|  |  |
| --- | --- |
| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 21 March 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 12.30-1.00pm | 2023 FULL 13593 | Novel white cap crowns for drill-free dental caries treatment in NZ children | Dr Joanne Jung Eun Choi | Mr Jonathan Darby and Dr Kate Parker |
| 1.00-1.30pm | 2023 EXP 15277 | Modulation of cough sensitivity using auricular stimulation in stroke | Associate Professor Yusuf Cakmak | Ms Catherine Garvey and Dr Sotera Catapang |
| 1.30-2.00pm | 2023 EXP 13668 | Recovery associated outcomes: a 15-year longitudinal follow-up of the Schizophrenia: Outcomes, Psychosis, Experience (ScOPE) project. | Associate Professor Tess Patterson | Mr Jonathan Darby and Mr Derek Chang |
| 2.00-2.30pm | 2023 FULL 13909 | KALVISTA KVD900-302 | Dr Anthony Jordan | Ms Catherine Garvey and Dr Andrea Forde |
|  | *Break* |  |  |  |
| 3.00-3.30pm | 2023 FULL 15406 | Eat, Sleep, Play- CP | Dr Sian Williams | Mr Jonathan Darby and Ms Jade Scott |
| 3.30-4.00pm | 2023 FULL 15233 | Study of an investigational medicine called OMS906 to find out if it is safe and well-tolerated to use in patients who have a rare kidney disease called C3G and ICGN | Dr Janak de Zoysa | Ms Catherine Garvey and Dr Kate Parker |
| 4.00-4.30pm | 2023 FULL 13153 | Pilot Study – Role of FAPI PET in patients with metastatic castrate resistant prostate cancer. | Dr Andrew Henderson | Mr Jonathan Darby and Mr Derek Chang |
| 4.30-5.00pm | 2023 FULL 15408 | NEU-411-PD101: A Study to Assess NEU-411 in Healthy Participants | Principal Investigator Christopher John Wynne | Ms Catherine Garvey and Dr Andrea Forde |

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

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that no apologies had been received.

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 21 February 2023 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1**   | **Ethics ref:**   | **2023 FULL 13593** |
|   | Title:  | Novel white cap crowns for drill-free dental caries treatment in NZ children - Feasibility Study |
|   | Principal Investigator:  | Dr Joanne Choi |
|   | Sponsor:  | Te Whatu Ora Southern |
|   | Clock Start Date:  | 09 March 2023 |

Susan Moffatt and Samuel Carrington 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 the consent process and the recruitment processes with the Researcher.

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 reason for not including criteria for termination of the study. This should be included in the Protocol and participant information sheet (PIS).
2. The Committee queried what questionnaire would be used at follow-up appointments. Currently only one questionnaire was included in the application, for use at the initial appointment to fit the crown. Should the researchers wish to use the currently submitted questionnaire at subsequent appointments, please can they edit this to include the correct timeframes.
3. The Committee queried the process by which the data would be monitored by an external body and where and when this data may be accessed and by whom. Please provide this information.
4. The Committee requested clarification that the manufacturer of the devices is a local medical device manufacturer and is a licensed manufacturer to GMP standards.
5. The Committee queried if the crown would be affected by heat or cold. Please provide this information.

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

1. Please note that children aged 5-7 ‘Assent’ and amend the PIS document for this group.
2. Please correct the number of participants to the proposed 64 and not the 60 as stated.
3. Please amend the data retention period to 10 years after a participant turns 16, or if practical, after the youngest participant is 16.
4. For completeness, please upload a copy of the cover letter that will be sent to parents of eligible child participants together with the PISs if it is being included.
5. Please clarify what is meant by Faculty of Dentistry data safety monitoring.
6. Please clarify collection of data through Titanium for cost benefit analysis referred to in the protocol. Please also specify if this will be included in the locality authorisation.
7. Please offer participants the option to receive a lay summary of results in the CF and refer to this in the main body of the PIS.
8. Please include the date and version in the footer of the PISs.

**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 Kate Parker and Mr Jonathan Darby.

|  |  |  |
| --- | --- | --- |
| **2**   | **Ethics ref:**   | **2023 EXP 15277** |
|   | Title:  | Modulation of cough sensitivity using auricular stimulation in stroke: a randomised crossover trial |
|   | Principal Investigator:  | Associate Professor Yusuf Cakmak |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 09 March 2023 |

Karen Ng was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried why the peer review information had not been incorporated into the trial regarding the 30 second break used to prevent tachyphylaxis. The Researcher clarified that in her experience a 30-60 second break was inevitable so not necessary to stipulate.
2. The Committee clarified with the Researcher that should there be a reduced urge-to-cough or no urge then this would still be measured and that this would not impact the data collection as this is the intended outcome. The Researcher also confirmed participants will be competent to provide consent and the testing would not be too complicated.

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 ability of participants to close their lips or hold the device depending on the effect or severity of the stroke. The Researcher noted that this has been considered and resolved. This should be specified in the protocol and participant information sheet (PIS).
2. The Committee requested the following changes to the Protocol:
	1. Please clarify the time interval between aural stimulation and the cough reflex test.
	2. Please specify who will be blinded.
	3. Please provide a timeframe for each event per session.

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

1. Please correct the aural stimulation time to be consistent with the protocol.
2. Please consider including pictures of the electrodes and ear so that participants know what to expect as the ear is a complicated anatomical structure.
3. Please add the right to withdraw.
4. Please explain for participants how long each of the three sessions will be and how far apart they are spaced.
5. Please amend the statement "If you agree, your coded data may be used for future cough and swallow research" to include an option to agree or disagree in the consent form of a yes/no box.
6. Please specify that only the left ear will be tested.
7. Please include reference to the importance of coughing in stroke patients, as part of the explanation of the study purpose.
8. Please consider including a table or flowchart showing the processes 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 Catherine Garvey and Ms Sotera Catapang.

|  |  |  |
| --- | --- | --- |
| **3**   | **Ethics ref:**   | **2023 EXP 13668** |
|   | Title:  | Recovery associated outcomes: a 15-year longitudinal follow-up of the Schizophrenia: Outcomes, Psychosis, Experience (ScOPE)project. |
|   | Principal Investigator:  | Associate Professor Tess Patterson |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 09 March 2023 |

Associate Professor Tess Patterson 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 this was a follow up study from an historic application (2007/08)
2. The Committee queried as to whether there was provision for future contact in the previous study. The initial contact will be made by a clinician who was not related to the previous study who is likely to be known to the participants. The only and the only information provided to those contacting participants initially would be names and contact details and the fact of their involvement in the earlier study.
3. The Committee clarified that Dr Barak would not have access or permission to access identified data due to his clinical role.
4. The Committee clarified that disclosure of information to a participant’s healthcare professionals would only occur in cases of imminent risk to the participant or to others.
5. The Committee noted that the requirements for Waiver of Consent for the initial contact to potential participants had been satisfied. The Committee suggest including a statement to this effect in the protocol.
6. The Committee clarified the background and experiences of interviewers and training/supervision provided by the Principal Investigator.

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 if the questionnaires were validated. The researchers noted they had not been. This should be noted in the participant information sheet (PIS).
2. The Committee queried as to how capacity to consent will be determined and by whom. This needs to be outlined in the protocol.
3. The Committee queried what would occur should participants disclose imminent risks such as acute suicidality to researchers but refuse to allow researchers to contact clinicians or Emergency Psychiatric Services. This should be included in the Protocol.
4. The Committee queried what would happen if a participant was unable to complete all study measures in one session, and if there would then be a further appointment. This needs to be detailed in the protocol and PIS.
5. Please amend the wording “third country” to “lower and middle income countries”.
6. The Committee requested further detail in the data management plan (DMP) about responding to breach of privacy (refer to the [HDEC DMP template](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/)).

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

1. The Committee noted that the protocol does not match the title and is not particularly descriptive, please amend.
2. Please amend the statement regarding HDEC approval to note that HDEC approves only the “ethical aspects” of the study.
3. On page 2 describe, more specifically, the health information that will be obtained from a participant's medical records. The Protocol sets out what is required (treatment regime, therapy, adherence, co-morbidities, any CTO, suicidality) and this information should be specified in the PIS/CF.

**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)*
* 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*).

|  |  |  |
| --- | --- | --- |
| **4**   | **Ethics ref:**   | **2023 FULL 13909** |
|   | Title:  | An Open-label Extension Trial to Evaluate the Long-term Safety of KVD900, an Oral Plasma Kallikrein Inhibitor, for On-demandTreatment of Angioedema Attacks in Adolescent and Adult Patients with Hereditary Angioedema Type I or II. |
|   | Principal Investigator:  | Dr Anthony Jordan |
|   | Sponsor:  | Kalvista Pharmaceuticals Ltd |
|   | Clock Start Date:  | 09 March 2023 |

Davina McAllister, Genevieve Morris and Dr Anthony Jordan 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 submission acknowledged that this is a resubmission. The Researcher clarified that the resubmission was due to safety concerns alerted by the sponsor but that this was resolved and not related to this trial specifically.
2. The Committee clarified that there would be no roll-over from the other study referred to in the submission as there were no New Zealand participants in that study.
3. The Committee clarified that breastfeeding participants were excluded due to the lack of data on the impact of the study drug on breast fed infants.

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 methods through which recruitment would occur and requested that this be noted in the protocol.
2. Please amend the data retention period to 10 years after a participant turns 16, or if practical, after the youngest participant is 16.
3. The Committee queried as to whether there would be blinding in this study. If there is no blinding, please remove.
4. The Committee noted that there was a lot of study visits with no compensation for time. The reimbursement for travel is adequate but the loss of time is significant, and the Committee requested further consideration be given to this.
5. The Committee queried if there would be compassionate provision of the drug after the study should the drug be considered to have therapeutic benefit.
6. The Committee queried if the manufacturer intends to license the study drug in New Zealand if the trial demonstrate clinical benefit.
7. The Committee queried the process for follow up of women who become pregnant while using the investigational product. Please provide this information.
8. The Committee queried whether the e-Diary provider would have access to participants’ identifiable data, for what purposes, and what steps would be taken to protect the privacy of participants. Please detail this in the participant information sheet (PIS) and data and tissue management plan.
9. The Committee queried if the 24 doses over 2 years would be accurate for this study or if this may differ in practice. Please include this in the protocol.

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

Main PIS/CF:

1. The age brackets for the assent forms are not appropriate, please amend. The 17-year-old cut off is not correct for New Zealand. Forms for 12-15, with assent, should be provided.
2. Please amend the mention of Ethinyl oestradiol and the exclusion based on the use as a contraceptive. This is not only used in a contraceptive capacity, and this should be noted in particular for all adolescent participants.
3. The Committee noted that this information on hormonal medications is not included in the consent form for younger participants 12-14. The Committee noted that this cohort is more likely to use these medications for management of menstruation.
4. Please review for typos.
5. Please review for Americanised references and spelling such as “racial origin” and “mom”.
6. Please include information as to how participants may withdraw from the study.
7. Please specify whether karakia would be available for tissue collection/disposal.
8. Please define an “eligible attack”.

Pharmacokinetic PIS/CF:

1. Please define an “eligible attack”.
2. Please amend blood volumes to millilitres over teaspoons.
3. Please clarify if the finger prick tests will all be on the same finger or if different fingers will be used.

**Decision**

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

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

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

|  |  |  |
| --- | --- | --- |
| **5**   | **Ethics ref:**   | **2023 FULL 15406** |
|   | Title:  | Eat, Sleep, Play: Investigating nutrition and body composition in children with Hōkai Nukurangi - cerebral palsy |
|   | Principal Investigator:  | Dr Sian Williams |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 09 March 2023 |

Dr Sian Williams 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 asked about the meal plan, and how the information will be delivered to the family and the child participant. The Researcher explained the information given to the family and the child will be individualized, and a meal plan will be planned around what the child participants want and when they are most physically active and that the timing of meal consumption will be tracked, and the child will be provided with a basic photo explaining what is happening.
2. The Committee asked about who completes the dietary intake using Intake24. The Researcher explained the child will sit down with the parent/caregiver and they will sign it together.
3. The Committee asked whether home visits are a possibility. The Researcher explained at this current time it is not possible as the DEXA scans are done at both in-person visits, so clinic attendance is required.
4. The Committee asked if the child is the only participant or if the parent is also seen as a participant. The Researcher explained the parent and the child will be participants.

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 the protocol has more information and clarity on the proposed intervention with dietary and activity advice, and how the information will be delivered to the family and the child.
2. The Committee queried whether consultation had been undertaken with the disability community, specifically the Cerebral Palsy Society and further raised the issue of whakama/shame regarding the possible inability of families to afford healthy options. Please provide further information around how this will be managed.
3. The Committee requested inclusion of screen shots of Intake 24 be uploaded with the response to Provisional Approval.

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

Child Information Sheet:

1. Please create a simpler version of the information sheet for 5-7 years old, as the current version is too complex for this age group. Please create a simpler assent form and consider including some simple photos (National Ethical Standard 6.27).
2. Please include contact details for researchers.

Parent Participant Information Sheet and Consent Form:

1. Please add when the child will complete their assent form to the table on page 2.
2. Please add that a 3-day food diary is required prior to visit 2 to the table page 2.
3. On page 5 please amend the following statement: “Coded study information will be kept by the sponsor in a secure, cloud-based storage indefinitely.” The Committee referred to Standard 12.13 which states that data should not be stored longer than is required for the purposes for which the information may lawfully be used but should be stored for the minimum period required by New Zealand law (currently 10 years for health data that relates to an identifiable individual).
4. Please add the source of funding for this study.
5. Please add the number of participants you are expecting to recruit.
6. Please double check the parental participant information sheet for general typo errors.
7. Please amend the advocacy email to advocacy@advocacy.org.nz.
8. Please remove the references to DHBs and replace with Te Whatu Ora and the relevant location.
9. For readability, please make the font of headlines be white writing on blue.
10. Please proof-read for typos and grammar.

**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 Mr Jonathan Darby and Ms Jade Scott.

|  |  |  |
| --- | --- | --- |
| **6**   | **Ethics ref:**   | **2023 FULL 15233** |
|   | Title:  | OMS906-C3G-001: A Phase 1b Proof of Concept Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of OMS906 in Patients with C3 Glomerulopathy and Idiopathic Immune Complex-Mediated Glomerulonephritis |
|   | Principal Investigator:  | Dr Janak de Zoysa |
|   | Sponsor:  | Omeros Corporation |
|   | Clock Start Date:  | 09 March 2023 |

Dr Janak de Zoysa 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 asked about the study drug access for participants after the trial has ended. The Researcher explained they have a verbal agreement from the Sponsor to continue to supply drug to participants in whom therapeutic benefit is shown, after the trial has finished. The Researcher noted that the study is open label for participants.
2. The Committee asked about the identification of the risk of infection with encapsulated organisms, in both the protocol and participant information sheet/consent form (PIS/CF) and meningococcal vaccination being required, but not Pneumococcal vaccination. The Researcher explained the reasons it was not monitored (per Protocol) but acknowledged the query and will discuss further with the Sponsor.

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 that the Researcher amend the data and tissue management plan to include local site data and tissue management policies that will be adhered to, including local storage details, and local disposal of tissue info (particularly, if karakia is available).
2. The Committee noted that a pregnant participant/partner participant information sheet/consent form should only be submitted as an amendment in the event that a pregnancy occurs so it can be fit-for-purpose. As such, these have not been approved for use with the current submission.
3. The Committee requested the Researchers confirm whether the registry that the trial has been registered in is WHO approved.

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

Main Participant Information Sheet:

1. Please amend the notification to GP; it should not be optional, please remove yes/no tick boxes.
2. Please note that the sponsor cannot stop the trial for any reason i.e., not for commercial reasons.
3. Please include more detail in the reimbursement section, to let the participants know exactly what they will be receiving.
4. Please reduce the detail regarding data protection etc., in the EU.

**Decision**

This application was *approved with nonstandard conditions* 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).*

|  |  |  |
| --- | --- | --- |
| **7**   | **Ethics ref:**   | **2023 FULL 13153** |
|   | Title:  | Pilot Study- Assessment of FAPI PETCT in Castrate Resistant Prostate Carcinoma patients with discordant disease at FDG PETCT |
|   | Principal Investigator:  | Dr Andrew Henderson |
|   | Sponsor:  | Prostate Cancer Foundation NZ |
|   | Clock Start Date:  | 09 March 2023 |

Dr Andrew Henderson and Rosane Joseph 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 investigator’s brochure discusses the investigational product in relation to types of cancer, but not the one currently being explored. The Researcher confirmed that this has been explored in prostate cancer before, and there is no expectation that prostate cancer patients will have increased risk in other patients it has been used on.
2. The Researcher confirmed this is investigator-initiated. The investigational product is provided free by the manufacturer, but they will have no access to identifiable data, or results other than published results, and no influence over publication.

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 data management plan and protocol refer to the previous Privacy Act. Please update the reference and ensure all information is correct.

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

1. Please proof-read for typos and grammar.
2. The Committee noted that the explanation of the purpose of the study is not particularly lay-friendly and noted that this was more simply explained in the protocol. Please consider amending.
3. Review for acronyms and lay readability.
4. Please review for typos.
5. Explain what FAPI is the first time this acronym is used.
6. The PIS reads as though participants are being referred by their Oncologist to the researchers only because of eligibility for participation in the study. “If you are eligible, you will be referred by your oncologist…” is not consistent with the intended manner of recruitment; please amend.
7. Statement regarding preference for excluding participants who have had a similar prior treatment does not contain rationale. Please explain why this preference is here.
8. The Committee noted that participants should not be expected to produce receipts for petrol/travel to the study site. Please provide a reasonable set amount of reimbursement for travel instead.
9. Please indicate who to contact if the participant wishes to withdraw.
10. In the black box warning please clarify that the investigational product is licensed overseas for use in imaging certain cancers and that this study is interested in how it works in mCRPC among New Zealand participants.

**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).*

|  |  |  |
| --- | --- | --- |
| **8**   | **Ethics ref:**   | **2023 FULL 15408** |
|   | Title:  | A Phase 1, Single and Multiple Ascending Dose and Food Effect Study of NEU-411 Administered Orally to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics in Healthy Subjects |
|   | Principal Investigator:  | Dr Chris Wynne |
|   | Sponsor:  | Neuron23, Inc. |
|   | Clock Start Date:  | 09 March 2023 |

Dr Chris Wynne and Julia O’Sullivan were present via videoconference for discussion of this application.

Potential conflicts of interest

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

Dr Andrea Forde declared a potential conflict of interest. By agreement Dr Forde remained for consideration of the application.

Summary of resolved ethical issues

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

1. The Committee queried whether the detection of LRRK2 gene was a robust indicator of Parkinson’s risk. The Researcher confirmed that detection of this gene alone was not a robust indicator, and that the communication of such a result to a participant as the potential of causing more harm than good. The gene test is being conducted to help analyse drug PK, and not for any other diagnostic reason. The Committee accepted this rationale for not feeding back the results of genetic testing and recommended advising the participant why.

Summary of outstanding ethical issues

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

1. For completeness, please include the risk identified in preclinical animal studies of looseness of stool/bowel change in non-human primate in the PIS/CF
2. The Committee was advised that stool frequency was monitored as an adverse event.
3. The Committee requested the risk of lumbar puncture is either highlighted or brought forward more. The Committee was assured that appropriate discussion would take place around the risks of it and were satisfied of inclusion of statement suggested by the Researchers that risks of lumbar puncture will be discussed further in the document.

**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).*

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 18 April 2023 |
| **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 4.45pm