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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 25 February 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11.30am-12.00pm |  | Committee welcome |  |  |
| 12.00-12.30pm | 2024 FULL 21177 | COG ARAR2221 | Dr Tristan Pettit | Jessie / Patries |
| 12.30-1.00pm | 2025 FULL 22164 | Making my own decisions about my health and wellbeing | Associate Professor Brigit Mirfin-Veitch | Cordelia / Albany |
| 1.00-1.30pm | 2025 FULL 21606 | VOLT ACL Study : Intraosseous Regional Administration of Diclofenac in Anterior Cruciate Ligament Reconstruction | Associate Professor Simon Young | Sandy / Patricia |
| 1.30-2.00pm |  | Break (30 min) |  |  |
| 2.00-2.30pm | 2025 FULL 21658 | Zolar | Dr Remy Lim | Sandy / Patries |
| 2.30-3.00pm | 2025 FULL 21267 | A team approach for tamariki with feeding difficulties | Dr. Sarah Leadley | Cordelia / Patricia |
| 3.00-3.30pm | 2025 FULL 21985 | The Effect of Retatrutide Once Weekly on Cardiovascular Outcomes and Kidney Outcomes in Adults Living with Obesity | Dr. Kalpa Jayanatha | Jessie / Albany |
| 3.30-4.00pm |  | Break (30 mins) |  |  |
| 4.00-4.30pm | 2025 FULL 20610 | Comparing two weight-based hypoglycaemia treatment protocols in children and teenagers using insulin pumps at the 2026 diabetes camp. | Mr Lindsay McTavish | Cordelia / Albany |
| 4.30-5.00pm | 2025 FULL 21628 | NICU patient responses to oxygen therapy | Dr Daniel MacKay | Jessie / Patricia |
| 5.00-5.30pm | 2025 FULL 22075 | A study in healthy women comparing Mi-Gel® and estriol gel applied topically for 6 consecutive days. | Dr Noelyn Hung | Helen / Patries |
| 5.30-6.00pm | 2025 FULL 21519 | A study in healthy women comparing Mi-Gel® and amitriptyline gel applied topically for 6 consecutive days. | Dr Noelyn Hung | Helen / Patries |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (Consumer/Community perspectives) (Chair) | 22/05/2018 | 22/05/2020 | 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) | 20/05/2017 | 20/05/2020 | 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 |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Present |
| Dr Andrea Furuya | Non-Lay | 03/03/2025 | 02/03/2029 | Present |

## Welcome

The Chair opened the meeting at 11.30am 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 26 November 2024 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2024 FULL 21177** |
|  | Title: | COG ARAR2221: A Phase 2 Study Using Chemoimmunotherapy with Gemcitabine, Cisplatin and Nivolumab in Newly Diagnosed Nasopharyngeal Carcinoma (NPC) |
|  | Principal Investigator: | Dr Tristan Pettit |
|  | Sponsor: | Children's Oncology Group |
|  | Clock Start Date: | 13 February 2025 |

Katherine Denton 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 sought clarity about whether samples would be sent overseas. The Researcher advised this is optional for banking and participants would consent to this in the optional consent form.
2. The Committee sought clarity if cisplatin plus gemcitabine, instead of cisplatin plus 5FU is an experimental aspect of this study. The Researcher advised this is approved in New Zealand and not considered investigational.

Summary of outstanding ethical issues

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

1. The Committee noted that there is an emergent issue with USA Federal Government funding for research. The Committee noted that studies had been suddenly terminated without regard to the welfare of participants, and that this could also impact New Zealand participants if a study was terminated without warning in breach of ethical principles and the New Zealand Ethical Standards. The Committee requested written assurances from the Sponsor’s Chief Medical Officer, Chief Financial Officer, and Chief Legal Officer, inclusive, that the USA Federal Government is not the source of any funding. If there is US Federal Government funding, this should be highlighted, and the study will require further consideration by the Committee**.**
2. The Committee request health information going overseas includes just month and year of birth rather than full date of birth, as this this is an identifier.

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

1. Please review for repetition and make more concise where possible for ease of readability.
2. Please clearly outline what standard of care is in New Zealand, so potential participants understand what treatment they would receive if they declined to join the study.
3. Please clearly outline all the experimental aspects of the study, for example, the calibration of radiation based on the participants response to the study drugs and the selection of the number of cycles of study drug post radiation.
4. On page 3 where it states that Nivolumab is approved in New Zealand by Medsafe, please clarify that this is for use in other cancers, and that this is an off-label usage.
5. On page 4 please state where in the USA the Central review will occur, city and state.
6. On page 5 please remove the detail about tissue banking, instead reference the separate tissue banking PIS/CF.
7. On page 2 of the older child assent form, and on page 5 of the parental PIS please add the safety plan from E3.1 which covers what will happen if anything should arise during the completion of questionnaires.
8. On page 12 please state that it is coded data that will be shared broadly, including with COG and HDEC.
9. On page 13 please clarify what is meant by there being a problem with access to nivolumab or if this won’t apply to New Zealand then delete this statement.
10. In the older child assent form please add additional information around privacy under ‘collection of information’. Such as how long information may be kept and who will have access to it.
11. Please change the wording from ‘you will not be penalised or lose benefits’ to less emotive language, such as ‘you will continue to receive standard of care’.
12. Please also include Māori cultural support information on the short form.
13. The future unspecified research PIS at the end of the assent forms is very heavy reading for children.

**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, and specifically also address the issue of continued federal funding for COG studies.
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 Dr Patries Herst.

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| **2** | **Ethics ref:** | **2025 FULL 22164** |
|  | Title: | Reimagining supported self-management of health and wellbeing with people with learning disability in Aotearoa New Zealand |
|  | Principal Investigator: | Associate Professor Brigit Mirfin-Veitch |
|  | Sponsor: | Donald Beasley Institute |
|  | Clock Start Date: | 13 February 2025 |

Associate Professor Brigit Mirfin-Veitch, Patrick Doherty and Nic McKenzie 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.

Mx Albany Lucas declared a potential conflict of interest and the Committee determined this was not substantial and Mx Lucas was able to participate in the discussion and decision.

Dr Thomas declared a potential conflict of interest and the Committee determined this was not substantial and Dr Thomas was able to participate in the discussion and decision.

**Summary of resolved ethical issues**

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

1. The Committee sought clarity around how the patient information form (PIF) would be used. The Researcher explained that there would be an in-person discussion about the study and if the individual is interested then the PIF would be given. This would be prior to issuing the participant information sheet (PIS).
2. The Committee noted the start date of 3 February 2025 and queried whether the research had already started. The Researcher confirmed that the study had not commenced, and that date would be revised.
3. The Committee sought clarity about whether family members and health workers would be discussing the participant or their own views. The Researcher advised that they would be seeking their personal views and experiences, and not about the participant.
4. The Committee noted and the Researcher agreed that family members cannot consent for participants with learning disabilities unless they are the Welfare Guardian, and that if an individual with learning disabilities cannot consent and has no one legally entitled to consent on their behalf, they cannot be included in this study.
5. The Committee queried if there would be a koha to participants. The Researcher confirmed there would be in the form of gift vouchers, as well as separate reimbursement for travel costs.
6. The Committee queried whether assistive technology would be used in the study. The Researcher advised that this would only be used with individual participants where they already use assistive technology.
7. The Researcher explained that once all the requested changes have been made to the PIS/CF it will be translated into an easy-read version for individuals with learning disabilities.

**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 all researchers are trained to redirect family members and health professionals if they start to discuss the participant with learning disabilities.
2. The Committee noted that the peer reviewer has not circled ‘approved’ on the scientific peer review form, please rectify.
3. The Committee requested a copy of the interview schedule.
4. The Committee requested a summary of the study be added to the start of the PIF.
5. The Committee requested that the Disclosure of Abuse policy is reworded to reflect the researcher’s obligation to ensure that any possibility of ongoing abuse is immediately reported.

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

1. Please submit an easy-read version of the PIS/CF for people with learning disabilities for HDEC approval.
2. Please add a statement to advise family/service workers/health professionals not to talk about the individual with learning disabilities, rather just to discuss their own views and experiences.
3. Please add a footer to each of the forms.
4. On page 7 please remove the personal address and instead use the sponsor address, for safety reasons.
5. Please change the wording on page 10 to reflect that HDEC only review the ethical aspects of the study.
6. Please provide a consent form for the focus groups which states that they must not share other participants information.
7. Please add a statement that participants have a right to access and request to correct information about themselves.
8. Please add a Māori cultural statement regarding data.
9. Please provide more information regarding who will have access to my information. The PIS/CF templates on the HDEC website give guidance on what should be included.
10. Please include information about the interview schedule, such as where it will occur and how long it will take.
11. On page 7 please include an ACC statement.
12. Please add contact numbers for Māori and Pasifika cultural support.

**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 Dr Cordelia Thomas and Mx Albany Lucas.

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| **3** | **Ethics ref:** | **2025 FULL 21606** |
|  | Title: | VOLT ACL Study: Intraosseous Regional Administration of Diclofenac in Anterior Cruciate Ligament Reconstruction |
|  | Principal Investigator: | Associate Professor Simon Young |
|  | Sponsor: | North Shore Surgical Centre |
|  | Clock Start Date: | 13 February 2025 |

Associate Professor Simon Young and Patrick Wong 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 sought clarity around the statement that standard of care is intraosseous diclofenac, as this is what the study intervention is. The Researcher explained that this is his preferred method of treatment and that he wants to do the study to validate it, however it is not standard of care for other surgeons.
2. The Committee questioned whether the peer reviewers’ comments around pain as an outcome measure had been addressed. The Researcher advised that they had updated their protocol in response to this, to assess pain while at rest and when moving.

**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 asked that the Data Management Plan be more specific around how data may be used in future. If there will be future unspecified research this will require a separate participant information sheet/consent form (PIS/CF).
2. The Committee recommend that a koha is provided to participants to acknowledge their contribution to the research.
3. The Committee noted that pregnant people should not be excluded as standard.
4. The Committee noted that currently there are conflicting statements in the PIS and CF around withdrawal of data if a participant withdraws. Please decide what the process will be and update documents to reflect this consistently.
5. The Committee requested that the section on data linkage be removed from the Data Management Plan as it is not applicable.

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

1. Please include a safety plan for carrying out quality of life questionnaires. Your answer to E3.1 would be acceptable.
2. Please remove the optional tick box for notifying the GP as this should be mandatory.
3. Please clarify that standard of care for someone who chooses not to participate in the study will be determined by their surgeon.
4. Please rephrase the wording on page 2 around ‘significant’ pain relief, to make it clear what would exclude them from participation.
5. Please state how participants would request findings of the study.
6. Please advise participants whether they will be required to undress for the physical examination, and that they can bring a support person.
7. Please remove reference to flipping of a coin for randomisation, instead state you have a 1 in 2 chance.
8. Please clarify that it is a paper dairy and provide any instructions about when this needs to be brought in.
9. Please use consistent language when referring to the participants GP, rather than alternating between usual doctor and health provider.
10. Please change wording on page 2 around ‘poorly controlled mental health’, as this is judgemental.
11. On page 8 please change Māori health support, to Māori cultural support.
12. Please remove the statement about data linkage as this does not apply to this study.
13. Please remove reference to direct benefits from the study as this is not yet known.
14. Please remove reference to randomisation being balanced, otherwise justification for this claim will be required.

**Decision**

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

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

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

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| **4** | **Ethics ref:** | **2025 FULL 21658** |
|  | Title: | An open-label, Phase 1 study to assess safety, tolerability, dosimetry, pharmacokinetics, and imaging properties of 89Zr-olaratumab (89Zr-TLX300-CDx) in participants with soft tissue sarcoma. |
|  | Principal Investigator: | Dr Remy Lim |
|  | Sponsor: | Telix Pharmaceuticals (Innovations) Pty Limited |
|  | Clock Start Date: | 13 February 2025 |

Dr Remy Lim, Faye Sommerville and Jess Fagan were present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

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

**Summary of resolved ethical issues**

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

1. The Committee clarified with the Researcher that this specific antibody and Zirconium 89 combination has not been used before in humans, and that it would only be suitable for use in soft tissue sarcoma. However similar trials have been done with other antibodies for other types of cancer.

**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 Telix will cover the $5,000 deductible in the event of an insurance claim.
2. The Committee requested the current medical registration certificate for Dr Lim.
3. The Committee noted that on page 58 of the protocol, it states that ‘the sponsor may terminate the study for any reason at the sole discretion of the sponsor’. This is incorrect, please change this to reflect that in New Zealand, trials may not be terminated solely for commercial reasons. The sponsor may only terminate the study for any of the reasons outlined in sections 11.34 to 11.37 of the National Ethical Standards.
4. The Committee noted the answers to C4 – C6 in the application form were patronising and requested the Researcher be mindful of this for any future applications.

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

1. Please add the simplified diagram from the protocol to show how parts A, B and C are related.
2. Please highlight the statement about this being a first in humans’ trial in bold and put a box around it.
3. Please add the picture from the Investigators brochure illustrating an antibody attaching to tumour cells.
4. Please use cold rather than naked when describing the antibody not being radioactive.
5. Please state that Zirconium 89 has been used in previous studies and give an indication of in how many people. Also, that this resulted in an acceptable whole body radiation dose according to the ICRP (radiological protection in biomedical research).
6. Please remove tick boxes for items that are not truly optional in the consent form.
7. Please remove consents for future unspecified research (FUR) from the main PIS/CF and include these in the FUR/CF.
8. Please remove the form for written withdrawal of consent from the FUR/CF, as verbal notification of withdrawal is all that is required.
9. In the FUR/CF there is reference to an image being used, this should be images or imaging.
10. On page 10 please remove the statement “while this study does not involve any interventional treatment you will receive the study drug in an interventional manner”, as this is confusing.
11. On page 11 please remove the statement “the benefits from the study should be weighed against the possible detrimental effects of radiation”, as there are no direct benefits from the study.
12. On page 11 please use gender neutral language.
13. Please remove reference to unborn child, as this is emotive, instead refer to fetal development. On page 11 it states, “there is potential risk for an abnormal child being born”, the use of abnormal would be considered discriminatory and should be rephrased.
14. Please clarify if all participants will receive a $600 payment or whether this is pro-rata, also state the tax implications for the participants for any payments.
15. Please clarify where it is stated that it is optional for some PET scans, as it appears this may not apply to New Zealand.
16. Please advise the participant if they will need to underdress for a physical exam and whether they can bring a support person.
17. Please remove the statement on page 11 that states the risk of fatal cancer is acceptable.
18. Please remove reference to teaspoons of blood, just use ml’s.
19. Please provide ratios as well as percentages when referring to risks.
20. Please verify if it is correct that tissue samples may be returned to participants on request. If not, please remove this statement.
21. In the benefit section please give an example of potential incidental findings, such as the additional scans could detect an otherwise unknown metastasis and lead to appropriate treatment.
22. Please review for spelling and grammar. On page 9 a sentence is repeated twice.

**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 Sandy Gill and Dr Patries Herst.

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| **5** | **Ethics ref:** | **2025 FULL 21267** |
|  | Title: | Evaluating a multi-disciplinary team approach for tamariki with feeding difficulties |
|  | Principal Investigator: | Dr Sarah Leadley |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 13 February 2025 |

Dr Sarah Leadley and Jamielee Rogers were present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

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

**Summary of resolved ethical issues**

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

1. The Committee noted that the cultural issues for Māori and Pasifika were well answered and that a good consultation with Māori had been undertaken.
2. The Researcher advised that ACTIVEating was originally a training clinic for students but has involved into a more interventional model. No research has been carried out on the clinic to date.
3. The Committee requested clarification whether the parents are participants. The Researcher advised that they are not.

**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 recommend a koha is given to participants to acknowledge their contribution. Also consider how cost of food used in the study can be mitigated for parents. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.8*)
2. The Committee requested that the protocol be revised to better outline the different phases of the study, what will be carried out at each phase, and illustrate how the intervention would be beneficial. Ensure that outcome measures are clearly linked to the study aims. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7)*
3. Please supply evidence of Māori consultation to ensure the study is appropriate for a New Zealand context *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.7).*

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 change ‘you’ to ‘your child’ throughout, as the child is the participant not the parent.
2. Please clarify that the feeding room is a separate room from where the parent and researcher will be observing them via video link. Additionally clarify as there will be multiple children in the feeding room at once and therefore multiple parents observing that any conversations about an individual child will occur in a separate room between the researcher and that child’s parent only.
3. Please highlight that the parent is consenting for their child to participate, currently it reads as though the parent is consenting for themselves.
4. Please add additional information into the older child PIS, such as a Māori cultural statement, information about their data, including that they have a right to access and correct their data, and an ACC statement.
5. Please don’t use the wording ‘please help us’ as this could be perceived as coercive.
6. Please change reference to the child being ‘happy’ to participate, to that they ‘agree’ to participate.
7. In the section ‘what will the study involve’ please clearly outline where and when visits will occur.
8. Māori data is a taonga, so please remove ‘potentially’.
9. Please change ‘feeding’ to ‘eating’ in all contexts throughout.
10. Please check formatting. Currently “if you choose not to take part” is on one page and the rest of the sentence is on the next page. This is an important point and needs to be one the same page.
11. On the assent form under ‘how we can help’ please rephrase “anything we learn about you is kept secret”. As the use of secret goes against teaching children to not have secrets.
12. Please add videography as an option to the consent form.
13. Please use plain language throughout and define terms in lay language.

**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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| **6** | **Ethics ref:** | **2025 FULL 21985** |
|  | Title: | A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Event-Driven Study to Investigate the Effect of Retatrutide on the Incidence of Major Adverse Cardiovascular Events and the Decline in Kidney Function in Participants with Body Mass Index (BMI) ≥27 kg/m2 and Atherosclerotic Cardiovascular Disease and/or Chronic Kidney Disease (TRIUMPH OUTCOMES) |
|  | Principal Investigator: | Dr Kalpa Jayanatha |
|  | Sponsor: | Eli Lilly and Company |
|  | Clock Start Date: | 13 February 2025 |

Rebecca Sisterson and Tanya Poppe were present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

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

**Summary of resolved ethical issues**

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

1. The Committee noted that the contraception appendix was very well written, concise with gender neutral language.
2. The Committee noted that inclusion of lifestyle guidance was very helpful.

**Summary of outstanding ethical issues**

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

1. The Committee noted that there is an emergent issue with USA Federal Government funding for research. The Committee noted that studies had been suddenly terminated without regard to the welfare of participants, and that this could also impact New Zealand participants if a study was terminated without warning in breach of ethical principles and the New Zealand Ethical Standards. The Committee requested written assurances from the Sponsor’s Chief Medical Officer, Chief Financial Officer, and Chief Legal Officer, inclusive, that the USA Federal Government is not the source of any funding. If there is US Federal Government funding, this should be highlighted, and the study will require further consideration by the Committee**.**
2. The Committee noted that if family members may be asked to monitor the participant for suicidal ideation, the participant should consent to that and specifically which family member, and the family member would need to have their own participant information sheet/consent form (PIS/CF).
3. The Committee requests the sponsor to consider continue providing the drug at the end of the study on compassionate grounds, due to potential detrimental impact on participants mental health if they regain weight and their symptoms return.
4. The Committee noted that the PIS should be introduced and explained by someone other than the study doctor.
5. The Committee noted that the stated time frame for the study was a commencement date of 16 April 2024, concluding in 2029. These dates will need to be revised.
6. The Committee requested an updated insurance certificate be submitted as an amendment, as the current one will expire before the end of the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.5):*
7. The Committee requested a current Medical Protection Society certificate for indemnity for the Coordinating Investigator.
8. The Committee stated that if there will be optional future unspecified research this should have its own PIS/CF *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.58)*.

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 make it clear that it is likely the benefits of the drug will only apply while the participant is taking the drug and once the study ends and they are no longer taking the drug they will potentially re-gain weight and their symptoms may return.
2. Please state what the process will be if a risk of suicidal ideation is identified, currently it reads that the participant will be asked if they would like to be referred, however there is a duty of care to act immediately.
3. Please add to the exclusion criteria that the participant must have a family member who is able and willing to monitor them for suicidal ideation.
4. Please clarify your reimbursement policy and consider people who may not have access to a vehicle or public transport, as well as support people.
5. State that the participant’s General Practitioner (GP) will be informed in event of clinically significant abnormal findings/concerns. Delete optional tick-box in relevant CF clause as this should be mandatory.
6. Please rephrase emotive wording such as ‘you will not be penalised or lose benefits’, to something less threatening like ‘you will continue to receive standard of care’.
7. On page 6 where it states that if the participant withdraws, they will need to attend a final visit, please rephrase so that this is at the discretion of the participant, as if they withdraw, they are not obligated.
8. On page 7 genetic testing is mentioned, please clarify if this will be carried out and provide explanation and a consent clause.
9. On page 10 please provide additional information about lifestyle counselling, when, where how often and for how long will this be.
10. On page 16 please specify which notifiable diseases you will be testing for and ensure you are only testing for valid reasons. Generic exclusion of people with HIV is discriminatory.
11. On page 17 please clarify the reasons the sponsor may stop the study, as it cannot be stopped for commercial reasons alone.
12. Please state how much you will pay participants for their time. Also explain that you will process the tax.
13. On page 17 please reword the Māori data statement and remove ‘potential’ when stating that Māori data is a taonga.

**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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| **7** | **Ethics ref:** | **2025 FULL 20610** |
|  | Title: | Comparative Efficacy of 0.15 Grams of Glucose in Children Using Automated Insulin Delivery Pumps vs 0.3 Grams of Glucose in Children Using Non-Automated Pumps or MDI (multiple daily injections) for Treating Hypoglycaemia at a Diabetes Camp |
|  | Principal Investigator: | Mr Lindsay McTavish |
|  | Sponsor: | Endocrine, Diabetes & Research Centre |
|  | Clock Start Date: | 13 February 2025 |

No representative for the Researcher 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 about how recruitment and consent/assent will be carried out, and whether this occurs before the camp or at the camp. Please clarify if all camp participants be asked to participate or just those who experience a hypoglycaemic event. The Committee raised concerns about participants and parents having sufficient time to consider their decision to participate and to ensure there was no coercion, in terms of feeling pressured to participate if invited in a group setting at camp.
2. The Committee queried how often the hypoglycaemic events are predicted to occur.
3. The Committee requested information about the camp be provided, such as whether the same children attend every year.
4. The Committee noted that in B18 of your submission it reads as though data has already been collected. Please clarify whether data has already been collected, and whether ethical approval had been obtained for this. B18 also states that this is an observational study, however this is an interventional study, as participants are assigned to different doses.
5. The Committee encourage the Researcher to attend the next meeting to answer questions and gain clarity around what the Committee are asking.
6. The Committee requested clarification about what the Coordinating Investigator’s relationship is to the camp.
7. All researchers should collect good quality ethnicity data unless there is a particular justification for not doing so. Ethnicity data for New Zealand sites is provided to HDEC at the time of the final report; please collect at a site level if not required for the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.20)*.
8. The Committee raised that in your submission answers to C5, no cultural issues were noted, however relevant cultural issues for this study would be information as a taonga, and participants may feel whakamā if experiencing a hypoglycaemic event at camp in front of other people.
9. The Committee noted that the responses to cultural consideration questions in the application form were incomplete. The Committee recommended including any statistics of the prevalence of the disease in Māori and Pacific peoples (or an explanation if unknown) when answering this question, as well as seeking guidance through consultation.
10. The Committee questioned the scientific validity of comparing 0.15g via AID pump to 0.3g without a pump and suggest that these doses should be compared both using the same pump. Randomising using mystery envelopes makes no sense if the comparison were between pump users and non-pump users, as participants would either have a pump or not. Please address this in the protocol.
11. The Committee requested information about the secondary outcome measure of rebound hyperglycaemia be added to the protocol, including how this will be managed for the participant. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8)*
12. The Committee requested clarification about whether future unspecified research would be carried out using the study data. If so, this would need to be consented to separately.
13. The Committee noted that if a study protocolises an interventional dose, then it is usual for the study to provide the medicine, however there is no allowance in the budget for medicine.
14. The peer review submitted doesn’t meet HDEC requirements of being independent from the study. Please provide an independent peer review. The [HDEC peer review template](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance/) can be used *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*

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 check for typos and grammar. Remove italics, for ease of reading. Ensure all dates are updated to reflect the study will now occur at the 2026 camp.
2. The main PIS/CF should be used for parents and participants over 16. There should be two assent forms, one for younger children and one for older children.
3. Parents are not participants so the Main PIS/CF needs rewording to state ‘you/or your child’. It should also be stated that parents are giving proxy consent on behalf of their child, not consenting for themselves.
4. Please provide more information in the older child assent form. This should include a Māori cultural statement, information on data management, including their right to access and correct data about them, and an ACC statement.
5. The younger child assent form needs to explain what will happen if the child has a hypoglycaemic event at camp.
6. Please change the wording “you have been chosen”, it is up to the participant and their parent to choose. It would be better to say “You have been invited to participate”.
7. On the assent form please change the wording that states parents “are happy for you to be a part of it”, as this is coercive.
8. The main PIS should state if a child does not assent, then they will not be included in the study.
9. Note that if any participants turn 16 during the study they will need to be reconsented using the main PIS/CF.
10. Please provide information about the secondary outcome of rebound hyperglycaemia and what this will mean for participants.
11. Please add an ACC statement.
12. The Committee noted that nothing can be raised in the consent form without first being explained in the main body of the information sheet. Please review the items in the consent form and review any that are not applicable. For example, sending tissue samples overseas, and risks with pregnancy, as this is not mentioned anywhere else.
13. On page 4 please state who has access to the coded data, other than the research team.
14. Please explain if Diabetes management software applies to all participants.
15. Please include exclusion criteria.
16. On page 5 please clarify that if a participant withdraws the Researcher will ask if they can continue to use data already collected. As no further data can be collected once they have withdrawn.
17. On page 3 please remove the statement that there are no risks to the participants family members.

**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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| **8** | **Ethics ref:** | **2025 FULL 21628** |
|  | Title: | SpO2 responses to changes in inspired FiO2 in NICU patients on non-invasive respiratory support therapies |
|  | Principal Investigator: | Dr Daniel MacKay |
|  | Sponsor: | Fisher & Paykel Healthcare Limited |
|  | Clock Start Date: | 13 February 2025 |

No representative for the Researcher 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 strongly recommend that the researcher attend future meetings to answer questions.
2. The Committee questioned the rationale for not publishing the research, in particular what will be done for Māori to acknowledge that their data is a taonga.
3. The Committee recommends participants be given a koha to acknowledge their contribution to research.
4. The Committee requested clarification about what screening you are referring to on page 6.
5. The Committee do not believe this is commercially sensitive research.
6. The Committee noted that the responses to cultural consideration questions in the application form were incomplete. The Committee recommended seeking guidance through consultation.
7. The Committee asked for clarification in the data management plan 7.3 if there will be future unspecified research. If so, this will require a separate PIS/CF. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*
8. The Committee noted the protocol contains a section on investigational equipment accountability and asked for clarification if the sponsor will be providing equipment or whether existing hospital equipment will be used, as it is indicated that the baby will receive standard of care.
9. The Committee request that the statement ‘no additional national or regional regulations are applicable’ is removed from the protocol, as this is incorrect.
10. The Committee queried whether clinicians would be receiving any funding or reimbursement from the sponsor.
11. The Committee noted that the scientific peer review is incomplete. Please provide another completed peer review. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26)*
12. The Committee noted that in the submission the answer provided to C3.3 stated that this study is using kaupapa Māori methodology. Please provide an explanation for how this study is using kaupapa Māori methodology.
13. The Committee noted that insurance will expire in April this year, so a new insurance certificate will need to be provided.
14. The Committee questioned how consenting will be carried out, given the sensitive situation of having a child in NICU.

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 state which Māori committee consultation was undertaken with. Currently only an individual is mentioned.
2. Please provide more detail about the purpose of the study. Provide specifics rather than a broad generalisation.
3. Please check for grammar and correct typos.
4. In the consent form please change caregiver to guardian, as per the Care of Children Act.

**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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| **9** | **Ethics ref:** | **2025 FULL 22075** |
|  | Title: | A multiple dose, open label, balanced, randomised, two-treatment, two period, two sequence, two-way crossover pilot study comparing Mi-Gel® (containing amitriptyline 5mg/g and estriol 0.3mg/g) to estriol 0.3mg/g in healthy women under steady state conditions. |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Aspen Pharmacare Australia Pty Ltd |
|  | Clock Start Date: | 13 February 2025 |

Linda Folland and Louise B. were present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

Ms Jessie Lenagh-Glue declared a potential conflict of interest and did not participate in the discussion or decision.

**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 why 2025 FULL 22075 and 2025 FULL 21519 were done as separate studies. The Researcher clarified that there are slightly different blood tests involved and that by making them separate studies mean they are shorter and more likely to retain participants.

**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 Coordinating Investigator email the secretariat to clarify why HIV and Hepatitis B and C testing is being carried out. If it is for staff safety as indicated in the PIS, this is not acceptable reasoning, as knowing the participants HIV/Hepatitis status does not protect staff from needle stick injury.
2. The Committee noted that insurance will expire before the end of the study and will need to be renewed.
3. The Committee noted that the submission did not address cultural issues for Pasifika. Of relevance is that anything involving genitalia is extremely sensitive and gender-matching of staff to participants is particularly important, especially for accompanying the participant to the bathroom.

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

1. Please remove the statement on page 2 that says at the end of the study there will be no further treatment available to you, as these are healthy participants.
2. On page 12 please include side effects associated with estriol.
3. Please correct the HDEC to Central not Northern B.
4. Please use assigned ‘female at birth’ rather than ‘woman’, as this is more inclusive.
5. Please state 2000mg rather than 2g for paracetamol, as mg is the more standard use.
6. Tampons can be used, please clarify if menstrual cups and discs can be used.
7. Please reword “start a family” in the contraception section.
8. Please include a statement notifying the participant if they will be required to undress for the physical examination.
9. Please use ratios as well as percentages in the risk section.
10. On page 2 please use ‘withdraw’ rather than ‘pull out’. Also note that any further monitoring would be with the participants consent.
11. On page 3 where it says doctor, please clarify if this means G.P.
12. On page 5 it states no bathroom visits. Please reword this to indicate where possible.
13. On page 9 please state the diary will be paper. Also clarify that checking for side effects means asking the participant not physically examining them.
14. On page 8 please reword to say that if you leave the clinic, you will be withdrawn from the study.
15. On page 11 please clarify that red blood cells will be disposed of immediately after analysis, but plasma will be kept for a year post study and the reasons for this.

**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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| **10** | **Ethics ref:** | **2025 FULL 21519** |
|  | Title: | A multiple dose, open label, balanced, randomised, two-treatment, two period, two sequence, two-way crossover pilot study comparing Mi-Gel® (containing amitriptyline 5mg/g and estriol 0.3mg/g) to amitriptyline 5mg/g in healthy women under steady state conditions. |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Aspen Pharmacare Australia Pty Ltd |
|  | Clock Start Date: | 13 February 2025 |

Linda Folland and Louise B. were present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

Ms Jessie Lenagh-Glue declared a potential conflict of interest and did not participate in the discussion or decision.

**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 why 2025 FULL 22075 and 2025 FULL 21519 were done as separate studies. The Researcher clarified that there are slightly different blood tests involved and that by making them separate studies mean they are shorter and more likely to retain participants.

**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 Coordinating Investigator email the secretariat to clarify why HIV and Hepatitis B and C testing is being carried out. If it is for staff safety as indicated in the PIS, this is not acceptable reasoning, as knowing the participants HIV/Hepatitis status does not protect staff from needle stick injury.
2. The Committee noted that insurance will expire before the end of the study and will need to be renewed.
3. The Committee noted that the submission did not address cultural issues for Pasifika. Of relevance is that anything involving genitalia is extremely sensitive and gender-matching of staff to participants is particularly important, especially for accompanying the participant to the bathroom.

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2. On page 12 please include side effects associated with amitriptyline.
3. Please correct the HDEC to Central not Northern B.
4. Please use assigned ‘female at birth’ rather than ‘woman’, as this is more inclusive.
5. Please state 2000mg rather than 2g for paracetamol, as mg is the more standard use.
6. Tampons can be used, please clarify if menstrual cups and discs can be used.
7. Please reword “start a family” in the contraception section.
8. Please include a statement notifying the participant if they will be required to undress for the physical examination.
9. Please use ratios as well as percentages in the risk section.
10. On page 2 please use ‘withdraw’ rather than ‘pull out’. Also note that any further monitoring would be with the participants consent.
11. On page 3 where it says doctor, please clarify if this means G.P.
12. On page 5 it states no bathroom visits. Please reword this to indicate where possible.
13. On page 9 please state the diary will be paper. Also clarify that checking for side effects means asking the participant not physically examining them.
14. On page 8 please reword to say that if you leave the clinic, you will be withdrawn from the study.
15. On page 11 please clarify that red blood cells will be disposed of immediately after analysis, but plasma will be kept for a year post study and the reasons for this.

**Decision**

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

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

## General business

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

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| **Meeting date:** | 25 March 2025 |
| **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. **Other business**

The sudden cessation of United States of America federal funding to research, including clinical research in human participants, was raised as having potential impact on New Zealand participants.  It was noted that the existence of any federal funding, e.g. NIH, CDC, HHS, USAID, or Federal Grants to Universities for indirect support of research, etc, is a question that will need to be asked of all Sponsors who are based in the USA starting with this meeting’s studies. This matter will be raised with the Chairs and Secretariat to ensure a consistent approach.

1. **Any other business**

The Committee farewelled Helen, thanking her for her long service and acknowledging the impact she has had on shaping the Committee.

The meeting closed at 5.30pm.