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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 04 June 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 11:30am-12:00pm | 2024 FULL 20129 | A Phase 3 study of 177Lu-TLX591 plus SOC versus SOC alone in Patients with mCRPC (ProstACT-GLOBAL) | Dr Simon Fu | Kate O’Connor & Joan Pettit |
| 12:00pm-12:30pm | 2024 FULL 20251 | ReNEW: A Clinical Trial to evaluate a new treatment in patients with Dry Age-Related Macular Degeneration (AMD) | Dr James Borthwick | Ewe Leong Lim & Amber Parry-Strong |
| 12:30pm-1:00pm | 2024 FULL 18606 | Te Puna Wairua: an Iwi-led pregnancy-care hub service | Professor Bev Lawton | Alice McCarthy & Barry Taylor |
| 1:00pm-1:30pm | 2024 FULL 20347 | A collaborative approach to choosing a behavioural intervention | Dr Rebecca Sharp | Maakere Marr & Devonie Waaka |
|  |  | **BREAK 30 MINUTES** |  |  |
| 2:00pm-2:30pm | 2024 FULL 19661 | A Phase 3 Study to Evaluate AOC 1001 in Patients with Myotonic Dystrophy Type 1 (DM1) | Dr Richard Roxburgh | Kate O’Connor & Joan Pettit |
| 2:30pm-3:00pm | 2024 FULL 19924 | A PILOT study to assess the efficacy and safety of Myrecil® in Genitourinary Syndrome of Menopause | Dr Sylvia Rosevear | Maakere Marr & Barry Taylor |
| 3:00pm-3:30pm | 2024 FULL 20305 | PBI-L608-B12: A Study to Evaluate L608 in Healthy Participants. | Dr Christopher Wynne | Alice McCarthy & Amber Parry-Strong |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Kate O’Connor | Lay (Ethical/Moral reasoning) (Chair) | 13/08/2021 | 16/08/2024 | Present |
| Mrs Leesa Russell | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Apologies |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Ms Alice McCarthy | Lay (the Law) | 22/12/2021 | 22/12/2024 | Present |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Present |
| Dr Amber Parry-Strong | Non-Lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Mr Ewe Leong Lim | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Dr Devonie Waaka | Non-lay (Intervention studies) | 18/07/2016 | 18/07/2019 | Present |

## Welcome

The Chair opened the meeting at 11.00am and welcomed Committee members, noting that apologies had been received from Mrs Leesa Russell  
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Devonie Waaka confirmed their eligibility and were co-opted by the Chair as a member of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 07 May 2024 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2024 FULL 20129** |
|  | Title: | A Multinational, Multicenter, Prospective, Randomized, Controlled, Open-Label, Phase 3 Study of Lutetium (177Lu) rosopatamab tetraxetan in Combination with Standard of Care Versus Standard of Care Alone in Patients with PSMA Positive Metastatic Castration-Resistant Prostate Cancer Previously after Androgen Receptor Pathway Inhibitor Treatment |
|  | Principal Investigator: | Dr Simon Fu |
|  | Sponsor: | Telix Pharmaceuticals |
|  | Clock Start Date: | 23 May 2024 |

Dr David Cade, Ms Brenda Cerqueira and Mr Charles Beasley 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 Coordinating Investigator (CI)’s experience with clinical trials. The Researcher confirmed the CI has experience on a similar trial with a related item. The Researcher confirmed sub-investigators on the trial have extensive experience with radiopharmaceuticals.
2. The Committee noted the CI has a dual role in public and private practice. The Committee queried equality of opportunity of access to research trials and how the recruitment would operate. The Researcher stated the CI was involved in multidisciplinary meetings in their public role and eligible patients from the public system could be referred to the study.
3. The Researcher confirmed the consenting process is undertaken by a study coordinator or research nurse and patients who are interested can then discuss further with an investigator.
4. The Researcher confirmed the trial would be registered in a WHO-approved clinical trials registry before commencement.

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 good quality ethnicity data based on New Zealand census categories is collected at a site-level for final reporting to HDEC. The Researcher confirmed this would be collected. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.20)*
2. The Committee noted the CI’s medical indemnity certificate has expired and requested this is renewed. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.6)*
3. The Committee noted the clinical trials insurance certificate does not specify New Zealand as a policy territory and requested a note from the insurer to confirm that New Zealand is a covered territory. The Researcher confirmed a new certificate specifying New Zealand has been issued and agreed to supply this. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1)*
4. The Researcher clarified Mercy Hospital would dose and image participants and Auckland City Hospital would manage participants. The Committee advised this would require locality authorisation in the EthicsRM system and requested the application form is updated to reflect this.
5. The Committee noted the application form stated GPs would not be notified but a study of this nature should have mandatory GP notification of study participation, and of any adverse events or significant abnormal results that arise during the study. Please update the information sheet and consent form accordingly.
6. The Committee requested more information on the CI’s clinical research background, and clarification bout whether the CI has completed International Council for Harmonisation of technical requirements for pharmaceuticals for human use good clinical practice (ICH-GCP) training.

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

1. Please include a very brief summary of standard treatment in New Zealand and make it clear what is available as part of study participation.
2. Please amend the short title to avoid acronyms, using lay friendly language on page 1.
3. Please define "very short distances" on page 2.
4. Please significantly simplify table of assessments, using lay language and replacing individual blood tests with one 'blood tests' row on pages 4-5.
5. Please delete tablespoon volumes for blood sampling on page 6 on.
6. Please use words rather than symbols to describe risk frequencies in the table on page 11.
7. Please summarise the post-dose radiation risks to others and precautions in the risk section on page 13; they may affect the individual's decision to participate.
8. Please describe use of images for future unspecified research (FUR) in the body of PISCF or as addendum with an optional yes / no consent on page 21.
9. Please avoid use of the word "treatment" throughout the sheet (eg "treatment visit", "treatment day" "study treatment") to avoid therapeutic misconception (as per Standard 7.8)

**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 supply evidence of ACC-equivalent insurance specifying New Zealand as a covered territory. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1)*
4. Please supply an updated MPS certificate or evidence of professional indemnity for the coordinating investigator. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.6)*

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

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| **2** | **Ethics ref:** | **2024 FULL 20251** |
|  | Title: | ReNew: A Phase 3, Randomized, Double-Masked, Placebo-Controlled Clinical Trial to Evaluate the Efficacy, Safety, and Pharmacokinetics of Subcutaneous Injections of Elamipretide in Subjects who have Dry Age-Related Macular Degeneration (Dry AMD) |
|  | Principal Investigator: | Dr James Borthwick |
|  | Sponsor: | Stealth BioTherapeutics Inct |
|  | Clock Start Date: | 23 May 2024 |

Mr Tony Mann 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 all sites are private eye clinics and queried how recruitment would be managed to ensure an equitable opportunity to participate in research. The Researcher stated in this population there is no suitable treatment for dry AMD and participants may be referred from specialists, optometrists or advertising but a diagnosis of dry AMD would be required. The Researcher confirmed there is a referral pathway from the public system.
2. The Researcher confirmed each site would undergo separate Māori consultation and locality approval.
3. The Committee advised the pregnancy PIS is only reviewed in the event of a participant or their partner becoming pregnant and has not been reviewed at this time.
4. The Committee queried if the open label extension would be a separate application or an amendment. The Researcher stated they believed it would be submitted as an amendment. The Committee stated this would be its preference and there is an expectation that if a participant enrols in a trial expecting an open label extension that this is not halted to bring the drug to market sooner.
5. The Committee noted the insurance certificate is due to expire four months before the end of the trial. The Researcher confirmed it would be extended during the course of the trial.

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 good quality ethnicity data based on New Zealand census categories is collected at a site-level for final reporting to HDEC. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.20)*
2. The Committee requested the list of prohibited concomitant medicines in section 7.2 of the protocol is included in the GP letter.
3. The Committee queried whether the study drug would preclude treatment for wet AMD if the condition progresses. The Researcher stated there is no evidence to suggest this would happen and if a participant developed wet AMD they would halt dosing. The Committee requested information explaining this is added to the information sheet.
4. The Committee noted that if advertising will be used, this needs to be submitted for review. This can be as an Amendment for review if they are to be used later.

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

1. Please replace 'subjects' with 'participants' throughout the document.
2. Please state approximately how many New Zealanders are expected to participate on page 2.
3. Please replace the phrase 'like the flip of a coin' with 'by chance' on page 2.
4. Please make it clear that participants will need to self-inject on page 3.
5. Please replace spoon measurements with mLs for blood volume estimates from page 4 on.
6. Please simplify the visit descriptions; the table is sufficient once study procedures are explained in lay language.
7. Please review the visit table and replace scientific terms with lay language (IMP, demographics, concomitant medications, adverse events etc).
8. Please correct the statement “During the study, you should not: You must never let anyone but yourself take the study drug” on page 11.
9. Please replace 'adverse events of the study drug' with 'risks of the study drug' on page 12.
10. Please move risks of subcutaneous injections from the 'Risks from ophthalmic procedures' subsection on page 14.
11. Please replace the text about being billed for standard medical care with information relevant to the New Zealand health system on page 16.
12. Please delete 'with your consent' from the bullet point regarding GP notification on page 17 as this should be mandatory in this study.
13. Please include that up to $150 per visit will be reimbursed for travel/parking expenses.
14. Please include a statement advising there are no alternative approved treatments for AMD in New Zealand, and if participants choose not to participate they will remain under a watch and wait approach with their regular provider.
15. Please avoid use of the word "treatment" throughout the sheet (eg "treatment visit", "study treatment") to avoid therapeutic misconception (as per Standard 7.8)

**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 GP letter to include the list of prohibited concomitant medicines.

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Ewe Leong Lim and Dr Amber Parry-Strong.

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| **3** | **Ethics ref:** | **2024 FULL 18606** |
|  | Title: | Hapū Whānau: Implementing iwi-owned service hubs to improve health outcomes |
|  | Principal Investigator: | Professor Bev Lawton |
|  | Sponsor: | Victoria University of Wellington |
|  | Clock Start Date: | 23 May 2024 |

Professor Bev Lawton, Associate Prof Liza Edmonds, Charlie Lambert, Matthew Bennett, Judy Ormanby, Professor Stacie Geller, and Varsha Parag 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 objective of fidelity where the measures were not explicitly mentioned or noted in the protocol. The researchers noted that this would be done through observation and the checking of the medical records of the women under the care of the providers.
2. The Committee clarified that the control data would be provided to the researchers in de-identified form.
3. The Committee suggested that the possibility of consenting in te reo or various Pasifika languages could be valuable.

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 researchers provide a justification for the unconsented secondary use of health data for the control group of participants. This justification should meet the requirements of the [*NEAC National Ethical Standards* para *7.47*](mailto:https://neac.health.govt.nz/national-ethical-standards/part-two/7-informed-consent%23_Waiver_of_consent_1)*.* Please include this in the Data Management Plan.
2. The Committee noted that the advertisements were not provided for review but that these would need to be approved before they could be used.
3. The Committee requested that locality authorisation would need to be done prior to the start of the study. This should be signed off by the organisation at which the study will be conducted and can be done through the locality form in ERM.

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

1. Please clarify and emphasise the two available paths to individuals who will be offered study participation and explain the control group. The Committee suggested that a flow chart or some diagram be used to better describe the different options).
2. Please explain why the NHI number of people who do not wish to participate is required.

**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 Barry Taylor and Ms Alice McCarthy.

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| **4** | **Ethics ref:** | **2024 FULL 20347** |
|  | Title: | A collaborative approach to choosing a behavioural intervention |
|  | Principal Investigator: | Dr Rebecca Sharp |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 23 May 2024 |

Dr Rebecca Sharp was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the study had been narrowed down to one site.
2. The Committee clarified that the first phase of the study was reviewed by AHREC.
3. The Committee clarified how recruitment would be undertaken. The researchers noted that several children would be identified by clinicians in the school who are already working with the children. The Committee then clarified the way in which recruitment would occur.
4. The Committee clarified that all children would be assenting age.

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 possibility of purposeful sampling for those of Māori ethnicity. The researcher noted that this has not been actively sought out due to the small sample size but that it would be made clear to the school that it would be preferable for a Māori student to be included.
2. The Committee queried if there had been Māori consultation done prior to this application and requested that this occurs before the research happens.
3. The Committee requested that it be explained to participants why withdrawal does not include withdrawal of collected.
4. The Committee noted that in section one of the Data Management Plan (DMP) that there was reference to people with dementia. Please correct this.
5. The Committee requested a statement be included in section 8.1 of the DMP that notes auditors and the HDEC may have access to identifiable data.
6. The Committee requested that the locality is specified as being the sole school recruitment will occur at.

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

1. Please include a statement concerning the risk of privacy breach.

Assent Form:

1. Please include a tick or cross option for children to indicate “yes” or “no” for participating in the study.
2. Please remove the phrase “this will be a secret” where it occurs across the assent forms and information sheets and consider amending to something less ominous-sounding.

**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 Maakere Marr and Dr Devonie Waaka.

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| **5** | **Ethics ref:** | **2024 FULL 19661** |
|  | Title: | A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Global Study to Evaluate the Efficacy and Safety of Intravenous AOC 1001 for the Treatment of Myotonic Dystrophy Type 1 |
|  | Principal Investigator: | Dr Richard Roxburgh |
|  | Sponsor: | Avidity Biosciences |
|  | Clock Start Date: | 23 May 2024 |

Dr Richard Roxburgh and Kay Yeoman were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the participants will be found through a registry. These people will have already had the genetic test identifying their condition as standard of care.
2. The Committee clarified that the type of drug has been used in New Zealand but this drug in particular has not been used in Aotearoa.
3. The Committee clarified that the researcher would be unlikely to be the treating clinician for these people prior to the study commencing.
4. The Committee clarified the way in which the open-label extension would be presented to the Committee and the researcher noted that this would be as a separate study. The Committee noted that it is the expectation that those deriving benefit from the study treatment be invited into the open-label extension.
5. The Committee noted that translation certificates for documents are out of scope for HDEC and these have not been reviewed.

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 ethnicity data is collected in a manner appropriate to New Zealand.
2. The Committee requested that Medsafe be referenced in addition to or instead of the FDA in the advertisements.
3. The Committee requested that data sent to the sponsor not contain the initials of participants as this is considered a risk of re-identification.
4. The Committee requested that the trial be registered with a WHO-approved clinical trial database.
5. The Committee noted that the pregnancy PIS has not been reviewed and that this should be provided only in the event a participant becomes pregnant as an amendment to the study.
6. The Committee requested clarification around previous genetic diagnostic testing referenced. Please ensure that this is clear in the PIS/CF.

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

Main PIS/CF:

1. Please start the PIS/CF with a short, lay-friendly title.
2. Please state the number of New Zealand participants.
3. Please include lay-examples available in New Zealand of contraceptive options and information. Please refer to the [HDEC template](mailto:https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-v.4.0-april2023.docx) for this.
4. Please delete repeated information concerning reimbursement.
5. Please remove the optional yes/no tick box from the statement in the consent form around withdrawal of data per the mandatory nature of this outlined in other study documentation.
6. Please remove the section where the participant is asked to indicate with initials for notification of their primary care physician.
7. Please remove the option for notification of General Practitioners (GPs) of abnormal results as for this type of study this should be mandatory.
8. Please clarify if the genetic testing is a study procedure or not and be clear around this. This could be included as a statement along the lines of “you are being invited to the study because you have been diagnosed through genetic testing as having this condition”.

Future Unspecified Research (FUR) PIS/CF:

1. Please indicate if this research may include genomic/genetic research.
2. Please clarify the option for withdrawal of samples for FUR.

**Decision**

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

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

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| **6** | **Ethics ref:** | **2024 FULL 19924** |
|  | Title: | A Randomized, Double Blind, Placebo-Controlled Pilot Study to Evaluate the Efficacy and Safety of Myrecil® in Genitourinary  Syndrome of Menopause. |
|  | Principal Investigator: | Dr Sylvia Rosevear |
|  | Sponsor: | Weir Science Ltd |
|  | Clock Start Date: | 23 May 2024 |

Mr Anthony Mann, Dr Iona Weir and Dr Sylvia Rosevear 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 no pre-selection to one treatment arm or the other.
2. The Committee confirmed that SCOTT is going to review this due to therapeutic claims.

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 planned recruitment for the study. The Researchers identified that some patients will be known by the CI and others will be referred. The study would like to recruit 45 and the CI has a database of 100+ women with this condition so they will be approached. The Committee noted to make sure white coat bias potential is addressed.
2. The Committee noted that the CI does not have clinical research experience as a lead or sub-investigator in a clinical trial. In addition, the Committee noted that the MPS certificate is providing indemnity for a ‘non-clinical’ role. The safeguards required to assure the safety of conducting a clinical trial are not demonstrated with this submission. The Committee requested that a co-CI located in New Zealand is appointed to ensure adequate oversight of the study. This doesn’t need to be commercial but should be someone with previous clinical trial leadership experience.
3. Section 7.1 of the data management plan states that screening samples will be identifiable, but the application form states all tissue will be deidentified. The Researchers clarified that samples at site will have identifiers, then be deidentified before being sent to sponsor. The Committee noted this is acceptable but should be consistently noted across the submission and documentation.
4. The Committee requested the Researchers review all use of Māori words and proper use of macrons.
5. The Committee queried the reference to cultural review process as this is not explained. After discussion, the Committee requested this is reworded as review of demographic data, not cultural review as it doesn’t make sense in this context and has a different meaning.

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

1. Under possible risks, severe side effects refers to ‘capsule’. Please remove.
2. Remove flipping a coin reference for randomisation.
3. Please explain assessments once only.
4. Please simplify table of assessments.
5. Vestibular health score referenced in the table is not relevant to participants. Please remove.
6. Please ensure measurements for fluids are written in millilitres, not teaspoons.
7. The Committee expect a participant’s GP to be notified of participation in this trial; please delete optional language in the CF.

**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 supply an updated MPS certificate or evidence of professional indemnity for the coordinating investigator. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.6)*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Maakere Marr and Mr Barry Taylor.

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| **7** | **Ethics ref:** | **2024 FULL 20305** |
|  | Title: | A Phase 1, Randomized, Double-blinded, Placebo-controlled Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Single Ascending Doses of L608 for Inhalation in Healthy Participants. |
|  | Principal Investigator: | Dr Christopher Wynne |
|  | Sponsor: | Novotech (New Zealand) Limited |
|  | Clock Start Date: | 23 May 2024 |

Dr Christopher Wynne, Dr Cory Sellwood, Lucy Druzianic, Julia O’Sullivan, Kayla Malate, Thinish Pillai, and Britney-Lee Nicholson 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 that sentinel dosing could be halted if there were less-than life threatening serious adverse events or safety issues.

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 raised the following regarding the Data Tissue Management Plan (DTMP) that were not relevant and required removal:
   1. Please remove reference to future unspecified research with leftover tissue.
   2. Please remove reference to health organisation databases.
2. The Committee requested to ensure Medicines Safety approval is sought before using their logo in ads.
3. The Committee requested confirmation of what availability there is for on the ground study doctor cover for Wellington-based participants, should this be intended. This can be provided as an Amendment and will require approval prior to using Wellington for follow-up visits.

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

1. Please provide information in the PIS to describe the inhaler device and state that it is not approved for use in New Zealand.
2. Under all the risks, please include a line assuring that participants will receive care if they experience any of these.

**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).*

## General business

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

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| **Meeting date:** | 02 July 2024 |
| **Zoom details:** | To be determined |

The following members tendered apologies for this meeting.

* Ms Kate O’Connor

1. **Review of Last Minutes**

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

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

The meeting closed at 3.30pm.