|  |  |
| --- | --- |
| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 10 June 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 10.30-11.00am | 2025 FULL 15161 | SICARIO: Expanding stroke therapy access: Stroke in patients with very large Ischaemic Core. | Dr  Teddy  Wu | Mr Dominic Fitchett & Dr Geoff Noller |
| 11.00-11.30am | 2025 FULL 19466 | MoST-TAP: A single arm, open-label, phase II signal-seeking trial of tiragolumab and atezolizumab in patients with advanced solid tumours | Dr Michelle Wilson | Ms Dianne Glenn & Dr Nicola Swain |
| 11.30am-12.00pm | 2025 FULL 23103 | Investigating a new testing method for detecting genetic material of microorganisms in spinal fluid samples in a New Zealand clinical laboratory | Miss Delphine Marjoshi | Ms Neta Tomokino & Dr Andrea Kinga Marias Furuya |
| 12.00-12.30pm | 2025 FULL 22970 | TRITON-CM: A Study to Evaluate Nucresiran in Patients with Transthyretin Amyloidosis with Cardiomyopathy | Dr Mark Davis | Dr Maree Kirk & Dr Andrea Forde |
|  | *Break (30)* |  |  |  |
| 1.00-1.30pm | 2025 FULL 22946 | JADE101-01: A Study to Evaluate JADE101 in Healthy Participants. | Dr. Rohit Katial | Mr Dominic Fitchett & Dr Nicola Swain |
| 1.30-2.00pm | 2025 FULL 23149 | Assessing the effects of low dose psilocybin in healthy menstruating persons (PsiMen) | Professor Suresh Muthukumaraswamy | Ms Dianne Glenn & Dr Andrea Forde |
| 2.00-2.30pm | 2025 FULL 22465 | School-age Tracking and Assessment of Moderate-to-late Preterms | Professor Jane Harding | Ms Neta Tomokino & Dr Geoff Noller |
| 2.30-3.00pm | 2025 FULL 22518 | NS-089/NCNP-02 in Boys with Duchenne Muscular Dystrophy (DMD) | Doctor Gina O'Grady | Dr Maree Kirk & Dr Andrea Kinga Marias Furuya |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mr Dominic Fitchett | Lay (the Law) (Chair) | 05/07/2019 | 05/07/2022 | Present |
| Dr Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Apologies |
| Dr Nicola Swain | Non-lay (Intervention/Observational studies) | 22/12/2021 | 01/06/2030 | 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 |
| Dr Andrea Kinga Marias Furuya | Non-Lay |  |  | Present |
| Dr Andrea Forde | Non-lay (Intervention studies) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 10.00am with a karakia and welcomed Committee members, noting that apologies had been received from Dr Amy Henry  
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Andrea Forde and Dr Andrea Kingas Marias Furuya confirmed their eligibility and were co-opted by the Chair as a member 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 13 May 2025 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **2025 FULL 15161** |
|  | Title: | SICARIO: Expanding stroke therapy access: Stroke in patients with very large Ischaemic Core. |
|  | Principal Investigator: | Dr Teddy Wu |
|  | Sponsor: | University of Newcastle |
|  | Clock Start Date: | 29 May 2025 |

Dr Teddy Wu and Sara Parkin 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 while the submission referred to a waiver of consent, the justification appeared to align more closely with a Best Interests argument under [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/). The Researchers advised that participants would receive the intervention regardless of study enrolment, and that the study primarily involves follow-up, which does not currently occur in standard clinical practice. If not enrolled, participants would still receive standard care, but follow-up would occur through other means and not in a timely or structured manner. The Committee considered that the risk of participation is low, although the participants are vulnerable. Based on the submitted documentation, the Committee was satisfied that the Best Interests of participants had been adequately addressed and confirmed they were comfortable with enrolment proceeding on that basis.

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 C.16 in the application form, and noted for Researchers to ensure ethnicity data is collected at site level.
2. The Committee queried the rationale for the routine exclusion of pregnant and breastfeeding participants. The Researchers advised that, clinically, pregnant individuals would not typically be excluded from receiving this procedure; however, the specific type of stroke being studied is extremely rare during pregnancy. The Committee suggested reconsidering the routine exclusion of pregnant/breastfeeding participants, given that they would be receiving the same clinical procedure regardless of study participation, and that these participants would receive structured follow up as was suggested earlier.

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

All:

1. Please review for typos and clarity of language across all sheets.
2. There is some mismatch between title of information sheet and what you are asking the person to do. Please clarify these.
3. The Committee requested the removal of the ‘yes / no’ tick boxes from the consent forms unless it is for a clause that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study).

Short Information Sheet:

1. Please review for repetition throughout the sheet.
2. Page 2 says “if you decide to provide permission on their behalf” The Committee reminded the Researcher that the person completing the form is giving their opinion, not permission on behalf of the participant. Review for all instances of this phrasing and amend.

Full Information Sheet:

1. Please include a paragraph to cover those enrolled under Best Interests.
2. Rephrase page 10 as the family are not giving consent for them, just giving opinion.

Continuation Information Sheet:

1. Please rephrase inclusion to not be waiver granted, but that enrolment was in Best Interests.
2. Review language about withdrawing and remove or rephrase about family consenting on their behalf.

**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).*

|  |  |  |
| --- | --- | --- |
| **2** | **Ethics ref:** | **2025 FULL 19466** |
|  | Title: | MoST-TAP: A single arm, open-label, phase II signal-seeking trial of tiragolumab and atezolizumab in patients with advanced solid  tumours |
|  | Principal Investigator: | Dr Michelle Wilson |
|  | Sponsor: | Omico |
|  | Clock Start Date: | 29 May 2025 |

Dr Michelle Wilson and Sarah Philipsen were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that there is no reimbursement of study-related costs for participants. However, the Committee considered that participation in the study may still offer a benefit to participants. The Committee was satisfied that, should any financial hardship arise, appropriate support would be provided in accordance with standard of care.

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 the potential commercial aspect of the study, given the pharmaceutical support involved. The Committee noted that the Participant Information Sheet (PIS) includes several statements indicating that Roche may receive benefits from the study being conducted. Following discussion, the Committee requested clarification both in the study documentation and directly to the Committee regarding the extent of Roche’s control over the initiation and termination of the trial (if any), to ensure that the study is not being conducted principally for the benefit of the manufacturer or supplier. This is to ensure whether ACC would provide cover for any injury caused. Please affirm the reasons why the researchers believe that “the trial was not to be conducted principally for the benefit of the manufacturer or distributor of the medicine” see Chapter 17 of the National Ethical Standards.
2. The Committee queried the routine exclusion of pregnant or lactating individuals, as well as those who are Hepatitis B/C or HIV positive, from the study. The Committee asked whether such individuals would be excluded from receiving standard treatment for solid tumours outside of the study context. The Committee noted that a strong rationale could be made for their inclusion, particularly if they would otherwise receive the same treatment. The Committee requested that the study team consider including these populations and advised that the HDECs do not support their routine exclusion without clear justification. Please justify any planned exclusion of these populations.
3. The Committee requested revision of the data and tissue management plan (DTMP) for inclusion of irrelevant items from template (such as under 16s mention) as well as typos.

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

1. Page 16 states the study will be taking bloods for investigation, but results won’t be made available. In New Zealand there are rights for people to access medical information about them. Please review.
2. No information is provided around how stool is collected, the provision of containers, storage in a refrigerator, etc.
3. Mandatory pregnancy testing on day 1 of each cycle and testing throughout the trial is disrespectful of women of childbearing potential who have enrolled understanding the need to avoid pregnancy. Please review.
4. Clarify when a barrier form of contraception needs to be used.
5. There is a statement that doctor “must” follow up if there is a pregnancy, but this must be done with consent of the participant or female partner, so rephrase this.
6. Check conclusion date in PIS as it is different to the one in the application form submitted.
7. PIS discusses further treatment that could be available in terms of ongoing access, but application form says it is not. Please ensure this is consistent and clear what access they may have.
8. Mention of an interpreter being available should be at the beginning.
9. Please clarify that HDEC only approve the ethical aspects of the study.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Dianne Glenn and Dr Nicola Swain.

|  |  |  |
| --- | --- | --- |
| **3** | **Ethics ref:** | **2025 FULL 23103** |
|  | Title: | Pilot study - Exploring the use of metagenomics in detecting viral/bacterial/fungal/parasite infections in cerebrospinal fluid in a New Zealand clinical laboratory. |
|  | Principal Investigator: | Miss Delphine Marjoshi |
|  | Sponsor: | Te Whatu Ora - Waitaha Canterbury |
|  | Clock Start Date: | 29 May 2025 |

Miss Delphine Marjoshi and members of her team were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried how the panel can be intended for RNA viruses, DNA bacteria, fungal and parasitic pathogens when current sampling is limited to just the RNA viruses, DNA and bacteria. The Researchers noted they do not have samples in storage for validating fungal and parasitic pathogens on hand as they are in early stages of development of the test. The Researchers clarified that this study is more of a feasibility study than a full formal validation
2. The Researchers clarified who will be responsible for tests overseas and who will be analysing the data. The Researchers clarified that they are using two different metagenomic pipelines after which their processes will be more fully informed.

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 clarity from submission responses provided and recommended contacting the Māori advisor seeking feedback for the waiver of consent in regard to protecting whakapapa and to ensure Māori consultation feedback is received that is specific to this application.
2. After discussion the Committee recommended using commercially available sources such as the American Type Culture Collection (ATCC) to have coverage of microbial controls for microbiome standards and to strengthen validation of test. Researchers had described using spiked bacteriophage controls and a panel of 6 previously positive CSF samples to test the method’s sensitivity.
3. The Committee requested clarity on the statement in the protocol indicating the positive control for the DNA workflow being used is optional. The Researchers explained that this wording was included in the protocol to indicate that this is optional for each separate patient sample, as if it is shown once that it is working, then it indicates that the technique and protocol is working. The Committee requested that the protocol be revised to ensure this processes and the reasoning behind it is clearly outlined.
4. The Committee requested more detail on statistical analysis to be used. Provide an explanation of how samples were selected from statistical standpoint and what methods will be used to analyse this data.
5. The Committee noted a statement acknowledging that novel microorganisms are more likely to be in animal or invertebrate vectors that are not abundant in New Zealand, however, requested that possibility of travel related infections be considered and provided in documentation.
6. The Committee noted that the HDEC cannot approve the protocol, only ethical aspects are approved by the Committee.
7. The Committee requested a clear process for incidental findings in the Data Management Plan. The Researchers should consult with a Medical Officer of Health on how to handle scenarios like discovering a notifiable disease previously unrecognised. The plan should state that if an unanticipated pathogen of public health, or animal health concern is identified, the code can be broken if necessary to inform public health authorities (even if the original patient may no longer be traceable). This plan should be documented in the protocol and communicated to any governing bodies.
8. The Committee suggested including participants from the age of 16, as this is the age of consent in New Zealand. If age range for participants is changed, the Protocol should be updated accordingly.
9. The Committee referred the Researchers to CLSI MM18-A2: Next-Generation Sequencing Methods for Diagnostic Use, noting that aligning the protocol with this standard could significantly strengthen the study’s approach in terms of integrity and safety, given the serious implications of diagnostic errors in CNS infections.

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

1. Please provide consideration in the whanau information sheet to inform people about gene testing and cultural implications.

**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 provide up to date Māori consultation for this application *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.7).*
5. Please update the data and tissue management plan, taking into account the feedback provided by the Committee around incidental findings *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Neta Tomokino, Dr Andrea Furuya, and Dr Andrea Forde.

|  |  |  |
| --- | --- | --- |
| **4** | **Ethics ref:** | **2025 FULL 22970** |
|  | Title: | TRITON-CM: A Phase 3 Global, Randomized, Double-Blind,  Placebo-Controlled Study to Evaluate the Efficacy and Safety of  Nucresiran in Patients with Transthyretin-Mediated Amyloidosis  with Cardiomyopathy (ATTR amyloidosis with cardiomyopathy) |
|  | Principal Investigator: | Dr Mark Davis |
|  | Sponsor: | Alnylam Pharmaceuticals, Inc. |
|  | Clock Start Date: | 29 May 2025 |

Melissa Kirk 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 Researchers confirmed that the patients are not currently known to the PI.
2. The Researchers explained their rationale behind exclusion of pregnant people from this study but that pregnant people would not be excluded from treatment for heart failure.

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 confirmation in writing that there is no United States federal government funding.
2. The Committee requested clarification on the insurance coverage amount as it appeared light for the length of the study.
3. The Committee noted that the submission indicated that no psychiatric Quality of life (QoL) questionnaires would be used in this study, while the PIS does indicate that these QoL questionnaires will be used. These questionnaires need to be submitted to the Committee along with a safety plan outlining processes if any risks are identified as a result of these questionnaires.
4. The Committee noted that there may be home visits during this study, for which a researcher safety plan needs to be provided.
5. The Committee requested that the Data Management Plan be reviewed for typos.
6. The Committee noted that the stated maximum treatment period of 4-7 years and the study period of 5-7 years should have consideration to New Zealand context regarding the retention of health data how this data will be managed and what processes will be in place for keeping New Zealand participants engaged in the study.
7. The Committee requested that further details are provided in the study design with more consideration for the nuances for New Zealand patients.
8. The Committee requested that the term ‘tokenization’ be changed to ‘deidentified data’ and any reference to tokenization removed, as tokenisation has other scientific meanings.
9. The Committee requested clarification on the meaning and reasoning behind the statement “The Sponsor may not accept the compensation claim if your injury was caused by the researchers, or…”
10. The Committee noted that only the ethical aspects have been approved by the HDEC not the overall study.

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

1. Please revise statement indicating that the investigational product is not approved in New Zealand to clarify that it also has not been approved by any health authority
2. Please ensure that it is clear to participants that people will be followed up until and including death and that vital registers will be utilised to determine date of death.
3. Please revise rounding for blood sampling for clarity to participants.
4. Please revise PIS for language more appropriate to the New Zealand context, such as, changing ‘check-up’ to ‘physical exam’ or “eye doctor” to “ophthalmologist” or “optometrist”.
5. Please outline if the sponsor will be paying for any optometrist visits
6. Please change references to side effects to adverse events.
7. Please revise wording in pregnancy and contraception section indicating that participants who become pregnant will be followed up with consent. Participants cannot be compelled to advise researchers of pregnancy or compelled to allow follow up.
8. Please provide additional wording to ensure that the PI is alerted of an emergency as well as the need to contact 111.
9. Please ensure that it is clear that it is the PI or investigator that defines what is study related healthcare.
10. Please provide a statement indicating that women of childbearing potential will be followed up for 24 months, as is outlined in the protocol. Please also include a statement indicating why this will be happening, outlining that there is currently no evidence of reproductive or developmental toxicity but this follow up to confirm this.
11. Please revise pregnancy and contraception section for appropriateness to the study population.
12. Please provide the maximum number of New Zealand participants that are expected to take part in the study.
13. Please provide statement outlining that precautions are being made to ensure that no decisions will be made by an investigator who may also be a participant’s GP.
14. Please ensure that GP notification is mandatory for all participants.
15. Please provide specific calculations and reimbursements for travel and expense.
16. Please expand on possible risks to participating in the study.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
4. Please update the data management plan, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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

|  |  |  |
| --- | --- | --- |
| **5** | **Ethics ref:** | **2025 FULL 22946** |
|  | Title: | A PHASE 1, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, SINGLE ASCENDING DOSE STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF JADE101 ADMINISTERED SUBCUTANEOUSLY IN HEALTHY VOLUNTEERS |
|  | Principal Investigator: | Dr Rohit Katial |
|  | Sponsor: | Jade Biosciences, Inc. |
|  | Clock Start Date: | 29 May 2025 |

Dr Rohit Katial, Lucy Druzianic, Mayoma Wijesundera, Gian Liu, Samantha Nie and Kayla Malate were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee acknowledged the letter confirming the absence of US federal government funding.
2. The Committee queried whether the payment was sufficient given the length of the study. The Researchers advised that they used their calculator to ensure that the payment is fair based on the number of visits and procedures involved, without being inducive.
3. The Committee queried whether trial participants may need a medic alert bracelet or similar, should something happen while on the trial. The Researchers advised that participation in the trial is added to all participants hospital records for this reason and that there is an on-call study doctor who can be contacted.

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 advertising should include the HDEC reference.
2. The Committee noted that neither the protocol nor Investigators brochure contained information about how the monoclonal antibody (MAB) is manufactured. Please advise how the MAB is manufactured with confirmation that this is to GMP.
3. The Committee requests the sponsor consider licensure in New Zealand should the trial be successful.
4. The Committee consider mandatory pregnancy testing at each visit to be excessive and overly intrusive, given that participants are informed of the need to avoid pregnancy whilst in the study and advised of appropriate methods of contraception.
5. The Committee noted on page 22 of the protocol, that it would be helpful to state the baseline and the absolute and relative change numbers for the immunoglobulins.

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

1. Please correct on page 14 where it states, “you will not be paid”.
2. Given this is a first in human study, please expand the statement around animal studies to specifically include non-human primates.
3. Currently it states that no side effects have been observed in animals, however it is likely that there will be some minor side effects, so please state what the anticipated adverse events may be, such as the potential to lower immunity.
4. Where it states that participants should use barrier contraceptives with highly effective contraception, the Committee queried if barrier contraceptives be used with specific hormonal contraceptives only. Barrier contraceptives in some participants seem excessive.
5. Please amend the future unspecified research form to indicate that HDEC only approve the ethical aspects of the study.
6. Please change drug to investigational product or investigational medicine or medication.
7. Please consider removing the saliva collection instructions from the PIS, as this will presumably be provided at the time of collection.

**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, if appropriate, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

|  |  |  |
| --- | --- | --- |
| **6** | **Ethics ref:** | **2025 FULL 23149** |
|  | Title: | An open-label trial to test menstrual cycle effects and tolerance to low dose psilocybin in healthy menstruating persons (PsiMen). |
|  | Principal Investigator: | Dr Suresh Muthukumaraswamy |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 29 May 2025 |

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

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that psilocybin is a Schedule 1 controlled drug in New Zealand and queried under which legal pathway it can be administered in a trial. The Researchers outlined the legal pathway is Section 22 of the Misuse of Drugs Regulations which allows for Minister’s consent for research use of Class A substances. Noting that they have applied concurrently for Ministerial exemption via Medicines Control, alongside the SCOTT (Standing Committee on Therapeutic Trials) approval and HDEC application. The committee noted that these approvals must be in place before any dosing.
2. The Committee noted that participants are not able to drive after receiving dosing, so transportation to and from the visits would need to be provided. The Researchers confirmed that they will pay for transportation costs, such as taxis.
3. The Committee noted that the photographs on page 8 of the participant information sheet (PIS) are very helpful.
4. The Committee queried whether the transcription service would involve confidentiality requirements. The Researchers advised that this would be done in house using AI which is set up to protect individuals' privacy and not share information to machine learning platforms.
5. The Committee noted that in the submission it was stated that consent to notify the GP of involvement in the study would not be sought however it is an option on the consent form that participants GPs will be notified of their involvement in this study. The Researchers confirmed that it was an error in the submission and consent to inform the GP would be sought.
6. The Committee queried whether the psychiatric screening would be completed by a registered psychiatrist or under supervision of a registered psychiatrist. The Researchers advised that this would be under supervision of a registered psychiatrist, as this is only a limited screening.

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 the payment is sufficient for the time commitment involved in this study, and given that the study population is female there may need to consider other support e.g. the need to provide for childcare. Whilst payment will be in gift cards it is important to consider if this might have any impact on participants who are on a benefit.
2. The Committee recommended being transparent in advertising about the time commitment and amount of payment, so that potential participants can consider if they accept this.
3. The Committee noted that the advertising should include the University logo and the HDEC reference.
4. The Committee noted that referral to crisis care in case of participant distress is insufficient and a more involved safety plan is required.
5. The Committee queried the need for participants to advise their employer of their involvement in the study, as this could be stigmatising. However, participants should be encouraged to check their employment contract to confirm if there could be any unintended consequences for participating in the study.
6. In the Data and Tissue Management Plan please include the name of governance policy document. Please remove reference to under sixteen-year-olds.
7. The Committee note that the sponsors insurance is due to expire in November this year, this will need to be extended for the length of the study.
8. The Committee noted that in the submission it was stated that the study would be significant for Māori and queried in what way. The Researcher acknowledged that this isn’t entirely accurate but did note that data is lacking about rates of premenstrual dysphoria in the Māori population.
9. The Committee queried the rationale for not collecting disability data when one in four people have some form of disability in New Zealand. The Researchers advised that people with disabilities would not be excluded but based on the design of the study, data around disability would not be included.
10. The Committee queried whether a translator would be available if required. Noting that it states in the consent form that the participant agrees that they have understood the form or that it has been read to them in a language that they understand. The Researchers stated that they are unable to provide a translator, and participants will need to speak English to participate, so they will need to make it part of the exclusion criteria.
11. The Committee queried the justification for not having a registered phlebotomist or health practitioner taking the blood samples.

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

1. Please clarify that use of a copper containing IUCD, but not a hormonal IUCD, is a contraceptive method that would not exclude a participant from this this study.
2. Please include advice to participants about the potential impacts of the study on insurance coverage e.g., for circumstances such as motor vehicle accidents, and the need to check their policies’ wording.
3. Please remove references to teaspoons of blood, use ml’s instead.
4. Please check for spelling and grammar.
5. Please add an option to the consent form regarding whether participants wish to consent to future research. On page 12 please change future research to be optional rather than mandatory, in line with page 13.
6. On page 14 please amend the statement to reflect that HDEC only approve the ethical aspects of the study.
7. Please use stronger wording around the need for participants to abstain from alcohol or other drugs or medicines with psychotropic effects during the study.
8. Please clarify that the dose will be a capsule given orally.
9. Please provide some details about what will happen on the day of dosing and whether participants should bring activities, e.g. books or laptop, to keep them occupied.

**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, if required, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Dianne Glenn, and Dr Andrea Forde.

|  |  |  |
| --- | --- | --- |
| **7** | **Ethics ref:** | **2025 FULL 22465** |
|  | Title: | STAMP - School-age Tracking and Assessment of Moderate-to-late Preterms |
|  | Principal Investigator: | Professor Jane Harding |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 29 May 2025 |

Professor Jane Harding and Dr Caroline Walker 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 the information for the DIAMOND study refers to a participant’s teacher receiving study results. The Committee queried whether this could have any implications for the student, particularly in relation to privacy, confidentiality, or potential impact on their educational experience. The Committee requested further clarification on the rationale for sharing results with teachers and how any associated risks will be managed.
2. The Committee queried whether parents or guardians would have access to the participant’s results or assessments. The Committee also asked whether there is a defined process for providing aftercare or follow-up support for whānau. The Committee requested clarification on how results are communicated to families and what support mechanisms are in place to ensure appropriate aftercare.
3. Teachers are included in the study but there is no information sheet which should be provided if they are participants. Clarify too whether participation is in the teacher’s own time or during school hours. Please also provide the letter provided to head of school, as this was not provided to the Committee.
4. Review teacher questionnaire for typos and grammatical errors.
5. Please review documents for language that frames/refers to children as a burden.

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

All:

1. Please review for typos (such as stating “relevant *to* Māori”).
2. The title of the study is first used then swapped over to the original study title and used the rest of the way. Please review for clarity and ease confusion when using study titles.
3. Ensure there is a separate risks and benefit heading.
4. The Committee requested the removal of the ‘yes / no’ tick boxes from the consent form unless it is for a clause that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study).
5. Please state that confidentiality may need to be broken in specific circumstances that place legal and other obligations upon researchers, e.g. if concerns arise with respect to possible or disclosed abuse that the researchers must act on.

**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 Neta Tomokino and Dr Geoff Noller.

|  |  |  |
| --- | --- | --- |
| **8** | **Ethics ref:** | **2025 FULL 22518** |
|  | Title: | A Phase 2 Study to Assess the Efficacy, Safety, Tolerability, and Pharmacokinetics of NS-089/NCNP-02 in Boys with Duchenne  Muscular Dystrophy (DMD). |
|  | Principal Investigator: | Dr Gina O’Grady |
|  | Sponsor: | NS Pharma, Inc |
|  | Clock Start Date: | 29 May 2025 |

Dr Gina O’Grady and Laura Mackay were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified with the Researcher the reason for not knowing exact recruitment numbers is due to the nature of the condition and that a child could experience disease progression and would then not meet the inclusion criteria.

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 inconsistent numbers for recruitment in the protocol on page 11. Please specify what is relevant for New Zealand.
2. The Committee queried the use of participant diaries to track study timepoints given the protocol states urine samples are to be collected into the same container over a 24-hour period. The Committee requested clarification on the diary’s intended use.
3. 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 either the Sponsor’s Chief Medical Officer, Chief Financial Officer, and Chief Legal Officer, inclusive or equivalent, 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**.**

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

1. Please review and adapt for New Zealand context. Examples include:
   1. Use of ‘blood draws’ to ‘blood test’.
   2. Confidentiality reference to US Law/HIPPA reference.
2. Reference to cost reimbursement states how that is done with the US-based study. The Committee suggested to refer this to the second consent form with the details for New Zealand participants.
3. Please add that ‘videos will then be destroyed’ when they are no longer kept. Please also include the purpose for the use of the videos, who will have access and whether the children in the videos will be identifiable.
4. The PIS for Tamariki (children) was good and age-appropriate, but the one for Rangatahi (young person) is too simplified to begin with. However, the Committee acknowledged it is unlikely for the older children to be included.
5. Committee noted and queried the routine exclusion of Children who may have a blood-borne virus that would have been transmitted in utero or at birth. The Committee considered that this routine exclusion in this group is not ethical.
6. If the Sponsor is a member of Medicines NZ and is committed to Medicines NZ guidelines, please state this definitively.
7. Side effects explanation for Tamariki could use a sentence along the lines of “we need to know if something happens to you. That something could be a good thing or a bad thing”.
8. There is a statement that the medicine, if it has a positive benefit, will be continued after the study until it becomes commercially available. Please clarify if this is when it is available in any country, or if it will no longer be provided as study continuation to New Zealand participants once it is commercially available in New Zealand.

**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 Dr Maree Kirk and Dr Andrea Furuya.

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 08 July 2025 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

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

1. **Matters Arising**
2. **Other business**

The Chair Mr Dominic Fitchett announced it would be his last meeting as his term has ended, and the Committee shared well-wishes.

1. **Other business for information**
2. **Any other business**

The meeting closed at 2.50pm