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| **Committee:** | NTA Health and Disability Ethics Committee |
| **Meeting date:** | 29 July 2025 |
| **Zoom details:** | 812 7953 3520 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11:00am-11:30am |  | Committee Welcome |  |  |
| 11:30am-12:00pm | 2025 FULL 23347 | Bioengineered Animal Tissue Graft Incontinence Sling Study | Clinical Associate Professor Michael Stitely | Dr Catriona McBean / Dr Andrea Forde |
| 12:00pm-12:30pm | 2025 FULL 23415 | 120-HG-201: A Study to Evaluate the Safety, Tolerability, and Efficacy of NGM120 in Pregnant Women with Severe Nausea and Vomiting | Dr James Stanley | Ms Catherine Garvey / Dr Andrea Furuya |
| 12:30pm-1:30pm |  | *Break (60 mins)* |  |  |
| 1:30pm-2:00pm | 2025 EXP 23527 | Analysis of outcomes for degenerative cervical myelopathy | A/Prof Joe Baker | Dr Catriona McBean / Dr John Pearson |
| 2:00pm-2:30pm | 2025 EXP 22941 | Aotearoa Antimicrobial and Laboratory Stewardship Databank | Dr Maxim Bloomfield | Mr Jonathan Darby / Dr Andrea Furuya |
| 2:30pm-3:00pm | 2025 FULL 22632 | Speech Therapy During Aphasia Rehabilitation | Mrs Nicola Gibbons | Ms Catherine Garvey / Dr Sharon Kletchko |
| 3:00pm-3:30pm | 2025 FULL 23336 | CO45042: A study to compare divarasib plus pembrolizumab with standard treatment in people with untreated NSCLC that has a change in a gene called KRAS G12C and has spread | Dr Gareth Rivalland | Ms Jessie Lenagh-Glue / Dr Andrea Forde |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Present |
| Dr Andrea Forde | Non-lay (Intervention studies)  | 09/06/2025 | 08/06/2030 | Present |
| Ms Catherine Garvey  | Lay (the Law) (Chair) | 09/06/2025 | 08/06/2030 | Present  |
| Dr Andrea Furuya | Non-Lay | 03/03/2025 | 02/03/2029 | Present |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Associate Professor John Pearson | Non-Lay | 09/06/2025 | 08/06/2029 | Present |
| Dr Catriona McBean | Lay | 03/03/2025 | 02/03/2030 | Present |
| Dr Sharon Kletchko | Non-Lay  | 09/06/2025 | 08/06/2029 | Present  |

## Welcome

The Chair opened the meeting at 11:00 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.

## New applications

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| **1**   | **Ethics ref:**   | **FULL 23347** |
|   | Title:  | A descriptive study to determine the feasibility of a minimally-invasive non-mesh incontinence sling procedure using a bioengineered animal tissue graft. |
|   | Principal Investigator:  | Associate Professor Michael Stitely |
|   | Sponsor:  | Te Whatu Ora |
|   | Clock Start Date:  | 17 July 2025 |

Assoc Professor Michael Stitely 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 acknowledged the full response by the Researcher to the previous decline and its gratitude for the feedback provided to the Committee,
2. The Researcher confirmed that the sheep-derived sling graft is fully bioresorbable over time and cannot be removed once implanted. In addition, absorbable sutures are used which are also intended to be completely absorbed by the body.
3. The Researcher clarified that the graft is processed from sheep foregut with no proteins that are shared with wool or lanolin. The proteins from the foregut are different from those that are related to wool or lanolin allergies. Any history of allergy to sheep proteins such as products containing wool or lanolin would be very rare, and participants will be screened for known reactions.
4. The Researcher confirmed the affiliation and position of the peer reviewer as the Head of Department at the Dunedin School of Medicine, Obstetrics, Gynaecology and Reproductive Medicine.
5. The Researchers clarified that they will be seeking locality approval from the hospitals in the publicly funded system first, then seek locality approvals from any private hospitals which will be involved in the 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 consider data privacy and security when contributing to and using offshore databanks. Highlighting that although the data needs to be available for use in future research, it also needs to remain safe.
2. The Committee requested that Māori cultural perspectives be further addressed. In particular, that the cultural sensitivities around female reproductive health, given that the intervention under study addresses stress incontinence which in females usually arises post-childbirth. The Committee requested recognition and inclusion of cultural advice obtained from the Māori research advisor into the study materials to ensure consideration and respect for the female body and childbearing in Māori culture. This should be reflected in the Participant Information Sheet (PIS), as appropriate.
3. The Committee requested the inclusion of specific data governance policies that will be followed in the Data Management Plan

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

1. Please clarify that there will be reimbursement for travel costs (without a requirement for receipts) in addition to any koha that may be provided.
2. Please consider revising the PIS format to include the databank section before the risk section, or cross reference, as information provided in the databank section would provide more context and clear understanding for the risks section
3. Please revise the PIS section on data withdrawal to clarify that participants can withdraw from the study at any time and for any reason. Explain that once data are anonymized in the databank, it is impracticable to identify and remove it, however, participants retain the right to withdraw from further participation.

**Decision**

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

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

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| **2**   | **Ethics ref:**   | **FULL 23415** |
|   | Title:  | 120-HG-201: A Phase 2 Randomized, Proof of Concept Study to Evaluate the Safety, Tolerability, and Efficacy of NGM120 in Pregnant Women with Severe Nausea and Vomiting (Hyperemesis Gravidarum) (EMERALD) |
|   | Principal Investigator:  | Dr James Stanley |
|   | Sponsor:  | NGM Biopharmaceuticals, Inc. |
|   | Clock Start Date:  | 17 July 2025 |

Drs James Stanley, Claire Thurlow, Charlene Botha, Vladimir Hanes, Brenda Dampier, Katherine Wu, Aimee Hawker 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 clarified that quality-of-life questionnaires are reviewed daily by study coordinators as part of regular diary checks.

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 a New Zealand-specific plan for integrating this trial with our maternity system. New Zealand’s model of care relies on Lead Maternity Carers (LMCs) who coordinate pregnancy care, delivery and post-partum care of mother and baby. The Committee acknowledged the Sponsor’s intention to have flexibility built into the protocol, however, requested further detail on how trial recruitment and participation in the New Zealand specific context. An appendix or document outlining the specific requirements for conducting this study in New Zealand can be provided (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.7).*
2. Specifically the Committee requested that the that recruitment and enrolment is managed so that it does not interfere with a participant enrolling with an LMC, and describing how the research team will liaise with both LMCs and GPs so that trial activities complement standard antenatal care rather than compete with it *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8).*
3. The Committee noted an inconsistency in the submitted documents where placenta collection was mentioned. Ensure that it is clear that the study will collect only cord blood (2–5 mL) and not the placenta *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8).*
4. The Committee requested clearer documentation of how trial attendance will be coordinated with antenatal and obstetric care for participants., and efforts to avoid duplication of visits. Considerations for formal agreements to minimise burden such as coordinating trial visits to coincide with routine check-ups should be made *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
5. The Committee requested consultation and suggested that the researchers consider approaching the New Zealand College of Midwives or similar advisory groups to ensure the trial is culturally and operationally acceptable to maternity care providers *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8).*
6. The Committee requested confirmation in writing from senior Sponsor executives that there is no federal funding from the United States for this study.
7. Please review the exclusion criteria to address a termination of pregnancy due to Hyperemesis gravidarum *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8).*
8. The Committee noted that the participants are not required to complete any withdrawal form if they wish to withdraw from the study and requested that the researchers not insist on this *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.13).*
9. The Committee requested that more detail be provided regarding genetic testing and biomarker analyses that will be performed. Explain what the purpose of analysis on the biomarkers is being conducted, specify which genes will be looked at and that only the drug, its actions, and how it is related to the condition will be analysed. Ensure that the genetic analysis is not open ended and that all this information is provided to the participants for discussion with family members *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15-7.17)*:

1. Please revise the PIS to refer to an ‘investigational medicine’ or study medicine’ rather than as “treatment”
2. Please update the PIS to include New Zealand-specific information and terminology. All references to medical care should reflect our local context, for example, use of LMC when explaining who will provide routine pregnancy care. Clearly explain the importance of the participant and study team working in coordination with the participant’s LMC or GP if the participant does not yet have a LMC during the study and preferably prior to enrolment; and that the research team will work closely with that LMC whether midwife or specialist Obstetrician.
3. Please add details to the PIS about how participation will overlap with normal pregnancy care, including whether and how trial clinic visits will be in addition to regular midwife/doctor visits, and that the study team will coordinate with participants’ usual care.
4. Please add more information into the PIS regarding what the investigation medicine targets and the risks to mother and risks to foetus, including relevant data to date from teratogenicity studies
5. Please expand the PIS to address cultural and family considerations. Given the importance of whānau in pregnancy decisions, advise participants they may wish to consult their family/whānau before deciding whether to participate.
6. Please include in the PIS that standard treatment will not be withheld from participants if they require it and any implications for their ability to remain on the study.
7. Please ensure that it is clear how the collection of cord blood in the study may affect the option of cord banking for the participant.
8. Please ensure that the cultural issues of all of, cord blood, cord and placenta are addressed
9. Please clarify the information that the study wishes to collect on the infant after birth as described in the protocol. Additionally note that any data collection on an infant needs to be consented after birth.
10. Please provide more detailed information around the purpose of assessments and that participants will not incur any costs, such as for ultrasound.
11. Please provide Māori support information in the PIS.
12. Please ensure the PIS specifies that any breast milk collection will exclude colostrum.
13. Please clarify that the intervention is not licenced by any regulator, as opposed to ‘not licenced by Medsafe.
14. Please revise reference to screening for bloodborne viruses, as antenatal bloods screen for bloodborne viruses in New Zealand is part of routine care.
15. Please revise references to side effects to refer to adverse events for issues that may be detected with the medicine.
16. Please remove the requirement for provision of receipts for reimbursement of costs. Ensure that stipend and reimbursement information is clear and consistent across the PIS.
17. Please ensure that payments for mobile data are reimbursed to participants.
18. Please include information indicating that data will need to be kept for 10 years after the youngest participant turns 16.
19. Please explain that any findings will be reported to both a participant’s LMC and GP.

**Decision**

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above.

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| **3**   | **Ethics ref:**   | **EXP 23527** |
|   | Title:  | Analysis of outcomes for degenerative cervical myelopathy in a New Zealand cohort – establishment of a New Zealand DCM Registry |
|   | Principal Investigator:  | Associate Professor Joe Baker |
|   | Sponsor:  | Te Whatu Ora |
|   | Clock Start Date:  | 17 July 2025 |

Assoc Prof Joe Baker 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 clarified that the researcher intends to conduct a cohort study and separately to establish a registry. These activities require different structures, data management processes and participant facing documentation. As such, the Committee suggested that the application be considered in two parts, or that it be resubmitted as two separate applications, for the cohort outcome study and the creation of a registry. The Cohort study can be treated as the primary focus with its own objectives, consent, and endpoints, and the establishment of a long-term registry can be a separate, future initiative. The cohort study can be carried out to inform the design of the registry. The cohort study documents need to be revised for this single purpose and the instruments that will be used to question the participants about their recovery be provided *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
2. The Committee noted that a robust governance plan for data management needs to be in place for a proposed registry. This includes who will oversee the data, how privacy and security will be maintained the establishment of a governance board including appropriate representation and/or consultation arrangements with relevant sectors including Māori. Procedures for handling data access requests, data linkage, future use of the registry data, and potential data breaches are required. As is a Participant Information Sheet to outline this information for participants. Requirements for setting up a registry can be found in National Ethical standards chapter 12 and can be incorporated *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15; 12.42-12.44)*.
3. The Committee suggested consulting with established registries to incorporate lessons for governance, content, data linkage and participant recruitment.
4. The Committee suggested using electronic data capture tools such as REDCap for collecting follow-up information instead of relying on paper questionnaires mailed to participants *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
5. The Committee noted that the project currently relies heavily on a single investigator and with unsecured funding and requested that the researcher considers building a broader project team to ensure the proposed registry can be sustained and maintained long-term. This includes seeking funding for research personnel and digital infrastructure. The Committee indicated that the application can be written in such a way that describes what processes would look like if funding were to be acquired *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.44)*.
6. The Committee requested that the response to peer reviewers’ comments be clearly provided, whether addressing how comments have been incorporated or providing justifications for not incorporating any recommendations. This can be done in a manner that is convenient to the researcher.
7. The Committee queried why consent to be in the registry would be kept in the patients’ clinical notes, as identifiable data is expected to be kept separate from anonymised or deidentified data. Any justification or reasoning for doing so, such as the need for following up people in the registry should be articulated in the protocol and PIS *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.42-12.44)*.
8. The Committee requested that the consenting process is revised to ensure that participants give written consent *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.1a)*.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15-7.17)*:

1. Please consider using the HDEC template for guidance on the information and detail a PIS should include and adapt as appropriate.
2. Please provide researcher contact details for participants.
3. Please remove any requirement for a participant to withdraw from participation in writing. This can be done verbally in person or by phone or email.

**Decision**

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above.

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| **4**   | **Ethics ref:**   | **EXP 22941** |
|   | Title:  | Aotearoa Antimicrobial and Laboratory Stewardship Databank |
|   | Principal Investigator:  | Dr Maxim Bloomfield |
|   | Sponsor:  | Awanui Laboratories |
|   | Clock Start Date:  | 17 July 2025 |

Dr Max Bloomfield was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee confirmed that the waiver of consent sought by the researcher is justified and included in the approval of this application.
2. The researcher clarified that the data sharing agreement was signed with specific discussion of and reference to this research application.

Summary of outstanding ethical issues

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

1. The Committee requested confirmation the Researcher has ongoing access to the pharmaceutical collection, including for study purposes. The researcher was asked to ensure that it is clear that the data sharing agreement with Te Whatu Ora covers access to data for the research purposes.
2. The Committee requested that the protocol be updated to include information on what type of data analysis will be conducted and how it will be done.
3. The Committee requested formalising study and data continuity plans to ensure that the data remains [accessible/publicly available and retained under approved governance arrangements] in the event the ownership of Awanui Labs changes or the Researcher takes on a different role. Specifically, written confirmation of the requirement that, if laboratory services transition to a new provider, all databank data will be transferred or remain available from the databank to future researchers.
4. The Committee requested that it be clearly stated that the data is not held privately by a private organisation, rather that it is data ‘held on behalf of..’.
5. The Committee requested that the protocol clearly state that the requirements for accessing the data includes being subject to ethical approval.

**Decision approved**

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 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).*

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| **5**   | **Ethics ref:**   | **FULL 22632** |
|   | Title:  | Comprehensive Individualised Aphasia Therapy Programmes During Inpatient Stroke Rehabilitation Stays: a comparison against usual care |
|   | Principal Investigator:  | Mrs Nicola Gibbons |
|   | Sponsor:  | University of Canterbury |
|   | Clock Start Date:  | 17 July 2025 |

Dr Catherine Theys 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 confirmed that the original approach to participants will be by clinicians who introduce their patients to the study, who will then refer participants on to the study team for the study team to then consent the participants.
2. The researcher clarified that the intervention and control arm would be carried out at different locations.

Summary of outstanding ethical issues

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

1. The Committee requested confirmation that the number of participants included has been informed by some statistical reasoning and ensure that any results provide meaningful results to the primary goal. Consultation with a biostatistician will assist in this process.
2. The Committee requested that it be made clearer in the protocol that this study is testing clinical equipoise as opposed to proving individual equipoise, highlighting why the intervention is expected to provide more benefit than standard of care in addition to any possible negative effects of more intensive treatment.
3. The Committee noted that there are sessions where data will be collected from family members. The participants need to be advised of the intention to involve their family members and family members will need to be provided with their own participant information sheet and consent form.
4. The Committee noted that the reference to an economic analysis could be clarified.
5. The Committee requested that the exclusion criteria for patients with psychiatric history be revised to include only groups for which this would affect the study outcomes. Currently the exclusion of ‘all psychiatric disorders’ includes a wide range of disorders that may be experienced over a lifetime.
6. The Committee noted that quality of life surveys will be used in this study and requested that information be provided about a safety plan if any issues arise from the quality-of-life surveys that require action. If, since these are inpatients, the study will rely on standard care this needs to be outlined.
7. The Committee noted that some of the questions in the surveys are not appropriate for hospital inpatients and can be removed.

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

1. Please include reference to the pilot study of 6-8 participants, including any additional requirements on those participants to determine any study modifications.
2. Please include information in the PIS that the study is not randomised, noting that participants in Christchurch receive the intensive therapy and participants in Dunedin receive the standard therapy available there and that outcomes will be compared.
3. Please include information around the group aspect of the intervention as participants will need to be aware of this. Include information on how privacy and confidentiality will be managed.
4. Please ensure that it is clear that students, with practical clinical experience and who are competent to deliver this therapy, will be involved in providing therapy.
5. Please ensure it is clear what is meant by reference to ‘a communication partner’ in the PIS.
6. Please revise the wording stating that after 20 sessions ‘treatment will be achieved’ to be more realistic, such as ‘progress towards reaching their goals’
7. Please ensure that it is clear that that the ‘right to support’ as outlined in Code of Health and Disability Services Consumers' Rights (the code of rights).
8. Please ensure that it is clear that HDECs only approve ethical aspects of the study not the study as a whole.
9. Please remove the yes/no option for GP notification as this is mandatory.

**Decision**

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

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

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

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| **6**   | **Ethics ref:**   | **FULL 23336** |
|   | Title:  | A Phase III, Randomised, Open-Label Study Evaluating the Efficacy and Safety of Divarasib and Pembrolizumab versus Pembrolizumab and Pemetrexed and Carboplatin or Cisplatin in Patients with Previously Untreated, KRAS G12C-mutated, Advanced or Metastatic Non-Squamous Non-Small Cell Lung Cancer. |
|   | Principal Investigator:  | Dr Gareth Rivalland |
|   | Sponsor:  | Roche Products (New Zealand) Ltd |
|   | Clock Start Date:  | 17 July 2025 |

Drs Gareth Rivalland and Jan Burd 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 the insurance statement from Switzerland covers participants in New Zealand.
2. The Committee noted that the investigational medicine would not be provided to participants in the control arm after the study. The Researchers outlined that, while crossover for beneficial drugs would be ideal, allowing “crossover” can complicate the analysis of long-term outcomes like overall survival benefits, which in turn affects regulators and the sponsors, as funders, when making future decisions on the licensed roles of the medicine
3. The Committee queried the study withholding standard chemotherapy in the experimental arm. The Researchers clarified that the current data on the experimental medicines indicates higher benefit than current standard care, showing significantly higher response rates with the investigational medicine combination. The Researchers further clarified that patients on the investigational arm would remain eligible to receive standard chemotherapy later if needed.
4. The researchers explained that the treating clinician will introduce the study during a patient’s appointment, but if the patient is interested, a research nurse will follow up to discuss the study and obtain consent.

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 acknowledged the researcher’s advice that that lung cancer at 16–17 is extremely rare, however, highlighted that individuals aged 16 can legally consent to research and requested that 16- and 17-year-olds not be automatically excluded from the study.
2. The Committee indicated that stopping a trial purely for commercial reasons is not allowed in New Zealand.
3. [The Committee noted that the insurance statement lists New Zealand in the document further confirmation that New Zealand participants are specifically covered was requested.]
4. The Committee commended the vomiting and nausea pamphlet provided and suggested that similar resources be provided for other common side effects such as neuropathy would be helpful for participants.
5. The Committee requested clearer communication about the genetic (DNA) testing involved in the study. It must be explicitly stated that participation requires a mandatory genetic test for a specific purpose. Additionally, the Committee asked for details on what will happen to the tissue and genetic information including information about where the tissue sample will be tested, who will have access to the DNA results, and how privacy will be protected.
6. The Committee requested that the sponsor apply for licensure in New Zealand if the study medicine is effective.
7. The Committee requested clarification on whether a pregnant person would routinely be excluded from treatment, and if they would not be excluded from treatment what would be the reasons for excluding enrolment in the trial.
8. The Committee requested that the Data and Tissue Management Plan (DTMP) be revised to ensure there is a clear distinction to New Zealand laws such as the Privacy Act 2020 and Health Information Privacy Code and internal ‘Te Whatu Ora’ policy documents.
9. The Committee requested that the DTMP reflects what will be occurring in this specific study as there are references to those under the age of 16.
10. The Committee requested clarification of the study’s timeline as presented to participants to ensure that the duration of participation is clear.
11. The Committee requested that the sponsor consider providing further compensation than standard reimbursement for participants, given the extensive time and the potential commercialisation of the product after the study.
12. The Committee requested the investigators re-examine the approach to mandatory pregnancy tests for women of childbearing potential at every treatment cycle. Currently, the protocol requires a pregnancy test at the start of each 21-day cycle without exception. The Committee acknowledged the importance of avoiding any risk to a pregnancy given the investigational medicines’ mode of action, however, also highlighted the need to respect the right to bodily autonomy and decisions participants can be included in. The Committee noted that discussion with participants can minimise if not preclude the need for such regular mandatory testing.
13. The Committee requested that the sponsor consider providing the investigational treatment to participants in the control arm after the study, especially if their disease progresses.

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

1. Please consider revising the PIS to only refer to the acronym PD-1. The spelled-out term could be distressing or confusing to patients, even though it’s a scientific term, and removing it will make the reading more participant-friendly.
2. Please revise ‘urines’ test to ‘urine’ test.
3. Please remove any references to legally authorised representatives giving consent for participants to be in research as this is not applicable in New Zealand.
4. Please consider revising the side effects section in the PIS to provide the main adverse events for the experimental treatment in the main document and a complete list of other side effects from other drugs can be provided in an appendix.
5. Please clarify the mandatory genetic testing component of the study and provide in the PIS that the study requires a DNA test of the tumour to determine eligibility for participation. Additionally, include information on what this means for the participant, explain that a part of their tumour tissue will be sent for genetic analysis, and clarify who will have access to these genetic results and how their privacy will be protected.
6. Please indicate whether Karakia is available at the point of tissue collection.
7. Please include reference to the fact that GP notification is mandatory in the PIS, as provided in the consent form.
8. Please revise language in the PIS regarding the psychological questionnaires. The Committee suggested including the statement provided in E3.3 of the submission regarding the management of potential risks identified from quality-of-life questionnaires. The PIS should not indicate that it is solely the participant’s responsibility to alert the researchers if they feel upset by any questions. Instead, please explain that the research team will monitor responses and check on participants’ well-being.
9. Please include a tick-box option for participants to indicate if they wish to receive a summary of the study results once the trial is completed.
10. Please remove reference to leukaemia in the pre-screening consent form.
11. Please clarify what is meant by ‘samples meeting the criteria for testing’
12. Please, refer to the trial medication as an ‘investigational treatment’ or ‘investigational medicine’ rather than calling it a ‘drug.’
13. Please review the list of ‘side effects’ and separate out adverse events. Ensure that PIS clearly differentiates between side effects caused by the study treatments and health events that can happen during the trial but aren’t caused by the treatment.
14. Please clarify that the investigational medicine is not approved by any regulator rather that indicating that it is not approved in New Zealand.
15. Please clarify vaccine guidance in the PIS and include that the study treatment can affect the immune system and certain vaccines might not be recommended during treatment. Outline that participants should check with the study doctors regarding vaccination prior to or during the trial.
16. Please revise contraception requirements for clarity and relevance. If a participant is using a highly effective form of contraception, additional barrier contraceptives are not necessary. Only participants who are not on such methods should be instructed to use condoms, in which case lube should also be used.
17. Please reword pregnancy reporting language stating that participants ‘must’ report a pregnancy as this cannot be a requirement. Phrasing that encourages reporting of pregnancy and outlines the follow-up process with the participant’s consent should be provided.
18. Please remove or rephrase any reference to ‘financial burden’ as a reason for not providing the drug in the section that discusses whether a participant can continue receiving the trial drug after the study. If the participant has been in the trial and the investigational medicine has been beneficial then the medicine should be available.
19. Please label ‘patient number’ clearly as ‘Participant Study ID’ as opposed to phone number in the patient card.
20. Please include CT scan risk information in the PIS risk section outlining the cumulative radiation exposure from frequent CT scans required in the trial and what affects they may have.

**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).*
4. Please update the data and tissue management plan, taking into account the feedback provided by the Committee (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).

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

## General business

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

The meeting closed at 3:40pm