|  |  |
| --- | --- |
| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 27 February 2024 |
| **Zoom details:** | 9738756003 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 12:00 - 12:30pm | 2023 FULL 13208 | ZERO2 Precision Medicine for Every Child with Cancer | Dr Andrew Wood | Helen / Albany |
| 12:30 - 1:00pm | 2024 FULL 18514 | HZNP-DAZ-303\_Study to Evaluate the Efficacy and Safety of Dazodalibep in Participants With Sjögren’s Syndrome With Moderate-to-Severe Symptom State | Doctor Sunil Kumar | Sandy / Patries |
| 1:00 - 1:30pm | 2024 FULL 19101 | 1305-0031- Fibroneer ON: A follow-up study to test long-term treatment with BI 1015550 in people with pulmonary fibrosis who took part in a previous study with BI 1015550 | Doctor Conor O'Dochartaigh | Cordelia / Patricia |
| 1:30 - 2:00pm | 2024 FULL 19526 | MK-3543-017: Phase 3 Study to Evaluate Safety and Efficacy of MK-3543 | Dr James Liang | Helen / Albany |
| 2:00 - 2:30pm |  | BREAK (30 mins) |  |  |
| 2:30 - 3:00pm | 2024 FULL 17961 | Detecting pulmonary hypertension (high blood pressure in the lungs) in premature newborns | Doctor Matthew Buckingham | Cordelia / Patricia |
| 3:00 - 3:30pm | 2024 FULL 18986 | PRN IM vs SC Needle Length RCT Study | Dr Gabby Shortt | Sandy / Patries |
| 3:30 - 4:00pm | 2024 FULL 19653 | Tailored to me: Evaluating the effectiveness and acceptability of behavioural assessments for people living with dementia | Dr Rebecca Sharp | Cordelia / Albany |
| 4:00 - 4:30pm | 2024 FULL 18361 | OMG-100 as a Treatment for Insomnia Disorder | Dr Alex Semprini | Helen / Patricia |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (Consumer/Community perspectives) (Chair) | 22/12/2020 | 22/12/2024 | Present |
| Mrs Sandy Gill | Lay (Consumer/Community perspectives) | 22/05/2020 | 22/05/2023 | Present |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Present |
| Dr Cordelia Thomas | Lay (the Law) | 22/12/2020 | 22/12/2024 | Present |
| Mrs Patricia Mitchell | Non-lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Mx Albany Lucas | Non-lay (Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Apologies |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members, noting that apologies had been received from Ms Jessie Lenagh-Glue.

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 23 January 2024 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **2023 FULL 13208** |
|  | Title: | ZERO2 Precision Medicine for Every Child with Cancer |
|  | Principal Investigator: | Dr Andrew Wood |
|  | Sponsor: | ANZCHOG |
|  | Clock Start Date: | 15 February 2024 |

Dr Andrew Wood and Dr Sarah Hunter were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried the AI component of the research. The Researcher stated the human interpretation of genetic results is where the cost comes from due to the time involved, not the test itself. The Researcher stated AI tools may aid with interpretation and literature searches to deliver more efficient results and curation.

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 participants are provided a copy of the original information when they are approached again to confirm whether or not they wish to receive the category 2 results and not a simple yes/no option.
2. The Committee noted the study would ask questions around family history of cancer and suggested caution to avoid breaching privacy. The Researcher agreed to review the data collection form to ensure it would not collect any information about specific individuals.

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

1. Please review the language on page 2 regarding precision medicine helping children with high risk cancer and amend if it may be applicable to individuals without high risk.
2. Please review the upper age limit for inclusion and ensure it is consistent.
3. Please include a statement advising that genetic counselling will not have any costs to participants.
4. Please include a lay-friendly definition of precision medicine. The current description may imply that every participant will receive a personalised result.
5. Please move the estimation that 20% of children with high-risk cancer will receive a personalised treatment to earlier in the sheet.
6. Please revise the statement regarding sample availability to state if you already have a sample or if a sample may be taken in the future.
7. Please revise the reference to ‘cancer genetic risk’ on page 14 to state ‘genetic cancer risk’ to be consistent with the rest of the sheet.
8. Please revise the reference to ‘your child’s diagnosis’ on page 16.
9. Please clarify the choice to receive genetic cancer results on page 17 are referring to category 2 results.
10. Please include a statement advising whether a karakia will or will not be available at the time of tissue collection/destruction.
11. Please revise the statement on page 2 of the future unspecified use of tissue form that ‘there are no plans for you to receive payment’ to clearly state participants will not be paid. This change may be made across all generic FUUOT forms without resubmission to HDEC. The updated form may be supplied the next time there is an amendment or progress report due.
12. Please include a statement on whether Karakia will or will not be performed on the FUUOT form. This change may be made across all generic FUUOT forms without resubmission to HDEC. The updated form may be supplied the next time there is an amendment or progress report due.
13. Please include a karakia statement on the generic additional tissue form.
14. Please include a child-friendly description of what tissue samples are on the assent form.
15. Please include a tick box instead of a signature box on the younger assent form.
16. Please define or remove the term incineration on the older assent form.
17. Please include mention of the New Zealand Privacy Act 2020 in the ‘What will happen to my information?’ section.
18. Please revise the statement on page 9 that data will be made anonymous as deidentified data may still be reidentified.
19. Please revise ‘cultural background’ to ethnicity if this is what is intended.

**Decision**

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

* 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).*

|  |  |  |
| --- | --- | --- |
| **2** | **Ethics ref:** | **2024 FULL 18514** |
|  | Title: | A Phase 3 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Dazodalibep in Participants With Sjögren’s Syndrome With Moderate-to-Severe Symptom State |
|  | Principal Investigator: | Dr Sunil Kumar |
|  | Sponsor: | Horizons Therapeutics Ireland DAC; PPD Part of Thermo Fisher |
|  | Clock Start Date: | 15 February 2024 |

Mrs Kathryn Stothers was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee queried whether participants would be expected to have a recent Covid booster or influenza vaccination. The Researcher agreed to confirm this with the Sponsor. The Committee requested the information sheet is updated to state whether this is or is not required.

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

1. Please revise the sheet to have larger margins to aid readability.
2. Please state whether or not a karakia will be possible at the time of tissue collection/destruction.
3. Please include a ‘yes / no’ tick box on the consent form to offer participants a lay-summary of the study results. Participants should not be expected to search online for results.
4. Please include information on how soon quality of life questionnaires will be reviewed and an explanation of the study’s safety plan and what will happen if participants indicate distress or concerning responses. The Committee suggested adapting the answer to E3.2 in the HDEC application form for this.
5. Please review the bullet point on page 7 “Tests that will help evaluate the effect of the research medicine on your SS” and whether this should be a heading.
6. Please change “willing to wait” to “willing to attend” on page 11.

**Decision**

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

1. 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 Sandy Gill and Dr Patries Herst.

|  |  |  |
| --- | --- | --- |
| **3** | **Ethics ref:** | **2024 FULL 19101** |
|  | Title: | An open-label extension trial of the long-term safety and efficacy of BI 1015550 taken orally in patients with idiopathic pulmonary fibrosis (IPF) and progressive pulmonary fibrosis (PPF) (FIBRONEER™-ON) |
|  | Principal Investigator: | Dr Conor O'Dochartaigh |
|  | Sponsor: | Boehringer Ingelheim |
|  | Clock Start Date: | 15 February 2024 |

Dr Conor O'Dochartaigh and Mrs Dale Thompson 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 noted the pregnancy information sheets had not been reviewed. If a participant or their partner becomes pregnant during the study please submit an amendment with the sheet for review.
2. The Researcher confirmed the Columbia-Suicide Severity Rating Scale (C-SSRS) would be administered face-to-face. Other surveys participants complete ahead of the visit would be reviewed at that time.

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 an information sheet for reimbursement for caregivers but no information in the main participant information sheet to describe this.
2. The Committee requested the Researcher supply the optional survey caregivers will be asked to complete.
3. The Committee queried if participants will be provided ongoing access to the study medicine at the end of the trial. The Researcher stated this would be dependent on study results and market availability. The Committee queried if compassionate supply would be possible. The Researcher stated this would need to be assessed on a case-by-case basis. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 10.15)*
4. The Committee noted page 23 of the information sheet contains a clause that participants understand the risks associated with pregnancy but page 14 states contraception is not required. Please address this discrepancy.

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

1. Please include a lay title for the study.
2. Please undertake a plain language review of the sheet as some paragraphs contain technical information that may be difficult to understand.
3. Please include information in the main participant information sheet on what role caregivers may have in the study and what information the optional survey will collect. Please specify the caregiver’s participation is only with the main participant’s consent. Please include a ‘yes / no’ tickbox on the consent form for this.
4. Please amend any references to being reimbursed for ‘time’ as this has tax implications. Reimbursement for parking and travel expenses is acceptable.
5. Please remove repeated references to participants being able to withdraw at any time as this only needs to be included once.
6. Please correct the typo on page 3 (’99 weeks’).
7. Please include a statement advising whether post-trial access will be available or not.
8. Please revise the term ‘trash’ to ‘rubbish’ on page 3.
9. Please revise the statement advising participants to avoid grapefruit to state they should not eat or drink it.
10. Please include information on how soon quality of life questionnaires will be reviewed and an explanation of the study’s safety plan and what will happen if participants indicate distress or concerning responses. The Committee suggested adapting the answer to E3.1 in the HDEC application form for this.
11. Please revise the statement that should participants develop suicidality their participation will be ended. The Committee suggested reframing this so it focuses on the participants and their wellbeing.
12. Please include whole numbers (“at least 3 out of 100 people”) instead of percentages when discussing risks.
13. Please specify follow-up visits will be done with the participant’s consent.
14. Please specify the approval status of the drugs in New Zealand on page 12 when discussing overseas approvals.
15. Please clarify who the ‘usual doctor’ is on page 17 under who can see identifiable information. Elsewhere the sheet refers to a GP.
16. Please include an apostrophe in ‘its’ on page 18.
17. Please refer to New Zealand instead of ‘your country’ on page 18 and include New Zealand law with the reference to EU law.
18. Please revise the statement that samples transferred to another company in the event the rights to the drug are sold will be held with the same protections as this cannot be guaranteed.
19. Please revise ‘local data protection authority’ on page 19 to Privacy Commissioner.
20. Please revise the clause regarding a family member being contacted about the participant’s health as no information in the sheet relates to this. Please revise the clause to refer to the participant’s GP.
21. Please include a statement advising participants they will not be disadvantaged if they do not enter the study.
22. Please define or provide examples of heavy activity on page 3.
23. Please include a statement advising participants if they have difficulty travelling to appointments, they are welcome to bring a caregiver with them and the caregiver is eligible for reimbursement for travel and parking expenses.
24. Please remove any ‘yes / no’ tick boxes on the consent form unless they are truly optional (ie the participant can answer ‘no’ and still participate in the study).
25. Please include statements advising that participants will need to remove clothing for the physical exam and are welcome to have a support person present. Please state whether gender matching (the person performing the exam being the same gender as the participant) will be possible.
26. Please state that HIV and Hepatitis are notifiable diseases and that pre and post-test counselling will be provided.
27. Please include the full HDEC cultural tissue statement instead of the abbreviated version.

**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 copies of any surveys that will be used in the study.

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

|  |  |  |
| --- | --- | --- |
| **4** | **Ethics ref:** | **2024 FULL 19526** |
|  | Title: | A Multicenter, Open-Label, Extension Study Evaluating the Safety and Efficacy of Bomedemstat for the Treatment of Participants Enrolled in a Prior Bomedemstat Clinical Study (MK-3543-017) |
|  | Principal Investigator: | Dr James Liang |
|  | Sponsor: | Merck Sharp & Dohme LLC |
|  | Clock Start Date: | 15 February 2024 |

Dr Gordon Royle, Ms Lisa Li, Ms Maria Segura, and Ms Esther Ji 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 indemnity for the Coordinating Investigator had expired and requested this be updated. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.6)*:

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

1. Please state how long participants may expect to receive the trial drug as it is unclear when the study will end.
2. Please refer to the Sponsor as Merck or MSD Ltd as ‘MSD’ may cause confusion with the Ministry of Social Development.
3. Please include statements advising participants they will need to remove clothing for the physical exam and are welcome to have a support person present. Please state whether gender matching (the person performing the exam being the same gender as the participant) will be possible.
4. Please state that participants will be expected to provide blood and urine samples every four weeks for up to 10 years (or the duration of the trial).
5. Please state whether or not a karakia will be available (the sheet currently says it ‘may’ be).
6. Please state pre and post-test face-to-face counselling will be available for the HIV testing so participants are prepared for the results and support is available if a positive result is detected.
7. Please include contraception in the ‘What else do I need to do?’ section on page 5.
8. Please state MK543 has been ‘tested’ in people rather than ‘given’.
9. Please use gender-neutral wording throughout the sheet.
10. Please include ‘with consent’ to the statement ‘you will be monitored’ on page 9.
11. Please revise section 15 (benefits) as participants are only in the trial if they are already receiving benefit from the drug.
12. Please remove section 16 as this contains repeated information.
13. Please remove the requirement for participants to provide receipts and instead have a stipend of a standard amount.
14. Please remove the statement ‘You will not be penalised or lose any benefits’ as the benefit of the trial is receiving the drug so withdrawal will affect this.
15. Please clarify the trial cannot be terminated solely for commercial reasons on page 13.
16. Please revise the right to access and withdraw information section with the prompts available on the [HDEC information sheet template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates)
17. Please include a statement advising the regular blood and urine tests are being done for safety reasons.
18. Please revise a positive Hepatitis result on page 4 to specify active Hepatitis B or C. Please correct New Zealand Health Department to the Medical Officer of Health.
19. Please clarify what directions are referred to on page 5 where it states ‘Take the trial drug by following the directions’.
20. Please include a statement advising exclusions to having an MRI (eg metal implants, pacemaker).
21. Please include a clause on the consent form that if a participant withdraws from the study any information collected up that point may continue to be used.
22. Please revise the “I understand that, if I decide to discontinue the trial treatment...” bullet point to be two smaller clauses. The Committee suggested ‘Alternatively’ begin as the second point.

**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 evidence of current professional indemnity. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.6)*:

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Mx Albany Lucas.

|  |  |  |
| --- | --- | --- |
| **5** | **Ethics ref:** | **2024 FULL 17961** |
|  | Title: | Pulmonary hypertension in the premature newborn; evaluating the clinical feasibility and utility of a diagnostic guidelines to detect late disease in a high-risk population in the New Zealand setting |
|  | Principal Investigator: | Dr Matthew Buckingham |
|  | Sponsor: | The University of Otago |
|  | Clock Start Date: | 15 February 2024 |

Dr Matthew Buckingham was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried whether the research had begun as the application indicated it started in December 2023. The Researcher confirmed recruitment for this study had not begun as ethical approval was not obtained. The Researcher stated they done a literature search and developed a survey to send to the neonatal units in New Zealand. The Researcher confirmed the survey is separate to this study and went through ethics at the University of Otago and Te Whatu Ora Waitaha’s local review process. The Committee noted its scope of review does not include research involving providers of health and disability services as participants, so this survey did not require approval from HDEC.

Summary of outstanding ethical issues

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

1. Please include information on the results of the survey sent to neonatal units.
2. Please specify what complications babies may be more at risk of as adults on page 3.
3. Please revise the statement that participation is free to state there is no cost.
4. Please change ‘Māori health support’ to ‘Māori cultural support’.
5. Please correct ‘your’ to ‘your baby’s’ on page 4.
6. Please revise ‘analgesia’ to ‘pain relief’ and undertake a general plain language review.
7. Please remove ultrasound from the sentence "With your consent we will give your baby some oral sugar analgesia to minimize pain and discomfort for the blood test and ultrasound scan" as the previous sentences state the ultrasound is painless. Please revise ‘for’ the blood test to state ‘from’ the blood test.
8. Please update the sentence “If your deidentified information is being sent overseas” on page 6 as data will be sent to Australia.
9. Please revise or insert a comma in the lay title to remove ambiguity (“Detecting high blood pressure in babies born too early, to improve their future health”).
10. Please revise “your baby’s” to “a baby’s” when first discussing pulmonary hypertension as this will not have been diagnosed yet.
11. Please introduce the PH acronym with brackets after it is first mentioned (“Pulmonary hypertension (PH)”).
12. Please undertake a general proofread to find missing words.
13. Please revise the section on page 2 to remove the reference to Auckland in brackets. Please rewrite the paragraph for clarity.
14. Please move “in New Zealand” to after “There is not currently a standardised guideline” on page 2.
15. Please revise the “What is the purpose of the study?” section to detail the study in chronological order.
16. Please specify the ethical aspects of the study have been approved by the Central Health and Disability Ethics Committee.
17. Please elaborate the statement “If high blood pressure in the lungs is identified it can also be treated with several different medications and specialists” on page 3 as this may imply several specialists are required.
18. Please specify images will be of “your baby’s” joints not “your joints” on page 3.
19. Please remove the repeated information about confidentiality of information.
20. Please adapt the cultural tissue statement from the [HDEC information sheet template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates)
21. Please revise uses of confidential to refer to identified or deidentified personal information. Please see the HDEC template for prompts.
22. Please remove the reference to holding information as required by law and state the study data will be held for 10 years after the youngest participant turns 16.
23. Please remove “with” from the sentence “You also have the right to request that any information about you that is incorrect with is corrected” on page 6.
24. Please review the consent form clauses to ensure they all refer to the first-person and remove references to “the participant”.
25. Please remove references to participation being confidential in the consent form.
26. Please clarify the responsibilities clause to refer to study-specific responsibilities.
27. Please revise the term unidentified data to deidentified.
28. Please remove the ‘yes / no’ tick box from the clause regarding withdrawn data continuing to be used as this is not optional.

**Decision**

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

1. 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 Cordelia Thomas and Mrs Patricia Mitchell.

|  |  |  |
| --- | --- | --- |
| **6** | **Ethics ref:** | **2024 FULL 18986** |
|  | Title: | A single blinded, parallel group, 2-arm randomised control trial investigating immunogenicity and reactogenicity of subcutaneous (SC) vs intramuscular (IM) administration of Pfizer COVID-19 vaccine in adults aged 18 – 75 years |
|  | Principal Investigator: | Dr Gabby Shortt |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 15 February 2024 |

Dr Gabby Shortt and Ms Mele Porter were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researchers confirmed the consent process would be undertaken over the phone and eligibility criteria explained before participants disclose any health information. The consent will be recorded through the electronic system. Participants who respond to study advertisements or an invitation from their GP or marae will be provided information about the trial before the phone call.

Summary of outstanding ethical issues

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

1. Please include information regarding the electronic consent process.
2. Please remove receiving the vaccination/boost as a benefit of taking part in the study as this is available otherwise.
3. Please change ‘Māori health support’ to ‘Māori cultural support’.
4. Please include information in the sheet regarding notifying the participant’s GP. There is a clause for this in the consent form but no information in the sheet.
5. Please revise the use of the term ‘obesity’ on page 1 as this stigmatising language. The Committee suggested replacing it with larger bodies or something similar.
6. Please correct the reference on page 7 to storing information for 15 years to 10 years. Please amend ‘required to’ to state ‘we will’.

**Decision**

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

* 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).*

|  |  |  |
| --- | --- | --- |
| **7** | **Ethics ref:** | **2024 FULL 19653** |
|  | Title: | Tailored to me: Evaluating the effectiveness and acceptability of behavioural assessments for people living with dementia |
|  | Principal Investigator: | Dr Rebecca Sharp |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 15 February 2024 |

Dr Rebecca Sharp and Lily Bigwood were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee confirmed with the Researchers that the person with dementia will be guided by a Researcher when completing the questionnaires should they need assistance or someone to talk the questions through with.
2. The Committee confirmed that the Researcher will not be alone with the dementia participant and won’t have too many people in the room, which may overwhelm the person.
3. The Committee noted that the start date says 01 January 2024 and confirmed this has not yet started.
4. The Committee queried that given Māori are overrepresented in the prevalence data, whether the Researchers are taking steps to ensure Māori are represented in the study. The Researcher responded that Māori recruitment is not being actively sought out, but appropriate consultation in the event there are Māori participants will be undertaken.

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 stated that the support person cannot give consent for someone with diminished capacity, and only someone with Enduring Power of Attorney (EPOA) or a court appointed welfare guardian can do so under the law (noting that this is not a medical experiment). The role of the support person was clarified through discussion, and the Committee stated that the different consent scenarios need to be clearly detailed in the study documentation. The Committee stepped this out as the following key components:
   1. The support person cannot give consent on behalf of the participant, nor should they be expected to explain the research to the participant.
   2. Those with capacity to consent for themselves should be supported to do so.
   3. Those with diminished capacity who cannot be supported to provide their own consent can have an EPOA or welfare guardian consent for them.
   4. In the case where someone is unable to provide fully informed consent and does not have an EPOA or welfare guardian, then [Right 7(4) of the Code of Health and Disability Services Consumers’ Rights](https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/) must be satisfied and enrolled under that, or otherwise those people must be excluded.
   5. If a person is competent to consent for themselves, they also need to agree to have the support person involved and whānau member too.
2. The Committee noted for next time to please use the [HDEC peer review template](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance) as it asks questions surrounding scientific validity they are after.
3. Regarding cultural considerations, the Committee stated that whakamā is hugely applicable here and should be acknowledged throughout documentation.
4. The Committee noted that the koha offered is quite low and that it would be nice to also show respect of providing kai during the sessions as a token of gratitude. In addition, the Committee suggested a stipend to be offered to cover the support person and/or the whānau travel costs, which should be outlined in their information sheets.

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

All:

1. Please refrain from referring to ‘time’ in the koha section as this could become taxable. Please state it’s for recognition of their involvement.
2. Remove references to “nothing bad will happen” as this cannot be promised.
3. Ensure there are footers with page numbers, title and version number.
4. Clarify that because analysis of data occurs as it is collected, that is why data already collected cannot be withdrawn.
5. Please include a cultural statement paying respect to tikanga Māori and the whākama experienced.

Main PIS/CF:

1. The Committee noted that the study can't promise nothing will change in the way they are treated.
2. The PIS doesn't refer to the questionnaires they will complete.
3. It also doesn't mention the whānau involvement. They should have the choice of who they want as support person, staff person and whanau person.
4. State that if they get tired, they can indicate that they want to take a break.
5. It’s not clear how many sessions in total there are. Please include.
6. An Easy Read PIS should only be used if someone cannot understand the full main PIS.
7. The PIS could include an advance-directive for a participant to indicate that if they deteriorate to the point they couldn’t consent any more they still want to keep participating, they give permission to remain in the study.
8. Clarify that if the whānau member withdraws, they can still take part.
9. The sentence that “you have been chosen as a possible participant as your support workers think you may find this useful” should be rephrased slightly because the participant’s view should be important. It currently reads as if others know best and that is why they should take part.
10. Please provide phone numbers at the end for contacts. The Committee acknowledged that the study staff are no longer provided work phones and providing personal numbers is a risk. The Committee noted that it would be best to provide a generic university phone number who can pass on a message to the study staff who can return the phone call and inform that call centre how to proceed with those calls.
11. A Māori cultural support contact should be included.

Support person PIS/CF:

1. Missing that they have a right to access and correct any information gathered about them.
2. The ACC statement is missing. This can be used from the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
3. The form states they can withdraw person for whom they have guardianship, but they are not necessarily performing that role so this should be removed. They can only consent and withdraw themselves.
4. The CF has words missing.
5. Requires them to be “happy” in CF which is unusual. Please remove.

**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 address all concerns regarding modifying the consent process, taking great care to ensure the key components raised are detailed clearly. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.59 - 7.74)*
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).*

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

|  |  |  |
| --- | --- | --- |
| **8** | **Ethics ref:** | **2024 FULL 18361** |
|  | Title: | Evaluation of the safety and efficacy of 150mg and 300mg of OMG-100 cannabis for insomnia: a phase IIB/III, randomised, double-blind, placebo controlled study. |
|  | Principal Investigator: | Dr Alex Semprini |
|  | Sponsor: | Oz Medicann Group |
|  | Clock Start Date: | 15 February 2024 |

Dr Alex Semprini and Dr Alex Martin 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 noted that CBD can show up on drug-screening tests sometimes and queried how this may affect participant’s employment. The Researchers confirmed that the CBD that does show up on these tests has THC in it, which the study product does not.
2. The Committee stated that the peer reviewer commented on the lack of screening on obstructive sleep apnoea and queried the Researcher’s response to that. The Researchers clarified that it is not possible for them to screen for that effectively which would require a sleep lab.

Summary of outstanding ethical issues

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

1. The Committee raised significant concern around the DASS21 being used. While they acknowledged with the Researcher that those with diagnosed mental health issues will be excluded, some of the questions being asked could trigger a mental health event, in which it is the Researcher’s duty of care to ensure this is followed up on and followed through on. After discussion, the Committee required a more effective and robust safety plan if participation could trigger such an event. The Committee and Researchers agreed that risk could be reduced by separating out some of the more triggering questions from the DASS21 or finding different questionnaires to use (or developing one themselves). The effect on day-to-day life can be measured differently to quality of life, as what is being measured is how they generally feel in relation to how they slept, and not if it improved their feelings of anxiety or depression. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.1-8.6, 8.9, & 8.18).*
2. The Researchers have attached a letter saying they will be given insurance, but the Committee need to see the full policy to approve the study. Please ensure this is provided with the next submission. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
3. The Committee noted that participants never have any face to face contact with researchers for this study, and requested to investigate if face to face contact is possible as it could have a cultural significance and impact over decision to take part.

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

1. For the side effects listed on page 5, please cite if possible, how common these are (such as commonly experienced, rare, etc.)
2. Please include or provide safety precautions around what participant should do regarding how to handle the study product, like keeping it out of reach of children, if they withdraw how do they dispose of it, etc.
3. It is common to state whether this product has been used in other areas. Please include information around this.
4. Please refrain from referring to ‘time’ in the koha section as this could become taxable. Please state it’s for recognition of their involvement.
5. There is a sentence that says someone can’t take part if they are pregnant or breastfeeding. The Committee expect to see an explanation as to why that is. Please also see the [reproductive risks template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) for guidance around this.
6. The Committee noted that nothing can be raised in the consent form without first being explained in the main body of the information sheet. Please review for items which are first mentioned in the CF but not explained elsewhere in the PIS.

**Decision**

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

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 26 March 2024 |
| **Zoom details:** | To be determined |

The following members tendered apologies for this meeting.

* Mrs Helen Walker
* Dr Patries Herst

1. **Review of Last Minutes**

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

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

The meeting closed at 4:30pm.