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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 24 September 2024 |
| **Zoom details:** | https://mohnz.zoom.us/j/96507589841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:00 - 12:30pm | 2024 EXP 21055 | The ASTRA Study | Professor Peter Gilling | Cordelia / Albany |
| 12:30 - 1:00pm | 2024 EXP 20921 | Betadine washout during orthopaedic surgery | Dr Thomas Haig | Sandy / Patricia |
| 1:00 - 1:30pm | 2024 FULL 21053 | 3133004: CHRONDI - ODM-111 in chronic diabetic peripheral neuropathy pain | Dr Joanne Finlay | Helen / Patries |
| 2:00 - 2:30pm | 2024 FULL 21060 | 3133003: CHRONOS - ODM-111 in chronic osteoarthritic knee pain | Dr Joanne Finlay | Helen / Patries |
| 2:00 - 2:30pm |  | **BREAK (30 mins)** |  |  |
| 2:30 - 3:00pm | 2024 FULL 20808 | INTERFANT-21 | Dr Siobhan Cross | Jessie / Albany |
| 3:00 - 3:30pm | 2024 FULL 20793 | Sunday Trial | Mr Manar Khashram | Cordelia / Patricia |
| 3:30 - 4:00pm | 2024 FULL 21225 | A Phase 1a/1b Study Investigating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Antitumor Activity of BG-60366 in Patients With EGFR-Mutant Non-Small Cell Lung Cancer | Dr Gareth Rivalland | Sandy / Patries |
| 4:00 - 4:30pm | 2024 FULL 21297 | LumAssure Raman Device collection of skin condition data | Dr Michel Nieuwoudt | Jessie / Patricia |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Mrs Helen Walker  | Lay (Consumer/Community perspectives) (Chair) | 22/12/2020  | 22/12/2024 | Present  |
| Mrs Sandy Gill  | Lay (Consumer/Community perspectives)  | 22/05/2020  | 22/05/2023  | Present  |
| Dr Patries Herst  | Non-lay (Intervention studies)  | 22/05/2020  | 22/05/2023  | Present  |
| Dr Cordelia Thomas  | Lay (the Law)  | 22/12/2020  | 22/12/2024 | Present  |
| Mrs Patricia Mitchell  | Non-lay (Health/Disability service provision)  | 08/07/2022 | 08/07/2025 | Present  |
| Mx Albany Lucas | Non-lay (Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 11:00am and welcomed Committee members, noting that no apologies had been received.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 27 August 2024 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2024 EXP 21055** |
|   | Title:  | A Prospective, Multicenter, open-label study of the Beacon Platform for Holmium Laser Enucleation of the Prostate (HOLEP) |
|   | Principal Investigator:  | Professor Peter Gilling |
|   | Sponsor:  | Andromeda Surgical |
|   | Clock Start Date:  | 12 September 2024 |

Dr Wikus Vermeulen, Dr Flavio Ordones, Dr Mishaal Ali, Ms Margaret Ross and Mr Nick Damiano 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 the application states the research will conclude in October 2025 and the insurance is due to expire in September 2025. The Committee advised insurance cover is required for the duration of the trial. The Researcher confirmed insurance would be extended if the trial is still active in September 2025.

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 advised that having a sponsor representative present during an intimate examination requires patient consent. Please include information regarding this in the information sheet and an option on the consent form for participants to consent to this.
2. The Researcher confirmed the robot is controlled by the surgeon at all times and does not operate autonomously. The Committee requested this is added to the information sheet.

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

1. Please include a statement that the participant’s GP will be informed of their participation.
2. Please remove reference to legal representatives consenting as this is not permitted in New Zealand.
3. Please include an explanation of what the procedure consists of and a diagram or image of the machine so participants understand what is involved.
4. Please include an image or diagram of a patient in the position required for the procedure.
5. Please include any risks associated with the participant being in the operative position with their legs in the air for an extended period of time and if use of the robot is expected to take longer than standard of care.
6. Please include the cultural tissue statement available from the [HDEC template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates)
7. Please adapt the wording so any potential participants who were assigned male at birth (ie have a prostate) but do not identify as male may still participate.
8. Please remove references to teaspoons when discussing blood volumes and state mL.
9. Please include information advising participants they will need to undress and whether they may bring a support person.
10. Please remove any tickboxes from the consent form unless they are for items which are optional (ie the participant may answer no and still participate).
11. Please include more information on the transrectal ultrasound and what it involves. The Committee recommended a chronological timeline of everything that will happen to participants.

**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 Dr Cordelia Thomas and Mx Albany Lucas.

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| **2**   | **Ethics ref:**   | **2024 EXP 20921** |
|   | Title:  | Intraoperative Betadine Lavage to Reduce Surgical Site Infection following Orthopaedic Surgery with Implants |
|   | Principal Investigator:  | Dr Thomas Haig |
|   | Sponsor:  | Te Whatu Ora Te Tai Tokerau |
|   | Clock Start Date:  | 29 August 2024 |

Dr Thomas Haig was not 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 advised if any participants under 16 are intended to be recruited this will require an amendment with the submission of assent forms.
2. The Committee noted the results of the study may have the potential to be stigmatising depending on how they are presented and requested the researcher be mindful of this.

Summary of outstanding ethical issues

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

1. Please insert a cultural statement regarding the use of information.
2. Please remove the tickboxes on the consent form clauses. Participants who sign the sheet will agree to all clauses.
3. Please undertake a general revision to check for missing words, typos and other syntax errors.
4. Please remove the reference to participating not affecting the ‘quality’ of the procedure as from the participant’s point of view it may.
5. Please state that health information will be kept for 10 years as this is required under the Health Information Privacy Code. Please amend the reference to international guidelines as this cannot be guaranteed.
6. Please include a statement advising that the participant’s GP will be informed of their participation.
7. Please address the discrepancy in withdrawing data and whether it will be used in the final write-up or not.
8. Please refer to deidentified data and not anonymous data on page 3 and 5.
9. Please quantify the 0.4% risk of betadine allergy in whole numbers (eg 1 in X people).
10. Please include a sentence after "it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatise, or discriminate against members of the same groups as you" to state what the researchers will do to mitigate this.
11. Please complete the sentence on page 6 "other discoveries that might come from this information".
12. Please add a phone number for Māori cultural support.

**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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| **3**   | **Ethics ref:**   | **2024 FULL 21053** |
|   | Title:  | 3133004: Efficacy and tolerability of ODM-111 in chronic pain due to diabetic peripheral neuropathy (CHRONDI) |
|   | Principal Investigator:  | Dr Joanne Finlay |
|   | Sponsor:  | Orion Corporation |
|   | Clock Start Date:  | 12 September 2024 |

Dr Jo Findlay, Dr Claire Thurlow, Ms Kim Huljich, Dr Xiaoxi Xie, and Dr Arvind Narayana 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 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 why the C-SSRS questionnaire would be used as a screening tool. The Researcher stated FDA guidance recommended any drug with central nervous system activity should have measures of suicidality. The Committee advised it is strongly opposed to the use of the C-SSRS questionnaires as a screening tool in these trials as participants who score too high on this scale will be excluded from participation in the trial and are released back into the community without any clear support or follow up. Although the intrusive questions regarding suicidality may not trigger a depressed or anxious person to actually commit suicide, it may trigger significant distress. If patients with severe anxiety need to be screened out, the Committee suggested using the HADS or the EQ-5D-5L questionnaires as screening tools. High scoring patients require immediate follow up with an appropriately qualified health professional to identify potential suicidal ideation and provide appropriate support. Lower scoring participants may be given the C-SSRS questionnaire in the presence of an experienced health professional. If an appropriate health professional is not available then there needs to be a psychologist/psychiatrist on call for people who require support. The Committee requested the protocol is updated to include suicidal ideation as a secondary outcome and not included as "additional safety measures". The Committee requested a formal safety plan for responding to participants who indicate distress or suicidal ideation is included in the protocol and some of this should also be reflected in the PIS. The Committee suggested adapting the answer to question E3.2 in the application form. The Researcher agreed to consult with the Sponsor on the use of the C-SSRS.The Committee requested the advertisements are updated to state it is a research study or clinical research study. Please include that the study has been approved by HDEC.
2. The Committee suggested including some basic inclusion / exclusion criteria in the information sheet so participants are aware of any major exclusions before reading the whole sheet.

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

1. Please include more information on the quality-of-life questionnaires and what will happen if a participant indicates distress or provides concerning responses to the questionnaires (eg a conversation with a doctor and referrals made as required).
2. Please remove the reference to a ‘flip of a coin’ when mentioning randomisation.
3. Please include reference regarding sending samples overseas in the cultural statement.
4. Please amend the statement on page 14 “all storage will comply with local and/or international data security guidelines” as this cannot be guaranteed. Please state it will comply with New Zealand guidelines and then specify any applicable international guidelines (eg, EU, USA).
5. Please amend the statement on page 15 regarding the right to be informed of overall results to simply state participants will be offered a lay summary of the study.
6. Please state how much participants will be paid/reimbursed and any tax implications.
7. Please add that genetic research is a potential issue in the cultural paragraph in the optional genetic sheet.
8. Please clarify what is meant by not performing activities that require mental alertness, judgement or physical coordination as this may preclude many common activities. Please clarify if driving while on the study drug would have insurance implications (eg the participant may not be covered).
9. Please clarify what is meant by a snack and that the study doctor will give examples.
10. Please state whether participants need to undress for the physical exam and if they may bring a support person. Please state whether the physical exam may be performed by someone of the same gender as the participant.
11. Please clarify that a smart phone will be provided if the participant does not have one or does not wish to use their personal one for the study and that it must be returned at the end of the study.
12. Please amend the ‘Who can take part in the study’ section as the information contained describes what participants must do in the study.
13. Please amend the statement that ethnicity data is collected for reporting to HDEC as ethnicity data is required under NEAC Standard 9.20. The Committee suggested just stating that ethnicity data will be collected.
14. Please include a clause on the consent form to agree to information being sent overseas.

**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 Dr Patries Herst.

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| **4**  | **Ethics ref:**   | **2024 FULL 21060** |
|   | Title:  | 3133003: Efficacy and tolerability of ODM-111 in chronic pain due to osteoarthritis of the knee (CHRONOS) |
|   | Principal Investigator:  | Dr Joanne Finlay |
|   | Sponsor:  | Orion Corporation |
|   | Clock Start Date:  | 12 September 2024 |

Dr Jo Findlay, Dr Claire Thurlow, Ms Kim Huljich, Dr Xiaoxi Xie, and Dr Arvind Narayana 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 outstanding ethical issues

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

1. The Secretariat notes that application 3 and application 4 were identical, except for the study populations. All comments made for application 3 relate also to application 4.
2. The Committee queried why the C-SSRS questionnaire would be used as a screening tool. The Researcher stated FDA guidance recommended any drug with central nervous system activity should have measures of suicidality. The Committee advised it is strongly opposed to the use of the C-SSRS questionnaires as a screening tool in these trials as participants who score too high on this scale will be excluded from participation in the trial and are released back into the community without any clear support or follow up. Although the intrusive questions regarding suicidality may not trigger a depressed or anxious person to actually commit suicide, it may trigger significant distress. If patients with severe anxiety need to be screened out, the Committee suggested using the HADS or the EQ-5D-5L questionnaires as screening tools. High scoring patients require immediate follow up with an appropriately qualified health professional to identify potential suicidal ideation and provide appropriate support. Lower scoring participants may be given the C-SSRS questionnaire in the presence of an experienced health professional. If an appropriate health professional is not available then there needs to be a psychologist/psychiatrist on call for people who require support. The Committee requested the protocol is updated to include suicidal ideation as a secondary outcome and not included as "additional safety measures". The Committee requested a formal safety plan for responding to participants who indicate distress or suicidal ideation is included in the protocol and some of this should also be reflected in the PIS. The Committee suggested adapting the answer to question E3.2 in the application form. The Researcher agreed to consult with the Sponsor on the use of the C-SSRS.The Committee requested the advertisements are updated to state it is a research study or clinical research study. Please include that the study has been approved by HDEC.
3. The Committee suggested including some basic inclusion / exclusion criteria in the information sheet so participants are aware of any major exclusions before reading the whole sheet.

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

1. Please include more information on the quality-of-life questionnaires and what will happen if a participant indicates distress or provides concerning responses to the questionnaires (eg a conversation with a doctor and referrals made as required).
2. Please remove the reference to a ‘flip of a coin’ when mentioning randomisation.
3. Please include reference regarding sending samples overseas in the cultural statement.
4. Please amend the statement on page 14 “all storage will comply with local and/or international data security guidelines” as this cannot be guaranteed. Please state it will comply with New Zealand guidelines and then specify any applicable international guidelines (eg, EU, USA).
5. Please amend the statement on page 15 regarding the right to be informed of overall results to simply state participants will be offered a lay summary of the study.
6. Please state how much participants will be paid/reimbursed and any tax implications.
7. Please add that genetic research is a potential issue in the cultural paragraph in the optional genetic sheet.
8. Please clarify what is meant by not performing activities that require mental alertness, judgement or physical coordination as this may preclude many common activities. Please clarify if driving while on the study drug would have insurance implications (eg the participant may not be covered).
9. Please clarify what is meant by a snack and that the study doctor will give examples.
10. Please state whether participants need to undress for the physical exam and if they may bring a support person. Please state whether the physical exam may be performed by someone of the same gender as the participant.
11. Please clarify that a smart phone will be provided if the participant does not have one or does not wish to use their personal one for the study and that it must be returned at the end of the study.
12. Please amend the ‘Who can take part in the study’ section as the information contained describes what participants must do in the study.
13. Please amend the statement that ethnicity data is collected for reporting to HDEC as ethnicity data is required under NEAC Standard 9.20. The Committee suggested just stating that ethnicity data will be collected.
14. Please include a clause on the consent form to agree to information being sent overseas.

**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 Dr Patries Herst.

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| **5**   | **Ethics ref:**  | **2024 FULL 20808** |
|   | Title:  | Interfant-21: International collaborative treatment protocol for infants under one year with KMT2A-rearranged acute lymphoblastic leukaemia or mixed phenotype acute leukaemia |
|   | Principal Investigator:  | Dr Siobhan Cross |
|   | Sponsor:  | ANZCHOG |
|   | Clock Start Date:  | 12 September 2024 |

Dr Siobhan Cross and Mrs Meredith Woodhouse 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 clarified identifiers need to be attached to bone marrow samples sent overseas for safety reasons. The results will be sent back to the site which will de-identify them before entering them. These results are also used for the participant’s clinical care.

Summary of outstanding ethical issues

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

1. The Committee requested the Researcher upload the questionnaires that will be used.
2. The Committee requested the Researcher supply a formalised safety plan to respond to participant distress.
3. The Committee requested the parent information sheet is updated to include information about questionnaires.

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

1. Please include more information about the questionnaires, who will complete them, what they are, what their content is and a safety plan if there are concerning responses.
2. Please replace references to teaspoons with millilitres.
3. Please make it clear on page 14 that bone marrow samples will have identifiers attached.
4. Please amend Māori health support to Māori cultural support in all sheets.
5. Please address the discrepancy on information collected about the child continuing to be processed. The consent form contains a mandatory clause but section 13 on page 16 suggests its optional.
6. Please explain what Blina and MARMA are as these are introduced in the flow chart.
7. Please check the wording under optional banking and whether this should read “if you do consent” (Third sentence of the first paragraph on page 15).
8. Please add a tick box on the consent form for participants to request a summary of results.
9. Please revise the sentence on page 2 about blinatumomab’s status to explain its status in plain language as it currently implies it is being used without approval.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Jessie Lenagh-Glue and Mx Albany Lucas.

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| **6**   | **Ethics ref:**  | **2024 FULL 20793** |
|   | Title:  | Sunday Trial: Scandinavian Trial of Uncomplicated Aortic Dissection Therapy |
|   | Principal Investigator:  | Mr Manar Khashram |
|   | Sponsor:  | Health New Zealand Te Whatu Ora Waikato |
|   | Clock Start Date:  | 12 September 2024 |

Mr Manar Khashram and Ms Gypsy Francis 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 Māori consultation will occur during the locality process.

Summary of outstanding ethical issues

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

1. The Committee requested the Researcher develop a formal safety plan for managing participants who indicate distress during the mental health questionnaires.

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

1. Please review for missing words or grammar
2. Please make the wording on page 3 clear that participants may withdraw from getting the stent before it is inserted and afterward may withdraw their data only.
3. Please amend the statement on page 3 “we will give the physician permission to give non-identifying information” to say “about you.” The Committee suggests using ‘doctor’ where it says ‘physician’.
4. Please state whether the home blood pressure monitor will need to be returned at the end of the study.
5. Please amend the statement “all collected data will be anonymous” to state it will be de-identified and stored securely.
6. Please clarify that ‘control scans’ do not control the condition as this may be misinterpreted.
7. Please quantify the risks (eg 1 in 10 people) in the side effects table on page 5.
8. Please amend the sheet so GP notification is mandatory.
9. Please insert an acknowledgement of information being a taonga.
10. Please introduce risks associated with pregnancy in the body of the information sheet as these are references on the consent form only.
11. Please remove reference on the consent form to samples being sent overseas if this will not be done.

**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 Dr Cordelia Thomas and Ms Patricia Mitchell.

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| **7**   | **Ethics ref:**  | **2024 FULL 21225** |
|   | Title:  | Phase 1a/1b, Open-Label Study Investigating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Antitumor Activity of a CDAC Degrading EGFR, BG-60366, in Patients With EGFR-Mutant Non-Small Cell Lung Cancer |
|   | Principal Investigator:  | Dr Gareth Rivalland |
|   | Sponsor:  | Beigene NZ Unlimited |
|   | Clock Start Date:  | 12 September 2024 |

Dr Gareth Rivalland, Ms Amrita Bhogal, Ms Tianmo Sun, Ms Bree Stenton and Ms Esmey Lee 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 clarified the dose escalation and safety mechanisms.

Summary of outstanding ethical issues

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

1. Please name the New Zealand coordinating investigator.
2. Please align the dosing information with the protocol and be clear how many tablets participants must take.
3. Please state that if HIV, Hepatitis B or Hepatitis C are tested positive this Medical Officer of Health must be informed.
4. Please simplify the information on page 4 about false positives and false negatives. The Committee suggests stating there may be a need to re-do these tests.
5. Please remove references to teaspoons for blood volumes and state the amount in millilitres.
6. Please amend the safety-follow up information on page 10 to state participants will be asked to and not ‘required’.
7. Please amend the information on pages 12 and 20 on terminating the study as a clinical trial in New Zealand may not be terminated solely for commercial reasons.
8. Please amend the information that “Genetic testing will also be performed on your biological samples, and, in some circumstances also an examination of your complete genetic material (genome).” Please state that genomic testing will be targeted to relevant mutations.
9. Please add genetic testing to the cultural statement on page 19.
10. Please remove the reference to "AIDS virus" on page 2 as this is stigmatising.
11. Please specify if pre/post HIV test counselling will be provided. Please include a statement advising what happens if a positive result is detected.
12. Please state if participants will need to undress for the physical exam, if they may bring a support person and if the exam can be performed by someone of the same gender.
13. Please review the sheet for gendered language (e.g. woman of childbearing potential can be “able to become pregnant”)
14. Please specify that "this may also include contacting others to learn about your well-being" will be through clinical means and not social media monitoring on page 12.
15. Please add “with your consent” to "your study doctor will medically follow your pregnancy" on page 17.
16. Please amend ‘may’ to ‘will’ on pages 18 and 19 regarding biological samples if these will be sent overseas and retained for 10 years.
17. Please correct the typo on page 19 "separated written consent".
18. Please state on page 25 if samples will be sent to the sponsor. It currently states they “may”.
19. Please add an option clause to the consent form for participants to request a summary of 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).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Sandy Gill and Dr Patries Herst.

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| **8**  | **Ethics ref:**  | **2024 FULL 21297** |
|   | Title:  | A Multi-Centre, Observational Study, for the Collection of a Raman Spectral Database Using the LumAssure Raman Device, in Adult Participants Undergoing Dermatological Assessments of Skin Conditions |
|   | Principal Investigator:  | Dr Michel Nieuwoudt |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 12 September 2024 |

Dr Michel Nieuwoudt 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 was grateful for the clarification around AI and satisfied it was not.
2. The Committee noted A7.2 of the application form should have been answered yes as it was declined the month prior. C3.3 answered incorrectly that the study is Kaupapa Māori which isn’t accurate.

Summary of outstanding ethical issues

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

1. The Committee noted the data management plan specified 45% female 45% male. Please clarify the range.
2. The Committee requested “train a device” is removed from the advertising.
3. The Committee suggested inserting images into the PIS to break up the text and give an idea of what the device looks like.

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

1. Please review for missing words and repeated words/sentences.
2. Please rewrite the first paragraph in plain language and remove the reference to Te Tiriti and the Declaration of Helsinki.
3. Please use gender-neutral pronouns when referring to the dermatologist.
4. Please combine the information on taking off clothing and having a support person present rather than repeating it.
5. Please replace the word disable with prevent on page 4.
6. Please remove the risk of eye exposure on page 4 if this area will not be part of the study per the protocol.
7. Please clarify the reference on page 5 to future research unrelated to the current study. Please make it clear if this is a requirement or participants have the option to say no to this.
8. Please make it clear that reimbursement is for travel costs, and parking is free at the research centre.
9. Please remove the text regarding researchers being familiar with the treaty of Waitangi and insert the cultural statement available on the [HDEC template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates) Please acknowledge the tapu of the head.
10. Please amend cultural support to Māori cultural support.
11. Please include information in the body of the sheet regarding images being sent overseas. The consent form contains a clause for this.
12. Please amend the clause on the consent form “I know where to find a summary of the results” to be a yes/no tickbox for participants to choose to receive a lay summary of results.
13. Please make the timing clear. The flow chart on page 2 suggests participants in the standard of care cohort will have to decide whether to participate at that appointment and the consent form contains a clause that the person has had sufficient time to discuss with their support network.
14. Please amend ‘chaperone’ to ‘support person’.
15. Please include a clause on the consent form to state if there are any adverse events, the participant’s usual health provider or GP will be notified.

**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 advertising.
3. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Jessie Lenagh-Glue and Mrs Patricia Mitchell.

## General business

1. The Committee requested legal advice from the Secretariat regarding tax implications for koha.
2. The Committee requested the Secretariat seek legal advice regarding how it can ensure medical professionals meet their obligations under best interests.
3. The Chair reminded the Committee of the date and time of its next scheduled meeting:

|  |  |
| --- | --- |
| **Meeting date:** | 22 October 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 4:30pm.