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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 24 November 2020 |
| **Meeting venue:** | Join Zoom Meeting  <https://mohnz.zoom.us/j/85876646609>  Meeting ID: 858 7664 6609 |

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| **Time** | **Item of business** |
| 11:30am | Welcome |
| 11:55am | Confirmation of minutes of meeting of 27 October 2020 |
| 12:00pm | New applications (see over for details) |
| 12:00-12:25pm  12:25-12:50pm  12:50-1:15pm  1:15-1:40pm  1:40-1:55pm  1:55-2:20pm  2:20-2:45pm  2:45-3:10pm  3:10-3:35pm  3:35-3:50pm  3:50-4:15pm  4:15-4:40pm  4:40-5:05pm  5:05-5:30pm | 20/CEN/249 (Cordelia / Peter)  20/CEN/250 (Sandy / Julie)  20/CEN/252 (Kate / Peter)  20/CEN/256 (Cordelia / Julie)  [break]  20/CEN/253 (Sandy / Julie)  20/CEN/254 (Kate / Peter)  20/CEN/255 (Helen / Julie)  20/CEN/ 247 (Cordelia / Peter)  [break]  20/CEN/248 (Helen / Peter)  20/CEN/251 (Kate / Julie)  20/CEN/245 (Sandy / Peter)  20/CEN/246 (Helen / Julie) |
| 5:30pm | General business:  Noting section |
| 5:35pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 22/05/2018 | 22/05/2020 | Apologies |
| 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 | Apologies |
| Dr Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Present |
| Mrs Kate O'Connor |  |  |  | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 22/05/2020 | 22/05/2023 | Present |
| Ms Helen Davidson | Lay (ethical/moral reasoning) | 06/12/2018 | 06/12/2021 | Present |
| Ms Julie Jones | Non-lay (intervention studies) | 22/05/2020 | 22/05/2022 | Present |
| Dr Jill Wilkinson | Non-lay (observational studies) | 22/05/2020 | 22/05/2023 | Apologies |

## Welcome

The Committee noted that it would be necessary to co-opt a members of another HDEC in accordance with the Standard Operating Procedures. Mrs Kate O’Connor confirmed her eligibility and was co-opted as the Chair of the Committee for the duration of the meeting.

The Chair opened the meeting at 11:30am and welcomed Committee members, noting that apologies had been received from Mrs Helen Walker.

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 22 October were confirmed.

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| 1 | **Ethics ref:** | **20/CEN/249** |
|  | Title: | Review of the SACAT Act |
|  | Principal Investigator: | Ms Marnie Carter |
|  | Sponsor: | Ministry of Health |
|  | Clock Start Date: | 12 November 2020 |

Ms Marnie Carter and Mr Brendan Stevenson 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 Study

1. This study will review the operation and outcomes of the Substance Addiction (Compulsory Assessment and Treatment) Act 2017. It is intended to show whether the Act is achieving its stated purposes and to identify areas where improvement can be made to the operation of the Act and outcomes for applicants, patients and whānau. The study includes multiple methods. These include:(i) qualitative interviews with service providers, clinicians who deliver the Act, people who have been placed under the Act and their whanau; (ii) descriptive analysis and multivariate analyses of data extracted from the PRIMHD dataset and hospital and outpatient data from the National Minimum Dataset; (iii)Documentary file review including review of policy and process documents related to DHBs’ delivery system for the SACAT Act, the clinical files of the people who were interviewed as part of the review (with their consent), and case law.

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 participants would currently be under compulsory treatment. The Researcher confirmed while some may still be in treatment for drug / alcohol addiction they would not currently be placed under the SACAT Act.

Summary of outstanding ethical issues

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

1. Please supply a data management plan that complies with [Chapter 12 of the National Ethical Standards for Health and Disability Research and Quality Improvement](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health). The Committee recommends adapting [the data management template](https://ethics.health.govt.nz/system/files/documents/pages/data-only-management-template-oct2020.docx) available on the HDEC website to ensure all necessary information is included.
2. The Committee suggested advertising the study on a noticeboard and then anyone interested can approach the study team rather than a treating clinician handing out flyers.
3. Please update the protocol to include a safety plan for how to manage a participant experiencing distress (e.g. if X is found the research team will do Y) and include information on this in the PIS.
4. The Committee recommended becoming familiar with the feeling of whakamā as this will potentially be present in some Māori participants.
5. The Committee queried whether service user participants would have access to information provided by their family and clinician. Likewise, the family and clinician would need to be made aware that information they provide may be accessed by the service user participant.
6. Please revise the protocol to obtain consent to access and link sensitive health information, or provide a strenuous justification of waiver, noting that obtaining consent should be the default starting point. The Committee is of the view that given the sensitivities involved, there is reason to believe that these participants would refuse consent if asked, and consultation about this should be undertaken.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please adapt the [PIS template available on the HDEC website](https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-sep20.doc) to ensure all necessary information is included.
2. Please revise the statement that there is no risk of personal injury to ‘minimal risk’.
3. Please include more information so it is clear to the participant what questions their family will be asked.
4. Please change the HDC contact address to [advocacy@advocacy.org](mailto:advocacy@advocacy.org)
5. Please copy the information about the SACAT act and respecting human rights in the application over to the PIS as this is information participants should know.

Decision

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

* Please supply a data governance plan to ensure the safety and integrity of participant data

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
* Please update the 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).*
* Please revise the protocol to obtain consent OR justify a waiver of consent for secondary re-use of health information.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.29).*

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| **2** | **Ethics ref:** | **20/CEN/250** |
|  | Title: | Effects of thyroid hormone levels on the eye |
|  | Principal Investigator: | Dr Stuti Misra |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 12 November 2020 |

A/Professor Geoffrey Braatvedt 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 Study

1. Thyroid eye disease (TED) is a complication of thyroid dysfunction which may result in ocular discomfort or can progress to severe vision loss. The standard treatment includes oral and intravenous steroids; in severe cases surgery and radiotherapy. Limited literature exists on the effects of these therapies on corneal structure and function. Importantly, a potential non-surgical treatment strategy, hyperbaric oxygen therapy, has not yet been investigated with its mechanism and mode of action unexplored.
2. Changes in the structure and function of the eye due to abnormal thyroid levels could result in eye diseases such as glaucoma, keratoconus, and dry eye. These diseases are associated with low levels of thyroid hormones in some studies. The proposed project is divided into four parts: 1) A retrospective descriptive study to examine presentation, treatment and outcome of TED patients from the ADHB eye clinics and a private endocrinology clinic. 2) To prospectively study the tear film, corneal structure (IVCM and corneal sensitivity measurement) including orbital biomechanics in TED. 3) To prospectively study the effects of thyroidectomy (for thyroid cancer) and radioactive iodine treatment; and finally 4) A prospective randomised controlled trial of hyperbaric oxygen therapy in those receiving methylprednisone treatment for TED.
3. Participants will undergo non-invasive measurements of their eyes and collection of a tear fluid sample. They will also answer a questionnaire regarding any dry eye symptoms. The following measurements will be taken: corneal tomography (measures corneal thickness and shape), Corvis ST (measures corneal biomechanics and intraocular pressure), ocular coherence tomography (measures optic nerve and retinal morphology), refraction (glasses prescription), tear film break up time (indication of dryness), and tear fluid thyroxine levels.

Summary of outstanding ethical issues

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

1. Please supply evidence of professional indemnity.
2. Please supply all interview questions / surveys to be used.
3. Please supply an independent peer review using the [scientific peer review template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/HDEC-Peer-Review-Template.docx)
4. Please provide an argument to justify a waiver of consent for the secondary re-use of health information.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please adapt the [PIS template available on the HDEC website](https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-sep20.doc) to ensure all necessary information is included, particularly the data section. Please include information on numbers of participants, study design, who can take part, what will happen to samples, reimbursement etc.
2. Please add an additional paragraph explaining why the study is being done and what the potential findings and benefits could be.
3. Please revise the protocol to ensure data is stored for 10 years. Please include information about this in the PIS.
4. Please include information in the PIS on petrol vouchers (or any other type of voucher or koha).
5. Please include information advising participants of their right to access and correct information held about themselves.
6. Please bear in mind that there is the potential for Māori participants to feel whakamā. Please note the head is tapu and acknowledge this in the PIS.

Decision

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

* Please supply an independent peer review for the current version of the study protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
* 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).*
* Please justify a waiver of consent for secondary re-use of health information.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.29).*

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| **3** | **Ethics ref:** | **20/CEN/252** |
|  | Title: | APOLLO-B: A Study to Evaluate Patisiran in Patients with Transthyretin Amyloidosis with Cardiomyopathy (ATTR Amyloidosis with Cardiomyopathy) |
|  | Principal Investigator: | Dr Hugh Goodman |
|  | Sponsor: | PPD |
|  | Clock Start Date: | 12 November 2020 |

Ms Liz Low and Ms Melissa Kirk 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 Study

1. The research project is being conducted to see if the study drug, patisiran, is safe and if it can improve outcomes for patients with transthyretin amyloidosis in the heart.
2. Transthyretin amyloidosis is a rare and serious disease that affects multiple systems of the body. It is caused by misfolding (into amyloid) of a protein
3. called transthyretin (TTR) which is produced mainly by the liver. The amyloid (the misfolded protein) can slowly deposit in many tissues and organs of the body and thus adversely affect the function of these organs. In transthyretin amyloidosis, the most commonly affected organs are the heart and nerves.
4. The trial drug, patisiran, substantially reduces production of transthyretin and it is hoped this will reduce the deposition of amyloid in the heart of affected patients.
5. The main goals of this research project are to see how the study drug affects patient’s everyday life and if the study drug can make it better.
6. Approximately 300 people will be included in this research.

Summary of resolved ethical issues

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

1. The Committee requested the Researcher justify the inclusion of a placebo arm. The Researcher stated there is currently no funded treatment available in New Zealand to withhold.

Summary of outstanding ethical issues

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

1. Please supply a data and tissue management plan. The Committee recommends [adapting the HDEC template to ensure all necessary information is included.](https://ethics.health.govt.nz/system/files/documents/pages/hdec-data-tissue-management-template-oct2020.docx)

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please revise the statement under the optional blood samples section about future research approved by HDEC. As this may take place overseas New Zealand HDECs will not approve it so this is not accurate.
2. Please undertake a revision of the sheet to make it more appropriate for a New Zealand context (e.g. replace ounces with grams).
3. Please specify which ‘central laboratory’ samples will be sent to on page 7.
4. Please clarify the duration health information will be stored for.
5. Please remove the condition to withdraw in writing and return to the site as this is not applicable in New Zealand and participants may withdraw at any time without anything further required.
6. Please remove any use of ‘authorised representative / legal representative’ as this is not applicable in New Zealand.
7. Please use the full cultural statement on both information sheets as human samples will be sent overseas.
8. Please remove the remuneration statement.

Decision

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

* Please supply a data and tissue management plan.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O’Connor and Dr Peter Gallagher.

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| 4 | **Ethics ref:** | **20/CEN/256** |
|  | Title: | Atrasentan in Patients with IgA Nephropathy (IgAN) |
|  | Principal Investigator: | Dr Kalpa Jayanatha |
|  | Sponsor: | IQVIA RDS Pty. Ltd |
|  | Clock Start Date: | 12 November 2020 |

Dr Kalpa Jayanatha and Ms Meagen Meyers-Hummel 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 Study

1. This study will recruit participants who have IgA Nephropathy (IgAN) and are either taking a stable dose of an angiotensin-converting enzyme (ACE) inhibitor, an angiotensin-receptor blocker (ARB) or who have taken these drugs in the past and were not able to tolerate the side effects. This is a Phase 3, randomized, double-blind, placebo-controlled study to compare the efficacy and safety of an experimental drug Atrasentan to placebo.
2. Atrasentan and matching placebo is administered orally to participants in the form of film-coated tablets. Unit dose strength is 0.75mg/tablet.
3. The study comprises an optional pre-screening period, a screening period, a treatment period and a follow-up period.
4. Total duration for study participation per participant is expected to be up to 140 weeks (excluding pre-screening activities up to 6 months prior to baseline for selected participants). Screening Period lasts up to 4 weeks, treatment period up to 132 weeks and follow-up period lasts up to 4 weeks.
5. Approximately 320 participants will be enrolled worldwide, with ~160 participants per treatment arm.
6. An Independent Data Monitoring Committee (IDMC) will be utilized for 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. Please revise the protocol so the EQ5D questionnaires will be reviewed within 24 hours and formulate a safety plan to address any issues.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please include information in the PIS that the questionnaires contain questions around mental health and wellbeing and the follow-up if issues are found (e.g. if X is identified the researchers will do Y).
2. Please remove the clause on halting the trial for commercial interest as this is not appropriate in New Zealand.
3. Please make it explicitly clear in the PIS that the third-party vendor is optional.
4. Please make it clear in the PIS that the pre-screening phase is optional.
5. Please revise the statement on page 17 about race and ethnicity data being sensitive information as this is not consistent with New Zealand privacy law.
6. Please revise the statement that all research involving humans is reviewed by HDECs as this is not accurate. Please rephrase to simply say ‘this study has been approved by the Central HDEC’.
7. Please insert ‘lead maternity carer’ into the pregnancy PIS where appropriate as in New Zealand many pregnant women have midwives. Please add a clause to consent to the baby’s health information after the birth as the mother can only consent to her own pregnancy information until after birth.
8. Please add a header to the pre-screening PIS.
9. Please insert a clause on the consent form to agree to data being sent and stored overseas.
10. Please adapt the HDEC template data confidentiality section.
11. Please include the cultural paragraph in all information sheets as information is a taonga.

Decision

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

* Please update the protocol to include a safety plan to manage any participant distress.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Cordelia Thomas and Ms Julie Jones.

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| **5** | **Ethics ref:** | **20/CEN/253** |
|  | Title: | Parent coaching for parents of young children with autism. |
|  | Principal Investigator: | Ms Lauren van Noorden |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 November 2020 |

Ms Lauren van Noorden and Dr Hannah Waddington 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 Study

1. The Early Start Denver Model (ESDM) is a promising intervention approach for improving the outcomes of young children with Autism Spectrum Disorder (Autism). There is also some evidence that parents can be taught to use the ESDM procedures with their own children. However, the existing ESDM parent coaching literature has evaluated 1:1 parent coaching, which is a resource intensive service delivery model. Furthermore, existing ESDM parent coaching literature has shown that not all parents who receive this intervention learn to use the strategies with a high level of accuracy (fidelity). Therefore, this study proposes to use a three-tiered intervention design, where parents will be taught to use the ESDM strategies in three additive phases, or until they reach fidelity. The first tier will be a group parent coaching programme, which could provide an efficient service delivery model if effective. For parents who do not reach fidelity during this first (group-coaching) tier, a second tier of 1:1 parent coaching will be offered. This stepped approach to parent coaching may ensure that parents can access the support they need to learn to use the ESDM strategies with their own children. However, for parents who do not reach fidelity during this second (1:1 coaching) tier, a third tier of individualised parent coaching will be offered and in-depth information will be collected from these parents about the challenges they faced in learning the ESDM strategies in the previous tiers, and what solutions they believe will help them to be successful in learning to use the strategies with their own children. At all stages of the study, data will be collected about parent use of the ESDM strategies, and any changes in child engagement, communication, and imitation skills.

Summary of outstanding ethical issues

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

1. Please provide evidence of professional indemnity for the CI’s supervisor.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please refer to ‘your and your child’ throughout the information sheets as both parent and child are taking part.
2. Please remove the word ‘confidential’ from the group participation as this cannot be guaranteed. It can remain for the 1-1 coaching.
3. Please add page numbers to the PIS and a footer with version number/date.
4. Please add a cautionary statement that benefit cannot be guaranteed after the statement anticipating the child will show improvement.
5. Please remove the clause on parent health information.
6. Please insert ‘and my child’s’ to the statement about information continuing to be processed after withdrawal.
7. Please consider referring to Down Syndrome as a ‘condition’ rather than a disability.
8. Please consider replacing the word ‘experiment’ in the tier 1 and 2 information sheets with ‘study’ or ‘research’
9. Please correct the use of first-person language on page 11.
10. Please clarify who coded study information will be kept by on page 11.
11. Please revise the language around parental consent. The Committee advised parental consent for children needs to be done by their legal guardian which often is the parent but as a legal technicality may not always be.
12. Please remove repeated questions that appear from question 23 of the Patient Demographic Survey.

Decision

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

* Please supply evidence of professional indemnity.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Sandy Gill and Ms Julie Jones.

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| **6** | **Ethics ref:** | **20/CEN/254** |
|  | Title: | BI 1404-0036: A study to test whether different doses of BI 456906 can help people overweight or obese to lose weight |
|  | Principal Investigator: | Dr Dean Quinn |
|  | Sponsor: | Boehringer Ingelheim Pty Ltd |
|  | Clock Start Date: | 12 November 2020 |

Dr Dean Quinn 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 Study

1. This trial will characterize the dose response curve for BI 456906 in patients with BMI ≥ 27kg/m2 (without diabetes) by assessing 4 doses and placebo. The response is defined as the percentage change from baseline in body weight at Week 46.
2. The main trial objectives are to demonstrate a non-flat dose response curve, to evaluate the size of the treatment effect (using the difference in mean percentage change between BI456906 and placebo at Week 46), and to characterise the dose-response relationship.
3. The primary treatment comparison will be randomised, without regard to whether patients
4. discontinued treatment early (and whether they subsequently received any permitted antiobesity treatments), or whether patients started the maintenance period with a lower dose than the dose that they were randomised to.

Summary of outstanding ethical issues

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

1. Please update the data and tissue management plan to address the e-diary data.
2. The Committee noted the insurance certificate was global and queried whether ACC-equivalent cover is guaranteed for New Zealand participants as overseas lawsuits could potentially deplete the available funds. Please provide evidence that New Zealand participants will have ACC-equivalent insurance available to them in the event of injury.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please soften the language in the advertisement and PIS. Please revise incorrect language e.g. ‘have overweight’. Please avoid use of the term ‘obesity’ as this is stigmatising.
2. Please add a statement to the PIS advising that participants will be given instructions on home storage and how to keep them safe from children.
3. Please undertake a revision to use lay language (e.g. ‘biomarker’ is not explained).
4. Please use whole numbers in addition to or instead of percentages when listing potential risks and side effects.
5. Please use the full cultural tissue statement in the FUR PIS.
6. Please provide written confirmation New Zealand is a policy territory covered by ACC-equivalent insurance.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please supply evidence of ACC-equivalent insurance available to New Zealand participants.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O’Connor and Dr Peter Gallagher.

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| 7 | **Ethics ref:** | **20/CEN/255** |
|  | Title: | Effect of Ketamine and brain stimulation on tinnitus loudness and distress. |
|  | Principal Investigator: | Mr William Pitts |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 12 November 2020 |

Mr William Pitts 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 Study

1. Tinnitus, often referred to as 'ringing in the ears', is a prevalent and disabling disorder worldwide. In New Zealand, tinnitus affects approximately 6% of the total population and severely impairs quality of life in a significant proportion of individuals. Current available treatments for tinnitus have a small effect, warranting new targeted treatment approaches. Several studies demonstrate altered activity in brain regions that are involved in the hearing processes, in individuals with tinnitus. The combined treatment of Ketamine and brain stimulation can normalize altered brain activity through learning, thereby reduce tinnitus perception and related distress. The current study will explore the safety and the effect of combined ketamine and brain stimulation on tinnitus perception and related distress, and also evaluate its effects on the brain’s activity in the regions associated with tinnitus.

Summary of outstanding ethical issues

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

1. The Committee requested an update to the data management plan in the protocol that complies with [Chapter 12 of the National Ethical Standards for Health and Disability Research and Quality Improvement](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health). The Committee recommended the Researcher adapt [the data management template](https://ethics.health.govt.nz/system/files/documents/pages/data-only-management-template-oct2020.docx) available on the HDEC website.
2. Please include a safety plan in the protocol detailing how researchers will respond to a participant in distress.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please remove the field for a participant’s name from the questionnaire and replace it with a study code.
2. Please include information in the PIS that the questionnaires contain questions around mental health and wellbeing and the follow-up if issues are found (e.g. if X is identified the researchers will do Y).
3. Please revise the statement that if ACC won’t apply then the University of Otago insurance will as this cannot be guaranteed.
4. Please move the paragraphs on ‘general concerns’ to the benefit section.
5. Please revise the information about petrol vouchers and clarify what participants will not be entitled to the full if they withdraw part way through. This information does not need to be in the consent form, the PIS is sufficient.
6. Please include information about HDEC auditor access in the PIS
7. Please revise the information about petrol vouchers and clarify that participants will not be entitled to the full value if they withdraw part way through. This information does not need to be in the consent form, the PIS is sufficient.
8. Please include information about HDEC auditor access in the PIS.
9. Please supply evidence of professional indemnity.
10. Please add a footer and page numbers to the PIS.
11. Please insert a cultural tissue statement as the study involves blood collection. Please include information on how much blood will be taken and how many tests are required etc.
12. The Committee suggested rephrasing ‘the Māori culture’ to tikanga Māori.
13. The Committee recommended sticking to a definition of wairua as referring to the soul as different iwi have different interpretations of what this means.
14. Please ensure that the visit schedule table text is large enough for a participant to read comfortably.
15. Please revise the advertising flyer ‘treatment phase’ and ‘post-treatment tests’ sections to be clearer.
16. Please include a pregnancy clause in the consent.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Helen Davidson and Ms Julie Jones.

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| **8** | **Ethics ref:** | **20/CEN/247** |
|  | Title: | AR882-104: A study assessing single and multiple doses of AR882, in adults with differing levels of kidney function or albumin in the urine. |
|  | Principal Investigator: | Dr Richard Robson |
|  | Sponsor: | Arthrosi Therapeutics, Inc. (Arthrosi Therapeutic |
|  | Clock Start Date: | 12 November 2020 |

Dr Richard Robson 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 Study

1. AR882 is being developed as a treatment for gout.
2. The study will assess single doses of AR882 in participants with different levels of kidney function (Part A) and different levels of urine albumin (Part B). The study team will use results from the groups in each Part to compare:

- How AR882 is absorbed, processed and cleared by the body (pharmacokinetics or PK)

- How safe and well-tolerated AR882 is

- The effects of AR882 on markers associated with gout and/or the kidneys (pharmacodynamics or PD).

1. Part A: Approximately 32 participants will be enrolled into 4 groups based on kidney function (normal, mildly reduced, moderately reduced, and severely reduced). Participants will receive a single 100 mg dose (4 capsules) of AR882.
2. Part B: 30 participants will be enrolled into 3 groups based on the amount of albumin in the urine (normal, mildly increased, and moderate-severely increased). Participants will receive a 75 mg dose (1 capsule) of AR882, once daily for 14 days.
3. In both parts of the study, blood and urine samples to measure study drug levels and effects on the body will be collected at specific time points, safety will be monitored, and any changes in health will be recorded.
4. The results will be used to guide the use of AR882 in people with reduced kidney function and / or albuminuria (increased albumin in the urine).

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 insurance certificate was global and queried whether ACC-equivalent cover is guaranteed for New Zealand participants as overseas lawsuits could potentially deplete the available funds. Please provide evidence that New Zealand participants will have ACC-equivalent insurance available to them in the event of injury.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. The Committee noted repetition in the PIS with information on a five night stay and four scheduled visits repeated several times.
2. Please rephrase the statement about given a chance to read the information sheet on page 4 to state participants will be asked to.
3. The Committee noted the study intends to collect data on any pregnancies but there is no pregnant participant / partner PIS. Please submit one through the amendment pathway if a pregnancy occurs during the trial.
4. Please clarify the statement on page 11 regarding CCST arranging a taxi or uber. Please clarify whether CCST has an uber account or if participants will be required to use theirs and be reimbursed.

Decision

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

* Please provide evidence of ACC-equivalent compensation.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

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

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| **9** | **Ethics ref:** | **20/CEN/248** |
|  | Title: | GS-US-540-9015: A study comparing how remdesivir is processed and cleared from the body, in adults with normal and reduced kidney function. |
|  | Principal Investigator: | Dr Michael Collins |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 November 2020 |

Dr Michael Collins 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 Study

1. Remdesivir (RDV) is being developed for the treatment of COVID-19.
2. Research suggests the kidneys play a role in clearing RDV from the body. The study team wants to assess this properly, by looking at RDV doses in adults with different levels of kidney function:
   * Group 1: mildly reduced kidney function
   * Group 2: moderately reduced kidney function
   * Group 3: severely reduced kidney function
   * Group 4: end-stage kidney disease and on hemodialysis
3. In each group, participants with normal kidney function will be selected as a 'match' for one or more participants with reduced kidney function. The match will be based on age, gender, and body mass index (BMI).
4. 10 participants with reduced kidney function and up to 10 'matches' will be enrolled in each group.
5. Every person in the study, except participants on dialysis, will receive a single dose of RDV. Participants on dialysis will receive one RDV dose before the start of a dialysis session; and a second dose at least 18 days later, after the end of a dialysis session.
6. Each RDV dose is given into a vein over about 30 minutes. The dose level for Groups 1 and 2 is 100 mg. The dose level for Groups 3 and 4 will be decided based on review of earlier dose groups, but will not be more than 100 mg.
7. The levels of RDV and its metabolites (breakdown products) will be measured in blood and urine samples collected at specific times after dosing. Safety
8. will be monitored, and any changes in health will be recorded.
9. The results will show the best doses of RDV to use, in people with different levels of kidney function.

Summary of outstanding ethical issues

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

10. Please revise the section on future use of data to be clear it would not be used in any future research outside of the context of this study.

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 suggestions made by the Committee.

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| **10** | **Ethics ref:** | **20/CEN/251** |
|  | Title: | Effect of air humidification and warming on surgical site temperature during spinal surgery. |
|  | Principal Investigator: | Dr Simon Manners |
|  | Sponsor: | Fisher and Paykel Healthcare Ltd |
|  | Clock Start Date: | 12 November 2020 |

Dr Simon Manners 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 Study

1. Air Surgical Humidification is a therapy designed to deliver warm (~37°C) saturated air (~≥95% relative humidity) to a surgical wound intraoperatively, to prevent evaporation and local heat loss. It comprises a patient interface, a heated delivery circuit, a humidification chamber, a humidifier, an unheated circuit, and flow source and designed to create an even distribution of flow over the open wound and provide effective coverage with warm humidified air.
2. Twenty eight patients aged 22 years and older undergoing elective 1 or 2 level spinal decompression (laminectomy or laminectomy and discectomy) between L1-S1 vertebrae who fit the study criteria and consent to take part will be randomised to receive standard of care (no intervention) or Air Surgical Humidification during their surgery. An anonymous photo of the surgical site will be taken from approximately 1.5 metres away from the surgical wound and outside the aseptic field by the research nurse immediately prior to incision, at 15-minute intervals during the surgery, and at closure. Core temperature from a nasopharyngeal probe will also be recorded immediately prior to incision, at 15-minute intervals during the surgery, and at closure.
3. Post operatively de-identified photos will be taken of the dressed surgical wound from 50 cm away while the patient is in recovery 30 minutes after wound closure during routine post op checks.
4. Re-admissions to hospital will be recorded for approximately 6 weeks until the patient’s routine post-op visit and clinical follow up. Re-admissions will be monitored through Middlemore Hospital patient tracking system that flags the patient’s participation in a clinical study on their patient records. The patient will also be asked at their post-op visit if they needed to be admitted to another hospital for any reason during the 6 weeks after surgery.
5. The patient’s participation in the study begins at consent and finishes at the post-op visit.

Summary of outstanding ethical issues

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please insert a picture of the device.
2. Please add more information about the device e.g. the air is sterilised, the device is already in use and has been extensively tested etc.
3. Please add an explanation of what FPH stands for when it is used in the body of the text.
4. Please tone down the black box first-in-human warning as the device has been in use before.

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 suggestions made by the Committee.

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| **11** | **Ethics ref:** | **20/CEN/245** |
|  | Title: | GEn1E-1124-001: A study assessing single and multiple doses of GEn1E-1124. |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: | GEn1E Lifesciences |
|  | Clock Start Date: | 12 November 2020 |

Dr Chris Wynne 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 Study

1. GEn1E-1124-001 is being developed for the treatment of acute respiratory distress syndrome (ARDS).
2. This is the first study of GEn1E-1124 in humans, and will enroll healthy male and female participants. The study will be conducted in three parts:

- Part A (3 dose groups) will assess single increasing doses of GEn1E-1124 or placebo.

- Part B (3 dose groups) will assess multiple increasing doses of GEn1E-1124 or placebo.

- Part C (1 dose group) will assess whether GEn1E-1124 reduces the body's inflammatory response to a lipopolysaccharide (LPS) dose.

1. Samples to measure study drug levels and the body's response to the drug (and LPS challenge, in Part C) will be collected at specific time points during the study Safety will be monitored, and any changes in health will be recorded. The results will be used to inform the further clinical development of GEn1E-1124.

Summary of outstanding ethical issues

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

1. Please update the HDC contact email to [advocacy@advocacy.org](mailto:advocacy@advocacy.org) in the Part B PIS.

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 suggestions made by the Committee.

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| 12 | **Ethics ref:** | **20/CEN/246** |
|  | Title: | C109-CTD1: A study assessing single and multiple doses of ALP001E, in healthy adults and adults with type 2 diabetes. |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: | PPD Global Limited (New Zealand Branch) |
|  | Clock Start Date: | 12 November 2020 |

Dr Chris Wynne 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 Study

1. ALP001E is being developed for the treatment of type 2 diabetes. This is the first study of ALP001E in humans. The study will be conducted in several parts, and will enroll about 96 participants across two New Zealand sites.

Part 1:

- Groups 1-5 will assess single increasing doses of ALP001E/placebo in healthy adults.

- Group 3 will assess single doses of ALP001E/placebo, taken with and without food.

Part 2 (optional):

- 1 group of healthy adults will assess single doses of ALP001E/placebo, in capsule and liquid form.

Part 3:

- 1 group of healthy adults will assess multiple doses of ALP001E/placebo.

- 3 groups of participants with type 2 diabetes will assess multiple increasing doses of ALP001E/placebo.

1. Samples to measure ALP001E levels and the body's response to the drug will be collected at specific time points during the study. Safety will be monitored, and any changes in health will be recorded. The results will be used to inform the further clinical development of ALP001E.

Summary of resolved ethical issues

1. The Committee identified no ethical issues with the application.

Decision

This application was *approved* by consensus.

## General business

1. The Committee noted the content of the “ noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| --- | --- |
| **Meeting date:** | 26 January 2021 |
| **Meeting venue:** | Zoom TBC |

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 5:35pm.