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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 05 November 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11.30am-12.00pm | 2024 FULL 21150 | GC45428: Study of the Efficacy and Safety of GDC-8264 in Preventing Cardiac Surgery-Associated Acute Kidney Injury and Major Adverse Kidney Events | Dr Shay McGuinness | Ms Kate O'Connor and Ms Joan Pettit |
| 12.00-12.30pm | 2024 FULL 21110 | Ketamine Sedation In Acute Traumatic Brain Injury: A Randomized Pilot Feasibility Study | Dr Jonathon Taylor | Ms Alice McCarthy and Mr Barry Taylor |
| 12.30-1.00pm | 2024 FULL 21505 | Vagus nerve stimulation for tinnitus | Professor Dirk De Ridder | Ms Maakere Marr and Mrs Leesa Russell |
| 1.00-1.30pm | 2024 FULL 12718 | Growing Screws for SCFE | Doctor Andrew Kim | Ms Kate O'Connor and Mr Barry Taylor |
| 1.30-2.00pm | *Break (30)* |  |  |  |
| 2.00-2.30pm | 2024 FULL 21453 | KRIYA-825-101: A Study to Evaluate VV-14295 in Adults with Geographic Atrophy Secondary to Age-related Macular Degeneration | Dr Chris Wynne | Ms Alice McCarthy and Ms Joan Pettit |
| 2.30-3.00pm | 2024 FULL 21241 | A study on the long-term effects of vamorolone in boys with Duchenne Muscular Dystrophy | Dr. Erik Andersen | Ms Maakere Marr and Ms Joan Pettit |
| 3.00-3.30pm | 2024 FULL 21460 | Psilocybin Feasibility Study | Prof Paul Glue | Ms Kate O'Connor and Mrs Leesa Russell |
| 3.30-4.00pm | 2024 FULL 21256 | TOUR006-T01: A Randomized Study to Investigate TOUR006 in Participants with Thyroid Eye Disease | Dr Rebecca Stack | Ms Alice McCarthy and Mr Barry Taylor |

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

## Welcome

The Chair opened the meeting at 11am and welcomed Committee members, noting that apologies had been received from Dr Amber Parry Strong.

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 01 October 2024 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2024 FULL 21150** |
|   | Title:  | A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of GDC-8264 in Preventing CardiacSurgery-Associated Acute Kidney Injury and Major Adverse Kidney Events. |
|   | Principal Investigator:  | Dr Shay McGuiness |
|   | Sponsor:  | Genentech Inc. |
|   | Clock Start Date:  | 24 October 2024 |

Dr Shay McGuinness 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 the matching of the volume of the study placebo to the investigational product is to match the size and shape of the oral dose.
2. The Committee clarified that the dosing for phase two was lower as part of the assessment of adverse events in phase one. This is justified per the phase one studies previously conducted. This is also to ensure that the safety is assured in the New Zealand study population.
3. The Committee noted for future applications that only the CV of the New Zealand PI is required for HDEC applications.

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 clarification as to what data/specimens would be destroyed after 15 years. Currently it is unclear across study documentation as to what exactly may be retained for data/specimens collected for this study alone vs. those collected for the biorepository. Please clarify this distinction clearly in the data and tissue management plan (DTMP) and the participant information sheets/consent forms (PIS/CFs.)
2. The Committee requested more information as to the data safety monitoring committee’s independence. The current structure appears to be quite internal to the Sponsor and the Committee requested clarification as to why this was the case, and whether this is consistent with what is required by the National Ethical Standards (see Table 11.1).
3. The Committee queried if mobile nurses would be utilised in this study and how this would be managed. The Researcher noted that this had yet to be determined, but that given the population was quite large and as the burden of travel for many participants would be great, it may be a beneficial tool. The Researcher intended to utilise this locally first to explore how this would practically work for the broader pool of participants. Should this occur, it should be clearly detailed in the PIS/CF, specifically this potential contact with contracted nurses that would come to the home should be consented and the process including privacy implications should be noted. The Committee clarified that the costs of this would be covered by the sponsor.

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

1. Please use the term “intervention” or “study medicine” instead of “treatment”.
2. Please include more information around the cell lines, and the risks of creating them, that are proposed in the optional parts of the study since cell lines are distinct and may continue indefinitely. Please clarify that the use of these cell lines will prohibit any attempt to reidentify the participant. Please also ensure that there is sufficient information around cultural considerations involved in this.
3. Since the HDEC does not have access to the protocol underlying the operation of the Roche biorepository, please provide more detail about how the repository resources are used, shared, commercialized, and around the privacy and management of data.
4. Please reconcile the time periods in the protocol and PIS when referring to post-surgery monitoring and discharge.
5. On page 2 please amend wording around participating in other studies to read instead, “you should not join another clinical trial”.
6. Please amend the wording around the biomarker analysis to remove the word “genes”.
7. Please clarify if the sponsor has committed to the NZ medicines guidelines. If they have not, please remove this section.

**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 Kate O’Connor and Ms Joan Pettit.

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| **2**   | **Ethics ref:**   | **2024 FULL 21110** |
|   | Title:  | Ketamine Sedation In Acute Traumatic Brain Injury: A Randomized Pilot Feasibility Study |
|   | Principal Investigator:  | Dr Jonathon Taylor |
|   | Sponsor:  | Monash University |
|   | Clock Start Date:  | 24 October 2024 |

Dr Jonathan Taylor 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 explained that the study’s proposed inclusion of non-consenting participants as presented does not meet the best interest requirements as set out in [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 justifications for including non-consenting persons and randomising them to 2 different study arms under a best interest test must be stepped out more clearly if the study wishes to meet the ethical standards.
2. The justification given that randomisation into both groups was equally poised in terms of risks and benefits was insufficient to describe how inclusion was in the best interest of participants. The Committee suggested that there be more focus on provision of additional benefit for study participants *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.7, 8.13, 8.15-8.18).*
3. The Researcher asked if it was clear that ketamine was used as part of the standard therapy in use in the unit. The Committee noted that this was not clear in the study documentation or the application to HDEC and would make a significant difference in the protocol. Comparing two standard of care options reduces the risk profile of the study.
4. The Committee noted that the study is not powered for efficacy. This should be amended in the protocol. The objectives and methods to answer those objectives may need to be outlined more precisely to be clear. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7 & 9.8).*
5. The Committee noted that there are many contraindications in the Investigators Brochure (IB) that are not in the protocol or PIS/CF as there should be several more exclusion criteria based on the IB.
6. The Committee suggested planning for contingencies with respect to the continued use of data for events such as potential participant death, or lost to follow up or if there are other issues with research participants or their whanau (e.g. discharging themselves before the consent-to-continue form is signed) . *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25, 11.30a, 11.31, 11.44).*

The Committee requested the following changes to the family 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 consider amending this to not be in the pamphlet format as it is quite hard to parse in this form.
2. Please amend the information sheet to include accurate information and certainty around what standard of care is and how it differs from the study procedure.

**Decision**

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

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| **3**   | **Ethics ref:**   | **2024 FULL 21505** |
|   | Title:  | Paired vagus nerve and auditory stimulation for the treatment of tinnitus: a proof-of-concept study |
|   | Principal Investigator:  | Professor Dirk De Ridder |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 24 October 2024 |

Mr Boen Deng and Dr Divya Adhia was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that much of the issues with the previous submission had been largely addressed in this submission.
2. The Committee clarified that inclusion of pregnant women would be possible after assessment of literature in the field.
3. The Committee noted that for a larger trial, (post-feasibility) that Pacific consultation is recommended, and alternative translations of the information sheets should be offered particularly in Tongan and Samoan.
4. The Committee clarified that both devices are research devices and should be presented as such.

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 clarified that the exclusion at 75 was the cut off age due to hearing loss and not due to the age that had been reached. The Researcher will need to state that this will be per their physiological condition, not their age. Please consider amending this criterion to ensure that the reasons are clearly defined and not arbitrary. Inclusion of those 18 years old and above is recommended and that screening be used to then determine whether older individuals should participate based on physiological information.
2. The Committee noted that koha and reimbursement are different concepts. Please consider this in the way this is presented in the participant information sheet/consent form (PIS/CF) by separating out what would be reimbursed vs what should be appreciated through a koha, or gift.
3. The Committee suggested using the MEDRA scale for categorising adverse events.
4. The Committee suggested that the composition of the data safety monitoring committee be reconsidered as it is currently not suitable in its current composition; a DSMC is different from an ethics committee. This does not have to be many people; it could be 1 statistician and 3 to 4 other colleagues who would be blinded. Please provide the charter for this as an amendment once formed.
5. The Committee noted the word “vouchers” in the adverts should be replaced with “reimbursement for parking and travel”.

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

1. Please be clear how the reimbursement will be paid and for what exactly. Please be specific about this.
2. Please clarify if reimbursement will be the same if someone is utilising the Driving Miss Daisy service.

**Decision**

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

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

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| **4**   | **Ethics ref:**   | **2024 FULL 12718** |
|   | Title:  | Static Versus Free Gliding Screws in Slipped Capital Femoral Epiphysis: A Randomised Controlled Trial |
|   | Principal Investigator:  | Dr Andrew Kim |
|   | Sponsor:  | Te Whatu Ora - Waikato |
|   | Clock Start Date:  | 24 October 2024 |

Dr Andrew Kim was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that presentation with this condition is typically due to pain that can result ultimately in gait problems.
2. The Committee clarified that the medical device manufacturers would be providing training for the surgeons using the devices.
3. The Committee clarified that the standard of care would be in the clinic follow ups and the x-rays.
4. The Committee reminded the researcher that it is a requirement to register the study with an WHO-approved clinical trials registry prior to starting the study.
5. The Committee queried the average age of potential participants. The Researcher noted that this would be around 12-14 years of age and that the condition was made worse by patients’ growth during this time.
6. The Committee queried whether the onboarding of hospitals outside of New Zealand and other hospitals within New Zealand had begun. The Researcher clarified that there had not yet been any steps taken towards this expansion as they are aiming to get the main site set up prior to any additional sites being brought on-board.

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 clarification with the statistician by the Researcher to determine what the study was specifically powered for: a Non-inferiority or a Superiority trial. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 10.27 & 10.28)*
2. The Committee requested some reworking of the information sheets to ensure that the benefits and risks of both arms are more evenly balanced. Specifically, reduce overemphasis in the description of the benefits of the new screws and make clear when potential benefits might be realized. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 10.18-10.25, 10.27 & 10.28)*
3. The Committee requested for clarification as to what training would be required for the use of the new screws and whether this had already been undertaken by the research team and what would be required going forward.
4. The Committee requested clarification as to the role the manufacturer would play in the study and why they may then have rights over the data per the data and tissue management plan (DTMP) as there would be no commercial benefit from the research. If they are not the sponsor or are not principally benefitting, then they should not be outlined as the beneficiary in the DTMP. If there is no commercial interest due to public funding, then this should be stated clearly as otherwise the manufacturer would have to provide ACC-equivalent insurance. As this may not be the case, please be clear. *(National Ethical Standards for Health and Disability Research and Quality Improvement, Chapter 17).*
5. The Committee requested a plan for timely follow-up of mental health questionnaires per the clinical duty of care. Please include this in the protocol.
6. The Committee queried the validation of the UCLA activity score and other measures in New Zealand. Please find more suitable questionnaires for these purposes as the activities listed therein may not be appropriate for this population.
7. The Committee noted that the Researcher may not be suitably qualified to be solely responsible for this study since a research background is not evident in the c.v.. The Committee suggested that the supervisor verbally referred to by the Researcher be listed as a co-PI. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.23 & 9.24).*
8. The Committee noted that there was no risk or benefits section in the protocol and that there were several other key protocol sections missing per the expected level of detail required for a clinical trial. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8).*
9. The Committee requested a second information sheet for younger children for easier reading. The Committee suggested that the current child information sheet be amended to be for the older children and that these be separated by “older” and “younger”, rather than by ages. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.22a).*

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 clarify that these screws are approved and used in other countries.
2. Please specify what is extra and different in participating in the study from standard of care.
3. Please provide more information about whether the surgeons have used these screws before.
4. Please refer to the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates) for guidance on the sections on identifiable and non-identifiable data.
5. Please remove tick boxes from the consent forms where the points should be mandatory, e.g., for notification of the participants general practitioner.

**Decision**

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

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| **5**   | **Ethics ref:**   | **2024 FULL 21453** |
|   | Title:  | A Phase 1/2, First-in-Human, Multi-Arm, Dose-Escalation Study to Evaluate the Safety, Tolerability, and Efficacy of an Adenoassociated Virus Vector VV-14295 Administered Suprachoroidally with the Everads Injector In AdultS with GeographIc Atrophy Secondary to Age-related Macular DegeneratiON (the VISION Study) |
|   | Principal Investigator:  | Dr Chris Wynne |
|   | Sponsor:  | Kriya Therapeutics, Inc. |
|   | Clock Start Date:  | 24 October 2024 |

Dr Chris Wynne, Lucy Druzianic, Julia O’Sullivan, Kayla Malate, Dr Oliver Comyn, Tessa McCann, Katie St. Ledger and Brian Furmanski 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 whether this therapy should be reviewed by GTAC. The research team noted that the medicine being tested is not likely to be incorporated or influence the human genome that it would be reviewed by SCOTT. The Researcher noted that either SCOTT or GTAC would review the study before it would start.
2. The Committee clarified with the Researcher the difference between the two Part 1A doses of the study product.

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 what steps had been taken to make the participant information sheets accessible to people who may be participating and unable to read small font sizes in a long document. The researcher noted that the font would be amended for people and the forms discussed with the PI and Ophthalmologist and others who may be able to aid in the understanding. The Committee suggested videoing the participant information sheet and requested this issue be considered by the researchers to ensure maximum accessibility.
2. Please reconcile your study documentation about how many New Zealanders will participate; in one place it says 12 (Submission Section A.11) and B.14 reads 23.
3. Please clarify in your submission document at A.10 what is Standard of Care in New Zealand.
4. Please make clear to participants and in the protocol that one of the potential benefits is having fewer injections over time, as opposed to the other FDA approved drugs. Make clear in the PIS that none of these drugs are approved in NZ. Also advise whether participation in this study would impact access to other medicines should they become available in the future.
5. The Committee queried why potential participants are prevented from having or receiving covid vaccines. The Researcher clarified that participation may blunt immune response to the covid vaccine. The Committee requested to provide clarity and advice around this regarding how it affects participation.
6. Please provide more information about what differs between the two Part 1A doses of the study product. The proposal is to start with 5E10 vg/eye, then move to 2E10 vg/eye. Make clear which dose is likely more risky for participants.

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

1. Please highlight that the device used is first-in-human and there are studies underway on the safety of the Everads Injector.
2. Please include that in addition to providing new information about the FIH gene therapy, you will also inform participants about any new information of the study device.
3. Please provide context for alternative options to participation, including there is no adequate treatment in New Zealand, especially what alternative options for treatment would be ruled out for them by participating, if any.
4. Please clarify if the Sponsor has committed to the NZ medicines compensation guidelines or remove.

**Decision**

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

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

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| **6**   | **Ethics ref:**   | **2024 FULL 21241** |
|   | Title:  | An open-label study to collect safety and effectiveness information on long-term treatment with vamorolone in boys with DuchenneMuscular Dystrophy who have completed prior studies with vamorolone |
|   | Principal Investigator:  | Dr Erik Andersen |
|   | Sponsor:  | Allucent |
|   | Clock Start Date:  | 24 October 2024 |

Dr Erik Andersen and Rose Ann Yap 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 the researchers established the case for the extension follow up study with one patient well and that this does not raise many new ethical concerns given the family has familiarity with the medicine being given and has been given an extension for access to this study under compassionate grounds.
2. The researchers confirmed that there was no threat to ongoing access on a compassionate use basis if a family chooses not to take part in the follow-up study. The person receiving this was enrolled in Australia and is the only person in New Zealand on this medicine. The CI is the prescribing doctor, and the participant is accustomed to being on this intervention.
3. The committee queried if there is movement for this drug to be registered in NZ. After discussion, it was concluded that if the drug did become available at cost in NZ, the participant will not be moved from compassionate access if they are still deriving clinical benefit. .

Summary of outstanding ethical issues

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

1. Given the observation period is up to 3 years, please ensure there is information about what happens after this about whether there may be continued compassionate access available.
2. Remove reference to spoons or cups when discussing volumes. Use millilitres instead.
3. Use the word study ‘medicine’ instead of study ‘drug’ – or go neutral with study intervention to differentiate between the other implications concerning ‘drugs’.
4. Under possible benefits, adjust this to include possible long-term benefits as participant would already be aware of the short-term benefits having been on it.
5. Regarding privacy in assent forms, change the word ‘secret’ to mean ‘private’.

**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).*

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| **7**   | **Ethics ref:**   | **2024 FULL 21460** |
|   | Title:  | Feasibility study of the effect of psilocybin in response to brief psychological input with psychological flexibility as a mediating factor |
|   | Principal Investigator:  | Professor Paul Glue |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 24 October 2024 |

Professor Paul Glue and Dr Valerie Tan 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. It was clarified that the advertisements are being used but recruitment still is routed through a health professional.
2. The researchers confirmed the procedures undertaken to avoid persons misrepresenting their behaviour in self-reported scales to get access to study intervention as part of drug-seeking behaviour. Both investigators will assess and interview all potential participants on their background and history with mental health issues. A letter of referral from the potential participant’s health care provider is also required for entry into 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. Revise the BECK scale, which refers to ketamine infusion therapy.
2. The Committee queried what the definition is for ‘brief psychological therapy recently with limited improvement’, especially what is considered recent, and limited improvement. Clarity around this should be provided in documentation.
3. The Committee suggested targeted cultural recruitment for population equivalence.
4. The Committee queried what information does the responsible adult get when this person comes home and how will they be supported in terms of the aftercare. The Researcher clarified that someone participating would not be released if they were distressed. Professor Paul Glue would be contactable, and a visit can be arranged. The Committee noted that this one-page information containing this should be provided, including who to contact and when.
5. The advertisement still has quite technical language around the drug name, 'psychological support' etc, as well as the participant information sheet (PIS). Please amend.
6. In protocol and PIS, please address risks, if any, of tapering off psychiatric meds prior to intervention session. Please also highlight if the study intervention can interact with other non-psychiatric medications.

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

1. Please clarify what the urine testing at screening is for – (both pregnancy and drugs of abuse.)
2. Provide more detail about the potential for a drug showing up on a drug test - this is because the drug is currently illegal in New Zealand. You may need to say why using it in the study is ok even though it is illegal. State that those with concerns that participation in this trial might affect employment (if they are regularly screened for illegal drugs) should not take part.
3. Please ensure both lead researchers names are available for participants.
4. Define ‘resources’ in "With limited resources available, some people find that there are limitations around brief therapeutic interventions".
5. Define recently in "have had brief psychological therapy recently with limited improvement". Is this within a year, few months, etc.
6. "You will be reimbursed a $50 supermarket voucher." appears under Week 6 and 12. Clarify if this is for both visits, and whether there is any reimbursement for the Day 1 and 2 visits such as travel costs. Clarify if there is any compensation for travel expenses.
7. Be consistent about use of terms ‘Visit ‘# and ‘Week’ # . A table of study visits may be useful.
8. Avoid the term "treatment", especially in the risks section to avoid risk of therapeutic misconception.

**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 Kate O’Connor and Mrs Leesa Russell.

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| **8**   | **Ethics ref:**   | **2024 FULL 21256** |
|   | Title:  | A Multicenter Phase 2b Randomized, Double-Masked, Placebo-Controlled Dose-Ranging Study of TOUR006 in Participants withThyroid Eye Disease |
|   | Principal Investigator:  | Dr Rebecca Stack |
|   | Sponsor:  | Tourmaline Bio, Inc. |
|   | Clock Start Date:  | 24 October 2024 |

No researcher 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 requested clarity around recruitment for an equality of opportunity. Given Southern Eye is private, they queried will study only be open to those accessing private services.
2. The Committee noted that the application says Kaupapa Māori methodology is being used, and this is presumably an error.
3. A Travel vendor is mentioned on pre-screening participant information, but not the main information sheet. Please clarify what is intended regarding reimbursements, and whether a third party will be given access to identifiable information.

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

1. Please remove addressing the legally authorised representative (LAR) in the first paragraph as these parties are not applicable in this country for intervention studies.
2. The Committee requested the word ‘treatment’ is not used in the information sheet when referring to an experimental unproven intervention to avoid therapeutic misconception. The Committee suggested study medicine, study intervention or investigational product may be used instead. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.19c*)
3. The statement "Rescue medication includes any standard of care treatment or procedures." would be better moved from page 7 and put up in the B3 bullet. Please also further define this.
4. For the reproductive risks section - move out of 'risks associated with study procedures', page 14.
5. It is unclear whether the study is paying for " a reasonable amount for your time" on page 17 or whether its just reimbursement of expenses. Comments suggested that payment would not be equitable depending on whether they were receiving the drug. This should be equitable.
6. Please clarify on page 17 if the sponsor has committed to industry guidelines.
7. Page 21 states "The Sponsor may stop the study at any time for any reason", but this should be clear it cannot be solely for commercial reasons.
8. In the consent form, notification of GP should not optional. Please also remove LAR panel.
9. There's a number of things the GP can't prescribe in their letter - more information about these disallowed medicines should be in the PIS.
10. It is not clear whether Part B is just those who received the placebo - clarify if this includes non-responders as it is detailed elsewhere that those who received the intervention would not go on to Part B.
11. In the screening form PIS, please ensure measurements for fluids are written in millilitres, not teaspoons.

**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 Alice McCarthy, Mr Barry Taylor, and Ms Kate O’Connor

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 03 December 2024 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

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

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

The meeting closed at 3.45pm.