaining that device insertion on rare occasions may not be successful.
6. Please correct the name of the ethics committee to Northern A.
7. Remove the Medicines New Zealand statement as this is a device study. The HDECs have a [new intervention-specific template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates) that has different wording for use.
8. Please note that third parties, such as auditors, may have access to de-identified information.
9. The Committee recommended providing a range of length and diameter of the stent in the illustrations.
10. Please highlight to participants after mention of the EQ5D, broadly what will happen if staff need to follow up on the results of it. e.g. referral, and that some questions may be sensitive.

**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 Andrea Forde and Ms Jessie Lenagh-Glue.

|  |  |  |
| --- | --- | --- |
| **5**   | **Ethics ref:**   | **2024 FULL 21551** |
|   | Title:  | A Multicentre, Randomized, Double-blind, Phase 2/3 Study of BCA101 or Placebo in Combination with Pembrolizumab for First Line Treatment of PD-L1-positive, Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma |
|   | Principal Investigator:  | Dr David Gibbs |
|   | Sponsor:  | Bicara Therapeutics |
|   | Clock Start Date:  | 06 February 2025 |

Dr David Gibbs and Deborah Allen were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee asked that it is clarified whether the compensation is $10 per day or per visit.
2. The Committee noted that there is an emergent issue with USA Federal Government funding for research. The Committee noted that studies had been suddenly terminated without regard to the welfare of participants, and that this would also impact New Zealand participants if a study was terminated without warning in breach of ethical principles and the New Zealand Ethical Standards. The Committee requested that the Sponsor provide written confirmation that the US Government is not the source of any funding and, as requested by the Committee, that this will be from the Chief Medical Officer, Chief Financial Officer and Chief Legal Officer inclusive. If there is USA Federal Government funding, this should be highlighted, and the Study will require further consideration by the Committee
3. The Committee noted that questionnaires involving questions about depression and suicidality should be conducted in the presence of a clinician, and a more detailed safety plan should be provided.
4. The Committee believe the use of Greenphire is unnecessary and have concerns at the broad access to data outlined in the policies provided. If an alternative option or not using it is available, please consider whether it should be offered for use at all to NZ participants. The Committee are very concerned with the privacy issues surrounding its use.
5. The Committee queried why there is a separate participant information sheet for genetic testing if this is part of the main study. This information can be condensed to what is relevant to the mandatory component of the study and folded into the main information sheet.
6. The Committee queried the exclusion of people who are pregnant or breastfeeding. The Committee queried if a pregnant or breastfeeding person would be excluded from standard treatment, and asked the Investigator to provide justification for this routine exclusion from the trial if their pregnancy or breastfeeding status would exclude them from the provision of the current standard of care.

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

All:

1. Please note that this medication is also approved for use in New Zealand, aside from being FDA approved.
2. Please remove the statement ‘my unborn child’s medical files may be reviewed remotely’.
3. Please review the pre-screening information for things that have a place in the main PIS but are not relevant to participants who may not end up in the study, such as references to Greenphire, emails and text messaging services.
4. The Committee noted an Intervention study-specific template was made available recently which has simplified language that will help with changes requested.
5. Please change or remove the wording to reflect that participants won’t have to pay for any medications required to treat side effects.

Main PIS/CF:

1. Please include information from the protocol which outlines what dose participants who are not selected for phase 3 will be on.
2. Please change wording regarding county and state on page 8, as these do not apply to New Zealand.
3. Please define what cfDNA is.
4. Please use gender neutral language. References to ‘all female participants who may be able to become pregnant’ can just be amended to ‘all participants who may be able to become pregnant’.
5. Please remove reference to race, as only ethnicity data should be collected.
6. Please clarify that extra costs for disabled people will be covered.
7. Please mention that a support person can be present for physical examinations.
8. Please include a safety plan for completing the questionnaires.
9. Please rephrase side effects as adverse events.
10. The Committee queried the inclusion of the medical visa component, and requested this is reviewed and justified – otherwise removed.

Optional Biopsy PIS/CF:

1. Be clear that the Sponsor will pay for any extra procedures or costs incurred.
2. Please state where the sample will be stored.

Optional Future Research PIS/CF:

1. Acronym of ‘ACS’, please remove.
2. Please be clear where samples are sent to and stored.
3. Please review the statement regarding compensation and state whether Medicines NZ guidelines are being adhered to. The HDECs have a [new intervention-specific template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates) that has different wording for use.

**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 Jade Scott and Ms Dianne Glenn.

|  |  |  |
| --- | --- | --- |
| **6**  | **Ethics ref:**   | **2024 FULL 18376** |
|   | Title:  | An international multi center randomized controlled trial to compare combined Portal and Hepatic Vein Embolization (PVE/HVE) with Portal vein embolization (PVE) alone. |
|   | Principal Investigator:  | Doctor Rukshan Fernando |
|   | Sponsor:  | Te Whatu Ora Te Toka Tumai Auckland |
|   | Clock Start Date:  | 06 February 2025 |

Doctor Rukshan Fernando and Mary-Anne Woodnorth 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 sought clarity that the HVE aspect of the study does not involve the use of a a new device. The Researcher advised that this is a novel concurrent combination of existing procedures, rather than involving new devices.

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 ethnicity data needs to be collected at a site-level and reported to HDEC in annual reports.
2. The Committee recommended ensuring recruitment of Māori participants reflects their overrepresentation in this disease presentation.
3. The committee recommended reviewing all documents to ensure they are relevant for a New Zealand setting, and to remove unnecessary repetition. Use or reference to the [HDEC templates](https://ethics.health.govt.nz/guides-templates-and-forms) would aid in this adjustment from international-based documents.
4. The Committee requested review on whether pregnant people need to be excluded from the study or if this could be considered on a case-by-case basis. If people who are pregnant need to be excluded, then a pregnancy test should be part of the protocol. Routine blanket exclusion should be avoided without proper rationales, and if a person would not be excluded if they were receiving the current standard of care, the justification needs to be provided for exclusion from the study.
5. The Committee noted an outline of a safety plan should be included in the protocol for what will happen if concerning responses are flagged in the quality-of-life questionnaires.
6. The Committee requested inclusion in the data management plan of Sponsor details and relevant organisational data governance. Please also review for relevant inclusion of sections.

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

1. Please include all the risks from the protocol for participants to be aware of.
2. Please explain that questionaries include questions which may be triggering, and state what the safety plan is if concerns are raised.

**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 Catherine Garvey and Dr Sotera Catapang.

|  |  |  |
| --- | --- | --- |
| **7**  | **Ethics ref:**   | **2024 FULL 22079** |
|   | Title:  | Randomised control trial, comparing incidence of biphasic anaphylaxis reactions in patients given oral Prednisone/Prednisolone against placebo |
|   | Principal Investigator:  | Dr Adrian Owen |
|   | Sponsor:  | Te Whatu Ora Waikato |
|   | Clock Start Date:  | 06 February 2025 |

Dr Adrian Owen 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 requested clarification around the allergy to prednisone exclusion and that they will be put in the non-treatment arm without being randomised, and whether these participants will be consented, followed up, etc. The Researcher confirmed this would be the case, and allergy to prednisone exclusion or those administered a corticosteroid and therefore excluded.

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 recommends using the National Ethical standards to ensure the study proposal is formulated to more reflect what protocol must contains all the relevant information. [Chapter 9 of the National Ethical Standards](https://neac.health.govt.nz/national-ethical-standards/part-two/9-research-development-and-design) contains further detail around what is required.
2. The Committee requested review of the data management plan (DMP) for typos and correct trial name.
3. The Committee requested provision of a copy of the thank you letter before it is presented to participants, presumably via the post-approval pathway.

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

1. Please review for typos and incomplete sentences, such as the one under voluntary participation.
2. Explain in lay terms what coded information is. This wording could be taken from the DMP.
3. Please add an option to consent for future research to ensure this is optional – currently there is no rationale provided for it to be mandatory.
4. Please add short term risks for prednisone.
5. Please explain in lay terms what a biphasic reaction is in lay terms.
6. Any references to ‘they’ to participants should be ‘you’.
7. Please clarify that a script for an Epipen will be provided and ensure participants are aware that this should be collected on discharge.

**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 Jessie Lenagh-Glue and Dr Kate Parker.

|  |  |  |
| --- | --- | --- |
| **8**   | **Ethics ref:**   | **2024 FULL 21521** |
|   | Title:  | A 2-Stage, Phase I/II, Active-controlled, Randomized, Observer-blinded, Dose-finding Study to Assess the Safety, Reactogenicity, and Immunogenicity of SK Japanese Encephalitis mRNA Vaccines (GBP560) in Healthy Adults (Aged 18 Years and Older). |
|   | Principal Investigator:  | Dr Cory Sellwood |
|   | Sponsor:  | SK bioscience |
|   | Clock Start Date:  | 06 February 2025 |

Dr Cory Sellwood, Kayla Malate, Julia O’Sullivan, Amanda Karunaratne and Lucy Druzianic 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.

Dr Andrea Forde declared a potential conflict of interest and the Committee decided to have her remain for the discussion.

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 the rationale presented in the submission for doing this study when there is no incidence of this virus in New Zealand and there are two licenced vaccines available. The Researcher stated that it is a Phase I/II study so is focused on safety and immunogenicity.
2. The Committee questioned why there was an exclusion for family members of the investigators. The Researcher gave a summary of reasons explaining the preference for excluding family members which the Committee accepted.
3. The Committee raised concerns about using Medidata and protecting participants information. The Researcher advised it would only have deidentified data entered.
4. The Committee raised concerns about folding Phase I and II into the same study particularly considering that the active dose of the drug substance had not yet been determined and that there was as yet no evidence of safety, tolerability, or efficacy, or PK or PD in humans. The Committee asked why the study design included both Phase I and II rather than separate Phase 1 and II. and use of active comparators rather than placebo in Phase 1. 1. After constructive discussion, the PI advised, and Committee confirmed it would receive the SCOTT approval letter and relevant related information. If similar concerns were raised in the TGA approval process the PI confirmed this would be conveyed to the Committee.
5. The Committee queried if 30 minutes after receiving the vaccination was long enough for observing potential adverse events besides anaphylaxis. After discussion, it was clarified that participants are assessed at every site visit and have a process to contact the after-hours doctor, and the Committee was reassured.

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 submission contained incorrect information on all of: current standard of care, Japanese Encephalitis, the licensed Japanese Encephalitis vaccines and the incidence (not prevalence as was in the Submission) of JE in New Zealand.
2. The Committee noted that claims of clinical equipoise are difficult to explain in the absence of an effective dose of the investigational vaccine. The Committee requested evidence of SCOTT approval, and any comments provided where possible to ensure the Committee can be assured of the scientific validity.
3. The Committee requested clarity around global numbers, at least in terms of the maximum and expectation around New Zealand sites if the Australian sites do not meet the target recruitment.

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

1. Please change ‘side effects; to ‘adverse events’ .
2. AS the adverse events of the investigational vaccine are theoretical and class based, please note that and please reference the source of the adverse events data for the licensed vaccines e.g. NZ Datasheet, SmPC or post marketing surveillance. Also provide information on frequency of occurrence.
3. For the reserve patients, please note that contributions will be taxed.
4. Please advise in other PISs that there is a separate CF for future unspecified research for participants to look at.
5. Please correct typos and grammatical errors.
6. Separate ‘Hepatitis B, C’ as ‘Hepatitis B or C’.
7. Ensure all Māori words are reviewed for proper macron placement.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Maakere Marr, Ms Catherine Garvey and Dr Andrea Forde.

|  |  |  |
| --- | --- | --- |
| **9**   | **Ethics ref:**   | **2024 FULL 21748** |
|   | Title:  | A PHASE 1/2A DOSE-ESCALATING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF ARO-ALK7 IN ADULT VOLUNTEERS WITH OBESITY WITH AND WITHOUT TYPE 2 DIABETES MELLITUS |
|   | Principal Investigator:  | Dr Christian Schwabe |
|   | Sponsor:  | Arrowhead Pharmaceuticals, Inc. |
|   | Clock Start Date:  | 06 February 2025 |

Dr Christian Schwabe, Kayla Malate, Julia O’Sullivan, and Lucy Druzianic were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee noted that nurses attending homes for study procedures should be covered by a safety plan, and the sites should ensure that this is in place. The researchers confirmed that third party nursing services would be utilised.
2. The Committee noted that there is an emergent issue with USA Federal Government funding for research., The Committee noted that studies had been suddenly terminated without regard to the welfare of participants, and that this would also impact New Zealand participants if a study was terminated without warning in breach of ethical principles and the New Zealand Ethical Standards. The Committee requested written assurances from the Sponsor’s Chief Medical Officer, Chief Financial Officer and Chief Legal Officer, inclusive, that the US Federal Government is not a source of funding. If there is USA Federal Government funding, this should be highlighted, and the Study will require further consideration by the Committee

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

1. Please state that the reserve participant payment is taxable.
2. The Committee queried requiring both barrier contraceptives and highly effective contraception e.g. hysterectomy or tubal ligation, and a review of this.
3. Please ensure ‘SC’ is defined in all PIS’s as subcutaneous.
4. Please review and correct for missing words, i.e. ‘from dosing at least 90 after’.

**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).*

|  |  |  |
| --- | --- | --- |
| **10**   | **Ethics ref:**   | **2024 FULL 21892** |
|   | Title:  | A Phase 1 Randomized, Double-Blind, Placebo-Controlled Study With A Food Effect Assessment To Evaluate The Safety, Tolerability, And Pharmacokinetics Of Single Ascending Doses And Multiple Ascending Doses Of PX578 In Healthy Adult Participants |
|   | Principal Investigator:  | Dr Chris Wynne |
|   | Sponsor:  | Pretzel Therapeutics |
|   | Clock Start Date:  | 06 February 2025 |

Dr Chris Wynne, Kayla Malate, Julia O’Sullivan, and Lucy Druzianic 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 automatic opt-in for receiving study results and acknowledged the rationale.

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 there is an emergent issue with USA Federal Government funding for research., The Committee noted that studies had been suddenly terminated without regard to the welfare of participants, and that this could also impact New Zealand participants if a study was terminated without warning in breach of ethical principles and the New Zealand Ethical Standards. The Committee requested written assurances from the Sponsor’s Chief Medical Officer, Chief Financial Officer and Chief Legal Officer, inclusive, that the USA Federal Government is not the source of any funding. If there is US Federal Government funding, this should be highlighted, and the Study will require further consideration by the Committee.
2. The Committee noted that the insurance certificate will need to be renewed before the end of the study.

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

1. Please condense the information on pages 8 and 9 around risks.
2. Please change the wording to reflect that the ethics committee only review the ethical aspects of the study.

**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:

|  |  |
| --- | --- |
| **Meeting date:** | 18 March 2025 |
| **Zoom details:** | To be determined |

1. **Other business**
* The Committee acknowledged the resignation of Dr Devonie Waaka, and the huge contribution she had made to the HDEC’s over her long service.
* The sudden cessation of United States of America federal funding to research, including clinical research in human participants, was raised as having potential impact on New Zealand participants. It was noted that the existence of any federal funding, e.g. NIH, CDC, HHS, USAID or Federal Grants to Universities for indirect support of research, etc, is a question that will need to be asked of all Sponsors who are based in the USA starting with this meeting’s studies. This matter will be raised with the Chairs and Secretariat to ensure a consistent approach.

The meeting closed at 5.50pm.