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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 06 August 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11:30am- 12:00pm | 2024 FULL 20603 | ITL-2001-CL-311: A Study to Investigate NTLA-2001 in Participants with Hereditary Transthyretin Amyloidosis with Polyneuropathy (ATTRv-PN) | Prof. Edward Gane | Ms Kate O'Connor & Mrs Leesa Russell |
| 12:00pm-12:30pm | 2024 FULL 20080 | A Phase 1b/2a, open-label single ascending doses and multiple ascending doses study in participants with Pi\*ZZ AATD | Dr. Catherina Chang | Dr Kate Parker & Ms Maakere Marr |
| 12:30pm-1:00pm | 2024 FULL 20671 | RVT-2301-201: A study to investigate the Efficacy and Safety of Mosliciguat in Participants with Pulmonary Hypertension Associate with Interstitial Lung Disease | Dr. Catherina Chang | Ms Catherine Garvey & Dr Amber Parry Strong |
| 1:00pm-1:30pm | 2024 FULL 19505 | Investigating exertion to assess dysfunction after mTBI | Ms Katherine Forch | Mr Barry Taylor & Ms Catherine Garvey |
| **1:30pm-2:00pm** |  | **Break 30 minutes** |  |  |
| 2:00pm-2:30pm | 2024 FULL 20519 | Clinical Biomarkers and Applications of Eye Tracking in Ophthalmology | Professor Helen Danesh-Meyer | Dr Amber Parry-Strong & Ms Kate O’Connor |
| 2:30pm-3:00pm | 2024 FULL 13358 | Feasibility study for PIPAC in New Zealand | Dr Jamish Gandhi | Mr Barry Taylor & Ms Maakere Marr |
| 3:00pm-3:30pm | 2024 FULL 20393 | LUMINA | Dr/Medical Director/ Radiologist Remy Lim | Ms Catherine Garvey & Ms Leesa Russell |
| 3:30pm-4:00pm | 2024 FULL 20801 | A Study Assessing DR-01 in Adults with Alopecia Areata or Vitiligo. | Dr Penelope Montgomery | Ms Kate O'Connor & Dr Kate Parker |

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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 | Present  |
| 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 | Apologies |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Apologies |
| Dr Amber Parry-Strong | Non-Lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Dr Kate Parker  | Non-lay (Observational studies)  | 11/02/2020  | 11/02/2023  | Present  |
| Ms Catherine Garvey  | Lay (the Law) (Chair) | 11/08/2021  | 11/08/2024  | Present  |

## Welcome

The Chair opened the meeting at 11.00am and welcomed Committee members, noting that apologies had been received from Ms Joan Pettit and Ms Alice McCarthy.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Catherine Garvey and Dr Kate Parker 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 02 July 2024 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2024 FULL 20603** |
|   | Title:  | MAGNITUDE-2: A Phase 3, Multinational, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of NTLA-2001 in Participants with Hereditary Transthyretin Amyloidosis with Polyneuropathy (ATTRv-PN) |
|   | Principal Investigator:  | Professor Edward Gane |
|   | Sponsor:  | Intellia Therapeutics, Inc.  |
|   | Clock Start Date:  | 25 July 2024 |

Professor Edward Gane, Lucy Druzianic, Julia O’Sullivan, Kayla Malate, and Abhi Bharathan 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 the study would be reviewed by the Gene Technology Advisory Committee (GTAC).
2. The Committee noted participants would need to take vitamin A supplements for the rest of their life. The Researcher explained this is a theoretical risk as the abnormal protein that will be ‘knocked out’ by the treatment carries vitamin A through the body and may reduce overall levels and potentially cause a deficiency over a long period of time. Therefore, participants will be asked to take a small dose daily that will be provided by the Sponsor. The Researcher explained it is expected all participants would cross over and receive treatment and so at the time of unblinding all participants who had received treatment would require supplementation. Any participants who withdraw from the study and do not cross over will be unblinded at the end of the study and those who received the active drug would require supplementation supplied by the Sponsor but those that received placebo would not.
3. The Committee noted pre-screening consent may be sought over text message and queried the feasibility of this. The Researcher clarified text messaging referred more generically to consent to access information about the participant and not seeking consent for genetic testing. The Researcher confirmed information about genetic testing and any results would be done face-to-face.
4. The Committee noted women of childbearing potential would be excluded and queried the inequity of access this would cause. The Researcher stated until there are sufficient animal breeding studies FDA requirements do not allow the Sponsor to include women of childbearing potential in studies of this nature. The Researcher agreed to ask the Sponsor if the inclusion criteria will be expanded if sufficient animal data is obtained.

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 Researcher clarified the natural progression of the disease is in years and participants in the placebo arm with progression may cross over to active treatment after 12 months. Those who do not have progression may cross over after 18 months. Participants in the active arm will cross over to placebo to maintain blinding. The Committee requested the diagram from the protocol explaining the crossover is included in the information sheet.
2. The Committee noted the pre-screening PIS stated the only alternative to having the genetic test done is to not participate in the main trial and queried participants who have a pre-existing diagnosis. The Researcher clarified it was worded this way so the test is not-optional and this PIS would only be given to participants who do not have an existing diagnosis. The Committee suggested this is re-worded for greater flexibility for participants on that trajectory.
3. The Committee requested the two optional future sheets are combined to one sheet with a simple decision tree to allow both choices.
4. The Committee noted the wording stating participants must be eligible to work in New Zealand for the duration of the study and requested confirmation those who could not work due to sickness or disability would not be excluded. The Researcher confirmed this was for tax purposes as participants require an IRD number. The Researcher agreed to clarify this.

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

1. Please include any restricted drugs that may be commonly used (eg paracetamol, ibuprofen, vaccines) in the PIS if participants should be aware.
2. Please include the crossover diagram.

**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 Kate O’Connor and Mrs Leesa Russell.

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| **2**   | **Ethics ref:**   | **2024 FULL 20080** |
|   | Title:  | A Phase 1b/2a Open-label Single Ascending Doses (SAD) and Multiple Ascending Doses (MAD) Research Study to Evaluate Safety, Tolerability, Pharmacokinetics and Pharmacodynamics in Participants with AATD Pi\*ZZ on WVE-006 (RestorAATion-2) |
|   | Principal Investigator:  | Dr. Catherina Chang |
|   | Sponsor:  | Wave Life Sciences UK Limited |
|   | Clock Start Date:  | 25 July 2024 |

Dr Rebekah Anstey, Christine Tuffery and Dr Cynthia Caracta 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 intervention was RNA editing and not gene editing. RNA editing in specific diseases like AATD addresses the mutation that exists that produces the protein malfunctional and edits the RNA to be translated to have the functional protein. In essence it uses the body’s own endogenous protein machinery to create a new protein with the correct message RNA. The Researcher stated it was not a permanent alteration and the effect of the drug is titratable which is the focus of these early studies. The Committee noted the study would not need approval from the Gene Technology Advisory Committee (GTAC) and would instead be reviewed by the Standing Committee on Therapeutic Trials (SCOTT).
2. The Researcher confirmed recruitment would be targeted and the supplied advertising material was intended as support material not generic advertising.

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 flyer contained complex language regarding RNA and suggested the information could be simplified. Please include an indication that risk is involved.
2. The Committee requested a justification for running a first-in-human and first-in-patient study concurrently and how the risks would be managed.
3. The Committee advised in New Zealand it is not acceptable to expect participants to pay for their own medicine to address side effects caused by a study intervention. The Committee requested this is removed from the information sheet and any extra medicines required to treat side effects are covered by the Sponsor.
4. The Committee queried if home visits would be offered in New Zealand. The Researcher confirmed they would be. The Committee requested a home visit safety plan is supplied.
5. The Committee noted it is unusual for a study to involve overnight stays without any payment. The Researcher confirmed they have requested a patient stipend.
6. The Committee advised the pregnant partner information sheet is not required and will be reviewed in the event a participant’s partner does become pregnant. If that situation occurs, please submit an amendment with the sheet.
7. The Committee queried if negative results would be published. The Researcher stated they would have to consult the Sponsor’s publications team.

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

1. Please include side effects from first in human studies as listed in the IB addendum.
2. Please remove references to spoons with blood measurements and state millilitres.
3. Please state a defined time limit that samples will be stored for on page 9 as indefinite storage is not permitted.
4. Please state how samples will be analysed. The main PIS should state specific purposes samples will be used for. The optional form may then be more generic about future unspecified testing.
5. Please include information on any stipend that will be available.
6. Please amend the line on page 13 stating participants are responsible for treatments even if standard of care as these should be covered by the study.
7. Please remove the reference to Scout Clinical if this will not be offered in New Zealand.
8. Please remove the requirement to claim expenses and offer a daily stipend for travel and food instead.
9. Please amend racial origin to ethnicity.
10. Please make GP notification mandatory and remove the ‘yes / no’ option on the consent form.
11. Please replace the reference to the Privacy Act 1993 to refer to the Privacy Act 2020 and the Health Information Privacy Code 1994 to 2020.
12. Please review the wording around compensation where the template refers to ‘some sponsors committing’ to the Medicines NZ guidelines on compensation. If the Sponsor has not committed to the guidelines please revise this or state whether it has.
13. Please remove reference to the national statement as this is for Australia only.
14. Please remove the legally authorised representative box on the consent form as this is not an option in New Zealand.
15. Please state a karakia will not be available on destruction of tissue samples.
16. Please include a lay-friendly explanation of RNA. The Committee suggested a statement explaining that it is not DNA or gene editing would be useful.

**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 provide a researcher safety plan for home visits addressing the concerns raised by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62).*

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

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| **3**   | **Ethics ref:**   | **2024 FULL 20671** |
|   | Title:  | A Phase 2, Randomized, Placebo-Controlled Trial to Assess the Efficacy and Safety of Mosliciguat in Participants with PulmonaryHypertension Associated with Interstitial Lung Disease |
|   | Principal Investigator:  | Dr Catherina Chang |
|   | Sponsor:  | Roivant |
|   | Clock Start Date:  | 25 July 2024 |

Dr Rebekah Anstey, Christine Tuffery, Jen Cormier, Sudhir Penugonda, and Summer Radler 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 Researchers confirmed that for this particular type of pulmonary hypertension, the only available treatment is treatment of the underlying lung disease. The placebo arm will allow for standard of care symptom treatment to continue. For all patients, they would want them to be on optimal therapy prior to the study and will be a discussion with the patient prior to participation. Those who worsen on placebo can crossover to the extension study after about 6 months, which will last for several years. The Committee was satisfied that those randomised to placebo will not be disadvantaged in terms of continued treatment availability.
2. The Researchers confirmed that paper copies of participant diaries are available for those who are not able to use digital copies.
3. The Committee noted that the FDA letter contained a number of outstanding items, and queried where the study was up to in terms of responding to these concerns. The Researchers clarified that they responded to the FDA comments and received no further comments or concerns, so are able to proceed. They further confirmed that the response package will be provided to SCOTT if requested, and will provide it to HDEC.
4. The Committee was assured of the titration guidance and procedures with blinding in the placebo arm that would not provide further risks when crossed over to the extension.

Summary of outstanding ethical issues

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

1. Please clarify the crossover and separation of what would be a study visit, and what would be a standard of care visit. Reassurance about what participants can and can’t do is important to specify in lay terms.
2. Please clarify what is meant by optional remote visits, such as whether some visits could be done via teleconference rather than in-person due to participant’s needs, or whether they are not required at all.
3. Reword reference in Main PIS to optional sub-study to confirm that this is not being done in New Zealand.
4. The reproductive risks section discusses contraception and then suddenly refers to using condoms during a partner pregnancy. Please swap this bit with the paragraph underneath.
5. Remove references to teaspoons and cups for blood volume, this should be in millilitres.
6. Submission form says participants will be reimbursed for their time, but this is not mentioned in the PIS. Please clarify what reimbursements are provided, and how these are provided.
7. Please ensure that the wording around compensation is accurate with regard to the Medicines NZ guidelines. If the Sponsor has not committed to the guidelines please revise this and replace with suitable wording to ensure it reflects ACC-equivalent insurance and any limitations.

**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 Catherine Garvey and Dr Amber Parry-Strong.

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| **4**   | **Ethics ref:**   | **2024 FULL 19505** |
|   | Title:  | Investigating a physical exertion testing protocol in the assessment of balance and visual function following sport-related mild traumatic brain injury (mTBI). |
|   | Principal Investigator:  | Ms Katherine Forch |
|   | Sponsor:  | Auckland University of Technology |
|   | Clock Start Date:  | 25 July 2024 |

Katherine Forch and Dr Sharon Olsen 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 aims are primarily to upskill physiotherapists and general practitioners (GPs) in order to have better care overall and better inform the care of those people experiencing sports-related concussion.

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 suggested that the full title as per the protocol be included consistently across the participant facing documents, and the simpler lay titles can be retained.
2. The Committee requested that the first time mTBI is used that there is an explanation as to what this is and then use consistent terminology after that point, either referring to mTBI or concussion throughout documents.

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

1. Please include and clarify the ways in which face-to-face discussions might occur as noted in the Māori consultation.
2. Please clarify what information will be retained from screening should someone not be eligible to participate, and that this is explained prior to screening.
3. Please clarify that the participants usual doctor will be informed of their participation.
4. Please state explicitly that this study will not replace usual care and that while information may be passed to the participants usual doctor, participants should still consult with their GP as normal.
5. Please be clear as to the koha available, including how much and when this will be received.

**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 Barry Taylor and Ms Catherine Garvey.

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| **5**   | **Ethics ref:**   | **2024 FULL 20519** |
|   | Title:  | Clinical Biomarkers and Applications of Eye Tracking in Ophthalmology |
|   | Principal Investigator:  | Professor Helen Danesh-Meyer |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 25 July 2024 |

No one from the research team 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 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 clarification of the commercial aspects of the device particularly as owned by the vendor and as they may be associated to the study.
2. The Committee requested a clear explanation of the involvement of researchers commercially in the device. “Intent to commercialise” is not sufficient. If the intent is to validate the device for commercialisation, please clarify this.
3. The Committee requested clarification as to whether the alcohol group would be excluded in this part of the study. Please ensure that a separate Data Management Plan (DMP) and Protocol are supplied containing only relevant information for this study not that concerning the alcohol cohort.
4. The Committee noted that the advertising should ensure that the image is relevant to the study. The picture supplied does not do this and the Committee note that an image with the person in relation to the portable device would be more informative.
5. The Committee requested that any statements in the adverts be moderated as currently the mention of savings to the health system is overstated.
6. The Committee requested that the protocol and the PISs are aligned in their mention of a longitudinal cohort with follow-up visits. Either include this in the PISs and a separate consent for this as relevant or remove from the protocol.
7. The Committee noted that the adverts must include the location of visits and the HDEC reference.

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

Fatigue PIS/CF:

1. Please be transparent about the intervention, including who owns it and who will benefit. Per the cover letter "It is VRF’s intention to commercialise the application of eye tracking to fund other projects, in addition to return-on-investment for shareholders.“. This needs to be made clear to participants.
2. Please include detail as to when and where the testing sessions will occur as well as how long they may take and whether there will be any reimbursement for expenses relating to travel (such as a fuel voucher).
3. Please note that the consent forms currently confuse de-identified data and anonymised data in terms of what cannot be withdrawn. Please correct this.
4. Please be clear as to how the questionnaire will be done. This should include who would fill it out, how the session to fill it may be conducted if investigator led.
5. Please remove all unnecessary identifier collection points from the questionnaire, such as names etc.
6. Please remove mention of “patient” and replace with “participant”
7. Please describe the device and note that it will require fitting which may involve touching of the head.
8. Please ensure that all contacts for HDEC are per the [template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc). Note the 0800 Ethic number has been replaced by the MoH general inquiries number.
9. Please provide a bigger picture in the PIS/CF. The current image is very small.

Neurological PIS/CF:

1. Please include detail as to when and where the testing sessions will occur as well as how long they may take and whether there will be any reimbursement for expenses relating to travel (such as a fuel voucher).
2. Please include information of the longitudinal cohort as required.
3. Please be clear as to how the questionnaire will be done. This should include who would fill it out, how the session to fill it may be conducted if investigator led.
4. Please remove all unnecessary identifier collection points from the questionnaire, such as names etc.
5. Please clarify the statement, "After your participation is completed you may request access to your data". Including whether the results of the testing may have any clinical significance.
6. Please remove mention of “patient” and replace with “participant”
7. Please describe the device and note that it will require fitting which may involve touching of the head.
8. Please ensure that all contacts for HDEC are per the [template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc). Note the 0800 Ethic number has been replaced by the MoH general inquiries number.
9. Please provide a bigger picture in the PISCF. The current image is very small.

**Decision**

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

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

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

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| **6**   | **Ethics ref:**   | **2024 FULL 13358** |
|   | Title:  | Can Pressurised Intraperitoneal Aerosol Chemotherapy (PIPAC) be used safely in a public hospital in New Zealand? A feasibility study |
|   | Principal Investigator:  | Dr Jamish Gandhi |
|   | Sponsor:  | Thermasolutions Inc. |
|   | Clock Start Date:  | 25 July 2024 |

Mr Isi Tonga 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 there was no commercial benefit to the supplier and that this is an investigator-initiated study. The Committee noted that the insurance obtained for the study would be additional to requirements as ACC should cover incidents occurring in the study and therefore not applicable to 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 requested that the researchers utilise the Data and Tissue Management Plan (DTMP) [template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-tissue-management-template-Nov2022.docx) per the HDEC website. Please note that REDCAP or QUALTRICS are the gold standard for data management and can be accessed through the hospital research office.
2. The Committee requested that the researchers provide a scientific peer review from an independent palliative care specialist per the [scientific peer review template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2021.docx)
3. The Committee requested proof of medical insurance for the PI as the one supplied was expired.
4. The Committee noted that on the Te Whatu Ora pamphlet there is a typo in the word “Whānau” in that the tohutō (macron) is missing from the first ‘a’.
5. The Committee noted that in the protocol it states that data analysis is likely to occur late 2023. 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 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).*
3. 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).*
4. Please supply a more detailed data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

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

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| **7**   | **Ethics ref:**   | **2024 FULL 20393** |
|   | Title:  | Impact of FAPI PET/CT in locally advanced lobular breast cancer (LUMINA) |
|   | Principal Investigator:  | Dr Remy Lim |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 25 July 2024 |

Dr Remy Lim, Fay Sommerville, Dr Andrew Henderson, and Sheridan Wilson 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 Researchers clarified that the intervention is adding a scan to their usual management and they will discuss follow up of new findings, which may change management.
2. The Researchers confirmed that the approach to false-positives/false-negatives will be the same as those in a clinical (standard of care) setting.

Summary of outstanding ethical issues

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

1. After discussion, the Researchers and Committee confirmed that the manufacturer or supplier of the peptide is not the study Sponsor, and this study is Investigator-initiated and not commercially sponsored. The Committee requested to review all study documentation to change any references to the Sponsor, such as in the participant information sheet. After discussion, it was concluded that Mercy Radiology is contractually responsible for the study and would be the Sponsor.
2. The Committee noted there will be both private and public patients recruited into the study. If public patients are recruited, locality review will be required from Te Whatu Ora | Health NZ locations.
3. The Committee noted that koha should be provided per visit, rather than at the end of the study, to ensure those who withdraw are also offered this.
4. A cap of $100 per participant for travel reimbursement is fair, but the Committee noted that if someone exceeds that in a way that is reasonable for what their travel requirements were, this should be flexible to ensure no one is out of pocket for participating.
5. The Committee stated to make sure notification to GP of the outcome of the scan, please make it clear that it is results from a clinical trial.
6. The Data Management Plan does not specify future use of data in as much detail as the participant information sheet. Please ensure this is relayed consistently in both documents.
7. Composition of Data Safety Monitoring Committee was left blank in the Protocol, so the Committee reminded the Researchers to ensure this is in place before starting.

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

1. Please clarify how the study will acknowledge the head is tapu and how the sacredness of this body part will be protected, such as stating they will be asked before the head is touched. In addition, do not need to say it is “very tapu”, and can just be referred to as tapu.
2. If the supplier of the peptide is not receiving any study information, the section stating they will needs to be amended.

**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 Mrs Leesa Russell.

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| --- | --- | --- |
| **8**   | **Ethics ref:**   | **2024 FULL 20801** |
|   | Title:  | A Pilot, Safety and Clinical Activity, Phase 1b Study of DR-01 in Adults with Alopecia Areata or Vitiligo |
|   | Principal Investigator:  | Dr Penelope Montgomery |
|   | Sponsor:  | Novotech (New Zealand) Limited |
|   | Clock Start Date:  | 25 July 2024 |

Dr. Tori Middlemiss, Andrea Kantor, Matthias Will, and Adeeba Aziz 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 that if successful, would the transfusions be needed on an ongoing basis. The participant information sheet mentions the possibility of continued access through an extension study and queried how realistic this is given the early phase of research. After discussion, the Researchers clarified they expect that the investigational medicine will be made available. The mode of delivery is expected to change to avoid the need for transfusions.

Summary of outstanding ethical issues

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

1. Information and risks of photographs are not covered in the participant information sheet or Data Management Plan given the site of interest could be near the face or a tattoo and therefore identifiable. Please amend these documents to outline this further.

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

1. Cultural issues section of the app form does not address the tapu of the head for Māori. Please address this in the PIS.
2. If the physical examination is of intimate areas or requires a participant to undress, please sufficiently outline this to warn participants in advance.
3. Use of “Institutional Review Board” instead of referring to Ethics Committee, please amend for New Zealand context.
4. Heavy reliance on use of the word ‘treatment’ when this is investigational. Where an alternative can be used, such as “dose group”, please amend.
5. Please remove any references to tablespoons for blood measurement. Please use millilitres.
6. On page 16, change "If required by applicable law, " and 'for scientific or security reasons." when discussing separate consent for taking birth outcome data.
7. Please finalize the reimbursement amounts on page 18.
8. Please review the wording around compensation where the template refers to ‘some sponsors committing’ to the Medicines NZ guidelines on compensation. If the Sponsor has not committed to the guidelines please revise this.
9. Please refer to ‘ethnicity’ instead of race.

**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 Kate O’Connor and Dr Kate Parker.

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 03 September 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 3.45pm