|  |  |
| --- | --- |
| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 23 January 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 12.30-1.00pm | 2023 FULL 19214 | CB06-036-102: A Study to Evaluate the Safety and Tolerability of Multiple Ascending Doses of CB06-036 in Participants with Chronic Hepatitis B | Dr Paul Hamilton | Ms Kate O'Connor and Dr Sotera Catapang |
| 1:00pm-1:30pm | 2023 FULL 19255 | MK-5684-003: Phase 3 study of MK-5684 versus alternative Next-generation Hormonal agent (NHA) in mCRPC | Dr Orlaith Heron | Ms Catherine Garvey and Dr Andrea Forde |
| 1:30pm-2:00pm | 2023 FULL 19219 | MK-5684-004: Phase 3 study of MK-5684 versus alternative Next-generation Hormonal Agent (NHA) in mCRPC post one NHA | Dr Carmel Jacobs | Ms Catherine Garvey and Dr Andrea Forde |
| 2:00pm-2:30pm | 2023 FULL 19089 | Study of EDG-5506 in Becker Muscular Dystrophy | Dr. Richard Roxburgh | Mrs Helen Walker and Ms Jade Scott |
| 2:30pm-3:00pm | 2023 FULL 16788 | The IPMN Trial: Feasibility of EUS chemoablation in IPMN pancreatic cysts | Associate Professor Michael Jameson | Ms Kate O'Connor and Dr Kate Parker |
| 3:30pm-4:00pm | 2023 FULL 18972 | Healthy ageing in adults with cerebral palsy | Dr Sian Williams | Mr Jonathan and Dr Sotera Catapang |
| 4:00pm-4:30pm | 2023 FULL 18694 | (AZ D8535C00001 / BCT 2302) CAMBRIA-2: An Adjuvant Endocrine-based Therapy Study of Camizestrant (AZD9833) in ER+/HER2- Early Breast Cancer | Dr/ Medical Oncologist Marion Kuper-Hommel | Ms Catherine Garvey and Dr Kate Parker |
| 4:30pm-5:00pm | 2023 FULL 15231 | The NEOgrads Playgroup Study- Promoting early motor development for preterm babies. | Miss Louise Pearce | Mrs Helen Walker and Ms Jade Scott |
| 5:00pm-5:30pm | 2023 FULL 18182 | Fibre and gut inflammation | PROFESSOR ANDREW DAY | Ms Kate O'Connor and Ms Jade Scott |
| 5.40pm-6.10pm | 2023 FULL 18151 | A study to test long-term safety of Iclepertin in people with schizophrenia who took part in a previous CONNEX study | Assoc Prof Sylvester Wayne Miles | Mr Jonathan Darby and Dr Sotera Catapang |
| 6.10pm-6.40pm | 2023 FULL 19337 | VT-10201: Single-Ascending Dose Study of VERVE-102 in Patients with HeFH or Premature CAD Requiring Additional LDL-C Lowering | Professor Russell Scott | Mr Jonathan Darby and Dr Kate Parker |
| 6.40pm-7.10pm | 2023 FULL 19342 | ATB1651-102: A Phase 2 Study to Assess the Safety, Tolerability and Effectiveness of ATB1651 in Adults with Mild to Moderate Onychomycosis (Fungal Nail Infection) | Doctor Cory Sellwood | Mrs Helen Walker 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 | Apology |
| 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 |
| Mrs Helen Walker  | Lay (Consumer/Community perspectives) (co-opted) | 22/12/2020  | 22/12/2024 | Present  |
| Ms Kate O’Connor  | Lay (Ethical/Moral reasoning) (co-opted) | 13/08/2021 | 16/08/2024 | Present |

## Welcome

The meeting was opened with a karakia 12.05pm and welcomed Committee members, noting that apologies had been received from Dr Derek Chang.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Kate O’Connor and Mrs Helen Walker confirmed their eligibility and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 21 November 2023 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1**   | **Ethics ref:**   | **2023 FULL 19214** |
|   | Title:  | CB06-036-102: A Randomized, Double-Blind, Placebo-controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, andPharmacodynamics of Multiple Ascending Doses of CB06-036 in Subjects with Chronic Hepatitis B |
|   | Principal Investigator:  | Dr Paul Hamilton |
|   | Sponsor:  | Shanghai Zhimeng Biopharma, Inc. |
|   | Clock Start Date:  | 11 January 2024 |

Dr Paul Hamilton and Kim Huljich were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified with the Researcher the recruitment methods, where a sub-investigator of the study will gauge interest with potential participants attending a clinic visit to be contacted about the study at a later date.

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 while the peer review provided contains expert opinions, these are not independent of the study. The peer review submitted doesn’t meet HDEC requirements of being independent from the study. Please provide an independent peer review. The [HDEC peer review template](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance/) can be used. They further noted that the FDA report would also be useful as evidence of independent peer review.
2. The Committee noted that proof of current indemnity for the coordinating investigator is required to be uploaded as the one provided has expired.
3. The Committee noted that a pregnant participant/partner participant information sheet/consent form should only be submitted as an amendment if a pregnancy occurs so it can be fit-for-purpose. As such, these have not approved for use with the current submission. They did further note however that as written, stating what information will be collected reads very intrusive, and suggested condensing the wording to state “complete obstetric and gynaecological history”.
4. Data and Tissue Management Plan (DTMP), Section 3 currently states that a site will follow site-specific SOPs based on New Zealand regulation. The Committee requested that the research network data policy across sites be referenced.
5. The DTMP also refers to participants under 16; please remove.
6. Please ensure that the advertisements state that the ethical aspects of the study have been approved by the Northern A HDEC.

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

1. Please refrain from referring to the study medicine as “treatment” as it is not proven yet. Please edit and reword this, including the reference on page 11 to non-placebo as the “treatment group”.
2. The PIS implies that participants must organise their own karakia at donation. The Committee recommended not putting the burden on participants for this and noted that it is more typical to state whether a karakia is available for destruction of samples rather than the taking of samples.
3. The Committee noted that unless the Sponsor has voluntarily committed to the Medicines New Zealand guidelines surrounding compensation, inclusion of that language on page 15 is irrelevant and should be removed.
4. Page 17 mentions data-linking, but there is none stated in the DTMP. Please make it clear what this is referring to in both documents.
5. As participants are people with chronic Hepatitis B, there is no need to state their cases will be notified as that should have already occurred in the acute phase.
6. If someone will become unwell, it is stated that they must contact the study doctor and that a visit will be scheduled. Please ensure there are arrangements for participants to be be seen as soon as possible, and if they cannot be seen immediately, that the study has arranged for urgent attention and care.

**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 data and tissue 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, 14.16&14.17).*
4. 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).*

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 Sotera Catapang.

|  |  |  |
| --- | --- | --- |
| **2**   | **Ethics ref:**   | **2023 FULL 19255** |
|   | Title:  | A Phase 3 Randomized, Open-label Study of MK-5684 Versus Alternative Abiraterone Acetate or Enzalutamide in Participants With Metastatic Castration-resistant Prostate Cancer (mCRPC) Previously Treated With Next-generation Hormonal Agent (NHA) and Taxane-based Chemotherapy |
|   | Principal Investigator:  | Dr Orlaith Heron |
|   | Sponsor:  | Merck Sharp & Dohme (New Zealand) Limited, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA |
|   | Clock Start Date:  | 11 January 2024 |

Dr Orlaith Heron, Penelope Eadie, Camila Febbo-Dobson, and Smita Boban 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. There are two medications identified in the documents, but it was not clear what would be used for the control arm of the two comparators provided for in the Protocol. The Researchers clarified that participants will receive whichever of the two comparators is appropriate taking into account what they have already received treatment with. The comparator that is not currently funded in New Zealand will be made available by the Sponsor to participants if appropriate.

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 reason given for not providing the study medicine after the trial is that it is not licensed in New Zealand yet, however this is not a reasonable justification for not providing it. It can be provided as an unlicensed medicine in New Zealand if participants are receiving therapeutic benefit The Committee requested this is investigated further with the Sponsor.
2. The Committee acknowledged that participants indicating severe depression and suicidal ideation will be referred to psychiatric help if this is identified in the quality-of-life surveys. The Committee queried if this care will be covered by the Sponsor and consideration of public versus private treatment. The Researchers responded that if it is deemed somewhat related to the study drug, the Sponsor does have policies for reimbursement of medical costs. This will be determined by the Sponsor and investigator. The Researchers noted that anything related to usual distress observed in cancer patients will remain internally handled by the hospital and clinicians, given their expertise. Anything that is determined to require further referral may receive this. and be reimbursed by the Sponsor. The Sponsor will provide more concrete policies regarding this.
3. Please confirm if payment for the sites will go to the hospital, or Te Whatu Ora generally.
4. The Committee requested the following changes to the Data Management Plan (DMP) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a):*
	1. Please review for typographical errors.
	2. Please expand on the data governance. The Sponsor likely has requirements around privacy and data management which have not been detailed in the DTMP.
	3. Please review and amend reference to participants aged under 16 for accuracy.
5. The Committee noted that the risk to reproduction identified to participants should reflect the fact that the IB states known reproductive toxicity in animal studies. While it is unknown risk for humans, the Committee wished to highlight this and it should be emphasised more to participants.

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

1. Please review for typos and grammar.
2. The Committee made a minor comment that “study medicine” or “medication” is more New Zealand specific than “study drug”.
3. The Committee stated that placebo or control participation does not exclude participants from ACC-equivalent compensation from the Sponsor, as this is related to participation in the trial, not what medication they take. To be ACC equivalent cover therefore should not exclude injury for those in the control arm.
4. Please check that the data privacy information that is being provided to participants is in line with what the third-party apps used state in their privacy policies. Currently, the data collected by third party apps could include identifiable information such as Date of Birth. Please clarify too that the information collected by the app is restricted to what is entered in the app and does not collect additional data like location.
5. The Committee noted the inclusion of an NZCR cultural statement in the template used by the study, and confirmed with the Researchers this was in error.
6. Notifiable diseases are not reported to the Ministry of Health, but to the Medical Officer of Health. Please amend.
7. Under contraception, there are barrier methods included (such as diaphragm) in addition to highly effective hormonal contraception used be the female partner. Unless there is concern about secretion in seminal fluid there should be no requirement for the additional burden of barrier contraception. The Committee noted in particular that the additional requirement for the use of a diaphragm placed an unacceptable burden on the female partner.
8. Under point 19 about what costs are on the participant, please clarify the sites policies surrounding arranging and paying for travel.

**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 data management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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

|  |  |  |
| --- | --- | --- |
| **3**   | **Ethics ref:**   | **2023 FULL 19219** |
|   | Title:  | A Phase 3, Randomized, Open-label Study of MK-5684 Versus Alternative Abiraterone Acetate or Enzalutamide in Participants with Metastatic Castration-resistant Prostate Cancer (mCRPC) That Progressed On or After Prior Treatment with One Next-generation Hormonal Agent (NHA) |
|   | Principal Investigator:  | Dr Carmel Jacobs |
|   | Sponsor:  | Merck Sharp & Dohme (New Zealand) Limited, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA |
|   | Clock Start Date:  | 11 January 2024 |

Dr Carmel Jacobs, Maddy Williams, Sophie Goodger, Soeren Geese 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. There are two medications identified as comparators in the documents, but it was not clear whether both will be used for the control arm in New Zealand. The Researchers clarified that participants will receive whichever comparator medicine is appropriate for them, and could include the medication approved but not funded in New Zealand.

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 reason given for not providing the study medicine after the trial is that it is not licensed here, however this is not a reasonable justification for not providing it. Unlicensed medicines can still be provided in New Zealand and if the participant has derived benefit from the trial continuing the medicine should be considered. The Committee requested this is investigated pre-emptively with the Sponsor in the event participants obtain therapeutic benefit.
2. The Committee acknowledged that participants who indicate severe depression and suicidal ideation will be referred to psychiatric help if this is identified in the quality-of-life surveys. The Committee queried if this care will be covered by the Sponsor and whether this might involve public or private referral. The Researchers responded that if it is deemed somewhat related to the study drug, the Sponsor does have policies for reimbursement of treatment. This will be determined by the Sponsor and investigator. The Researchers noted that anything related to usual distress observed in cancer patients will likely be dealt with by the hospital and clinicians given their expertise Anything that is determined to be unusual will then be referred on and reimbursed by the Sponsor. The Sponsor will provide more concrete policies regarding this.
3. The Committee requested the following changes to the Data Management Plan (DMP) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a):*
	1. Please review for typographical errors.
	2. Please expand on the data governance to ensure that this reflects the Sponsor’s specific likely has requirements around privacy and data management.
4. The Committee noted there is no such thing as a legal representative for enrolling in clinical trial in New Zealand, and this should be amended in the submission.

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

1. Please review for typos and grammar.
2. A minor stylistic comment that “study medicine” or “medication” is more New Zealand specific than “study drug”.
3. The Committee stated that placebo or control participation does not exclude participants from ACC-equivalent compensation from the Sponsor, as this is related to participation in the trial. Please amend the compensation section to remove the potential exclusion of participants in the control arm based on the medications they will receive.
4. Please check that the data privacy information that is being provided to participants is in line with what the third-party apps used state in their privacy policies. Currently, the data collected by the third-party apps may include identifiable information such as Date of Birth. Please clarify too that the information collected by the app is restricted to what is entered in the app and does not collect additional data like location.
5. Under contraception, there are barrier methods included (such as diaphragm) in addition to highly effective hormonal contraception used by the female partner. Unless there is concern about secretion in seminal fluid, there should be no requirement for the additional burden of barrier contraception. The Committee noted in particular that the additional requirement for the use of a diaphragm placed an unacceptable burden on the female partner.
6. Please clarify the relevant site policies for arranging and paying for travel.

**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 data management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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

|  |  |  |
| --- | --- | --- |
| **4**   | **Ethics ref:**   | **2023 FULL 19089** |
|   | Title:  | A Phase 2 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Effect of EDG-5506 on Safety, Biomarkers,Pharmacokinetics, and Functional Measures in Adults and Adolescents with Becker Muscular Dystrophy |
|   | Principal Investigator:  | Dr Richard Roxburgh |
|   | Sponsor:  | Medpace Australia Pty Ltd. |
|   | Clock Start Date:  | 11 January 2024 |

Dr Richard Roxburgh, Miriam Rodrigues, Dr Zarina Williams, and Kshemina Mhaskar 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 protocol refers to adults and a small number of adolescents, but all other documentation only refers to adults. The Researchers confirmed that in New Zealand the study will only be enrolling adults.
2. The Committee queried whether there will be restrictions on recruiting family members. Given this is an X-linked hereditary disease, the Committee sought reassurance that a small number of families of potential participants would not be overburdened. The Researcher responded that at most, only a couple of members of the same family would be recruited, and any more would be incredibly unlikely. Further, the study team are familiar with the target population and stated that there are not many potential participants in each family.

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 current proof of indemnity for the coordinating investigator is uploaded as the one provided has expired.
2. The Committee noted the standard comment of the Sponsor can “stop it for any reason”. The Committee reminded the Researchers that stopping for commercial reasons can’t be the only reason.
3. The Committee acknowledged that participants indicating severe depression or suicidal ideation will be referred to psychiatric help if identified in the quality-of-life surveys. The Committee queried if this care will be covered by the Sponsor and whether public or private referrals will be made. The Committee also requested clarification of the process followed if psychiatric distress is identified as an incidental finding, and not as a direct result of participation. Part of assessing quality of life means that there may be these incidental findings, and the Committee wish to ensure there is a prompt and adequate response to what is presented. Please seek clarification from the Sponsor.
4. The Committee queried the exclusion of HPV, HCV and HIV diagnoses, and why confirmatory testing for HIV is planned to be carried out in the US. These are notifiable in New Zealand, so there needs to be a clear pathway of how these will be reported if not confirmed in NZ. The Researchers responded that there may be interactions between the study medication and medications to treat those conditions. The Committee noted that any risk of interaction should be highlighted in the participant information sheet (PIS).
5. The Committee noted that in a previous study’s protocol under Amendment 4 (version 5.0), dated 01 Aug 2023, reverted contraception language to previously approved language from Protocol Amendment 2 (Version 3.0) 29 April 2022. The Sponsor became aware on 31 July 2023 that the vendor conducting the GLP FEED study, which had previously been provided to the Sponsor in audited draft format, had reason to question the integrity of the study due to an ongoing internal investigation related to study personnel. This study had supported revision of contraception requirements in Amendment 3 (page 2 of 91). The Committee queried if this integrity issue had been addressed and resolved by the Sponsor and requested comment from the Sponsor on this.
6. Please clarify if participants’ faces will be blurred or obscured in the study-related videos.

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

1. There is description of an activity monitor that participants will wear, as well as a device that tracks information. These appear to be referring to the same thing, please review and amend for consistent terminology.
2. Please provide clarification on whether participants will be using a paper diary or an electronic one. If the electronic diary is also an application on participants phones, information about the privacy policy should be provided, and what information is collected.
3. Page 11 discusses the device being able to track non-study information. The study should limit data collection to what is necessary such as activity tracking, not social media use etc. Please revise.
4. Study flyer indicates that transport and accommodation expenses will be covered. Please ensure this is explicit in the PIS.
5. Protocol states that CYP3A4 inhibitors or inducers are an exclusion criteria, but this is not stated in the PIS. Please include this, with examples, in the PIS.
6. There is known reproductive toxicity. This should be stated in the PIS.
7. Radiation exposure equivalent provided is American-specific with ‘flying coast to coast’. Please provide an alternative explanation.
8. Please include reference to the optional video in the body of the PIS.
9. The CF asks participants to consent to informing their GP of study participation, but this is not in the body of the PIS. Please amend.

**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 Mrs Helen Walker and Ms Jade Scott.

|  |  |  |
| --- | --- | --- |
| **5**   | **Ethics ref:**   | **2023 FULL 16788** |
|   | Title:  | A single-arm intervention study of the feasibility of endoscopic ultrasound-guided pancreatic cyst chemoablation (EUS-PCA) using gemcitabine and paclitaxel for intraductal papillary mucinous neoplasms (IPMN) in two New Zealand tertiary interventional endoscopy centres. |
|   | Principal Investigator:  | Associate Professor Michael Jameson |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 11 January 2024 |

Associate Professor Michael Jameson and Eibhlin Corrigan 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.

Ms Jade Scott declared a potential conflict of interest and the Committee decided to include her in the discussion.

Summary of resolved ethical issues

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

1. The Committee discussed the rationale behind the inclusion of the study population, and why it is not a feasibility study in participants who are eligible and willing to undergo surgery.
2. Procedures for incidental findings are provided in the data management plan, but not detailed in the protocol. The Researchers responded that the findings on the planned genetic analysis will mostly be of uncertain significance but can be notified to a participant’s GP.

Summary of outstanding ethical issues

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

1. The Committee noted that extended storage for specified research can be included under the Main PIS as an option in the CF. This should be kept separate from Future Unspecified Research (FUR).
2. Please specify in the FUR PIS that genetic testing could be involved and list the risks and benefits.
3. Please review sheets for typos and comment boxes left in.
4. Please do not use tablespoons for blood, use millilitres.
5. Reference to pancreatitis says it “can be painful”; please elaborate on the risks.
6. Please remove optional tick boxes for informing the participant’s GP in the CF as this is a mandatory component.
7. Please make it clear that there may be some costs to get to appointments or visits.
8. Please include brief information around risks of an extra MRI as part of the study, such as claustrophobia.
9. Please include a contraception statement such as the need for not getting pregnant, and for how long.
10. It is not clear in the PIS that access to the cyst(s) will be through the stomach wall. A diagram would be useful.
11. Please specify for the 50% cancer figure that skin cancers are included.
12. Under Māori data sovereignty, the statement “We allow Māori organisations to access de-identified study data, for uses that may benefit Māori” should state anonymous instead. The Committee recognise this is included in the template and will be looking at updating this in future as smaller studies run the risk of potential identifiability unless things are anonymised.
13. Provide a point in the PIS/CF for seeking permission to contact participants later for follow-up information, explaining what kind of information will be collected.

**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).*

|  |  |  |
| --- | --- | --- |
| **6**   | **Ethics ref:**   | **2023 FULL 18972** |
|   | Title:  | Healthy ageing needs for adults with cerebral palsy: a qualitative study across New Zealand and Australia |
|   | Principal Investigator:  | Dr Sian Williams |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 11 January 2024 |

Dr Sian Williams, Professor Sue Stott, Woroud Alzaher 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 with the Researchers the rationale for the minimum age for participation being 30.
2. The Committee confirmed that a support person will be encouraged to be present throughout the study, not just initially.
3. The Researchers clarified that a member of the study’s consumer-advisory group cannot be a participant.
4. The Researchers gave a comprehensive answer on how distress is responded to, and following discussion indicated that questions are unlikely to give rise to disclosure of suicidal ideation but that any concerns identified would be addressed.
5. The Researchers confirmed that identifiable participant information stays in New Zealand and will not be shared with the Australian advisors.

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 invitation letter should state that the ethical aspects of the study have been approved by Northern A HDEC.
2. The Committee requested confirmation that participants would be referred to the PIS and required to complete a consent form before completing the online questionnaire, particularly as this collects identifiable information. Please also clarify whether data is collected if participants start but do not complete or wish to continue in the study.
3. The Committee requested a confidentiality agreement with the transcription service responsible for transcribing the interviews.
4. The Committee noted to account for the difference in New Zealand and Australian dollar when providing a koha amount.

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

1. Please state that if feasible, in person interviews can be an option.
2. Page 2 states "The questionnaire can be completed online". It will be helpful to mention other options as well i.e., or by telephone, etc.
3. Please include information about HDC advocacy service. Their contact information for relevant inclusion can be found under the [HDEC Main PIS template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).

**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).*

|  |  |  |
| --- | --- | --- |
| **7**   | **Ethics ref:**   | **2023 FULL 18694** |
|   | Title:  | CAMBRIA-2: A Phase III, Open-Label, Randomised Study to Assess the Efficacy and Safety of Camizestrant (AZD9833, a NextGeneration, Oral Selective Estrogen Receptor Degrader) Versus Standard Endocrine Therapy (Aromatase Inhibitor or Tamoxifen) as Adjuvant Treatment for Patients with ER+/HER2- Early Breast Cancer and an Intermediate-High or High Risk of Recurrence Who Have Completed Definitive Locoregional Treatment and Have No Evidence of Disease. |
|   | Principal Investigator:  | Dr Marion Kuper-Hommel |
|   | Sponsor:  | Astra Zeneca |
|   | Clock Start Date:  | 11 January 2024 |

Dr Marion Kuper-Hommel and Jenni Scarlet 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 there would be ongoing access to the study medication in the event of therapeutic benefit. The Researchers responded that usual care with this type of medicine is for 7 years (that is, the study period). Ongoing safety monitoring will continue beyond that.
2. The Researcher clarified that the Sponsor will supply a non-Pharmac funded medication for participants in additional to the investigational product, and clarified that at the time of the application, this was not approved by Medsafe, but received approval shortly after submission of the ethics application.
3. The Researcher clarified recruitment via simple information about the existence of the study on the Sponsor’s website, with the study name and contact details.
4. The Committee queried how recruitment in clinics will work. The Researchers clarified that their treating clinician would introduce the study with the participant information for them to consider with follow up by the research nurse if they are interested. The clinical investigator then consents them into the study.
5. The Committee noted that the submission form states ethnicity data will not be collected. The Researchers confirmed this will be collected at a site-level.

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 rationale behind the 28 day prohibition on egg donation and 6 months for sperm donation.
2. The Committee noted that a pregnant participant/pregnant partner participant information sheet/consent form should only be submitted as an amendment if a pregnancy occurs so it can be fit-for-purpose. As such, these have not approved for use with the current submission.
3. The Committee requested the following changes to the Data Management Plan (DMP) (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a):
	1. Please amend references to participants under 16 as there are none in this study.
	2. Please provide more information under the governance statement including relevant New Zealand legislation.
	3. Participant information sheet asks for participants to download an app to their device, but there is no information about this appt in the DMP. Please include information about the data that the app is collecting and that it is only for the trial.

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

1. Please provide the addresses of the laboratories and biobanks.
2. In the Main PIS, stated that if someone gets pregnant, it will be monitored. Please amend to state that the study will seek permission from the pregnant person.
3. If the genetic screening test is not being provided by the study or is part of the trial, please remove from the PIS.
4. The protocol states that hormonal contraception is not acceptable for contraception in the study, but the PIS lists Mirena and Jadelle as acceptable forms of contraception. It is also unclear why a diaphragm would be necessary. If the purpose is to prevent exposure to secreted investigational medicines or metabolites by a sexual partner, then an internal or external condom would be a more suitable recommendation. Please revise this section.
5. The Committee noted that there is a table of common side effects but includes rare side-effects. These should be listed separately.
6. Please ensure there is adequate information detailing what data is collected by the app used in this 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 data management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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

|  |  |  |
| --- | --- | --- |
| **8**   | **Ethics ref:**   | **2023 FULL 15231** |
|   | Title:  | The NEOgrads playgroup study: Improving developmental motor outcomes through intensive Early Intervention in preterm infants: A feasibility study. |
|   | Principal Investigator:  | Miss Louise Pearce |
|   | Sponsor:  | Auckland University of Technology |
|   | Clock Start Date:  | 11 January 2024 |

Louise Pearce, Naaz Shaikh, and Dr Sian Williams were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried the consent process surrounding any parents who may be under 16 and noted a slight issue with under 16s giving consent on behalf of their child given their age and discussed the implications of this: s 36 Care of Children Act. The Committee clarified that if any of the parents are over 16, they can automatically give consent. If any of the parents are under 16 but considered competent to provide consent, they can do so.
2. The Committee clarified the target control group for this 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. The Committee noted that home visits may be conducted. Please provide a home visit safety plan for researchers for review.
2. In the data management plan, please include information about the use and storage of video.
3. Please provide a copy of the log-book participants will be asked to fill out.
4. The Committee noted that if this is being run for a Masters project out of the university, the university provides indemnity for staff, not students. The data is under the governance of the institution. The Committee strongly recommended that the HDEC application has the supervisor as the CI.
5. The Committee requested clarity surrounding the intellectual property of the design of this program if there is benefit and discussed protection of the applicant in this regard.
6. Please provide the training manual for review.
7. Please provide the proposed recruitment video if this is to be used.

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

1. Please include the “consent discussion” in the correct place in the flow diagram.
2. Please add a sentence explaining how a participant can withdraw from the study such as contacting the researcher.
3. Correct the approving HDEC to be Northern A.

**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 Mrs Helen Walker and Ms Jade Scott.

|  |  |  |
| --- | --- | --- |
| **9**   | **Ethics ref:**   | **2023 FULL 18182** |
|   | Title:  | Ex-vivo assessment of interactions between fibre and inflammation using 3-D cultured biopsies  |
|   | Principal Investigator:  | Professor Andrew Day |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 11 January 2024 |

Dr Alan Aitchison 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 when participants would first be informed about the study. The Researcher responded that they will be introduced to the study when arrangements are made for colonoscopy and that with potential participant will have time to take the information sheet home. Consent will be taken at the colonoscopy appointment by the 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 requested confirmation that the similar trial noted in the application has received HDEC approval.
2. The submitted application mentions not collecting ethnicity, but that’s a requirement in New Zealand unless justified. Please ensure this is done.
3. The Data and Tissue Management Plan addressing governance and oversight of the data, such as University of Otago data governance policies.

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

1. There is information from the PIS the HDECs routinely expect to see. Reference to the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) for guidance is recommended.
	1. Provide information about withdrawing the sample in the event the participant changes their mind, and if there is at any point at which the tissue can no longer be withdrawn.
	2. The option for karakia upon destruction is noted in the CF, but not mentioned in body of PIS.
	3. Please remove references to teaspoons/tablespoons for volumes of blood, use millilitres.
	4. Provide information on how long samples will be kept for.
	5. Contact details for advocacy, HDEC and cultural support are required.
	6. Ethics approval statement should be included and can be taken from the template.
	7. Please state who will have access to the data.
	8. Nominate who the funder is.
	9. CF and assent form should have a space where the consenting researcher signs.
2. Please clarify that there is no direct individual benefit to participating in this research.
3. Th age group information provided is good and please also include a child friendly assent form (AF) to indicate that the child understands what the study is about and what their rights are. The HDECS have exemplar templates for this on their website. The Committee also suggested use of images in information sheets for children.
4. The CF for children aged 16-17 should have “children” references removed.
5. Please specify in the CF that participants can receive a summary of study findings, not the return of individual study results.

**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 data and tissue 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, 14.16&14.17).*

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 Jade Scott.

|  |  |  |
| --- | --- | --- |
| **10**   | **Ethics ref:**   | **2023 FULL 18151** |
|   | Title:  | An open label, single arm, extension trial to examine long-term safety of Iclepertin once daily in patients with schizophrenia who have completed previous Iclepertin Phase III trials. (CONNEX-X) |
|   | Principal Investigator:  | Associate Professor Wayne Miles |
|   | Sponsor:  | Boehringer Ingelheim Pty Ltd |
|   | Clock Start Date:  | 11 January 2024 |

Associate Professor Wayne Miles and Deborah Campbell were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee confirmed with the Researchers that there are a few participants eligible to rollover into this study and they will not be unblinded regarding their intervention in the parent study. The duration of this will be twice as long as the previous study. In terms of ongoing access, the company is hopeful will be sufficient for them to get funding to supply ongoing access.
2. The Committee was assured that any noted impairments do not affect capacity to consent.
3. The Committee noted the prohibition of other treatment or intervention that may help participants, given the duration of the extension study. The Researchers responded that there are participants cannot receive cognitive remedial therapy because this could interfere with the study results. The researchers confirmed that part of the consent process is discussing alternatives with participants at length.
4. The Committee queried if all assessments are validated and fair on this population and the Researcher confirmed that they consider these fair and achievable.

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 confirmed with the Researcher that New Zealand is covered by the Sponsor’s insurance but require evidence that New Zealand is endorsed officially as a policy territory. This can be provided as a letter rather than amending the certificate.
2. C.19 of the application form states transport will be provided for people with mobility issues and the cost will be covered; however, this is not made clear in the participant information sheet.
3. The Committee noted the large number of documents uploaded with the non-review notation but that some of these are required to be reviewed, such as questionnaires. Since they have been classified as non-review documents, they have not been considered as part of this initial review.
4. The CI’s indemnity about to expire, please ensure this is updated and provided.
5. The Committee queried exclusion of those with HPV, HCV and HIV. The Researcher responded that there may be interactions between the study medication medications prescribed for those conditions. The Committee stated that this exclusion because of the potential interaction should be highlighted in the participant information sheet. If there is no evidence in phase 2 and the concern about the risk has been addressed, consideration should be given for these people to participate in future studies.
6. Please ensure that the DTMP includes specific information regarding organisational data governance.

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

1. In the main PIS, there is a list of things “you must continue to not”. Please rephrase this.
2. Please mention that no karakia will be offered for samples at time of destruction.

**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 data and tissue 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, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Jonathan Darby and Dr Sotera Catapang.

|  |  |  |
| --- | --- | --- |
| **11**   | **Ethics ref:**   | **2023 FULL 19337** |
|   | Title:  | Open-label, phase 1b, single ascending dose study to evaluate the safety of VERVE-102 administered to patients with heterozygousfamilial hypercholesterolemia or premature coronary artery disease who require additional lowering of low-density lipoproteincholesterol |
|   | Principal Investigator:  | Professor Russell Scott |
|   | Sponsor:  | Verve Therapeutics and IQVIA RDS Pty Limited |
|   | Clock Start Date:  | 11 January 2024 |

Professor Russell Scott 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.

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 Researcher confirmed there is an umbrella long-term follow-up which has separate HDEC approval and insurance.
2. The Committee queried if it is likely there would be significant burden on a particular family given the study involves aa familial condition. The researcher stated that they are aware of two potential participants from the same family; and that there is no risk of germline editing in this 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. The Committee confirmed that the study has been submitted to SCOTT and GTAC. Please also provide the GTAC review material including any conditions and decision once received. This will not affect the 90-day provisional limit.
2. The Committee queried the submission of Part B of the study where Part A is not yet underway but will inform some of the significant details of Part B. The Committee requested that Part B be submitted as an amendment.

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

1. Please clarify further the importance of the long-term (15-year) follow up so that participants are aware that while this involves a separate consent, it is an important part of enrolment in this study.
2. Please clarify that travel costs will be covered.
3. The Committee suggested rewording for clarity to distinguish the PCSK9 gene in the liver from the PCSK9 protein in the blood,( the production of which is regulated by the PCSK9 gene).

**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 Mr Jonathan Darby and Dr Kate Parker.

|  |  |  |
| --- | --- | --- |
| **12**   | **Ethics ref:**   | **2023 FULL 19342** |
|   | Title:  | A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy, Safety, and Tolerability ofATB1651 in Adults with Mild to Moderate Onychomycosis |
|   | Principal Investigator:  | Dr Cory Selwood |
|   | Sponsor:  | AmtixBio Co., Ltd and Novotech |
|   | Clock Start Date:  | 11 January 2024 |

Julia O’Sullivan and Dr Cory Selwood 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 confirmed that the insurance would be adequate despite there being an amount only in Australian dollars.
2. The Committee clarified that the excess on the insurance would be paid by the sponsor in case of a claim.
3. The Committee highlighted the importance of determining ongoing access and potential licensure of the medication in New Zealand.

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 use of a RAT and /or a “Covid vaccine test” as mentioned in the submission. Please clarify this.
2. The Committee queried why there was a requirement for audiometry assessments in the submission. The Researcher will clarify this with the Sponsor.
3. The Committee queried the exclusion of HIV, Hep B and Hep C patients. Please provide a study-specific rationale for these exclusions.
4. The Committee have been made aware by SCOTT that this product is a Class I irritant to the eyes and that this must be communicated clearly to the participants in the participant information sheet. Please ensure this is included.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee.

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 20 February 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 7.30pm