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| **Committee:** | STH Health and Disability Ethics Committee |
| **Meeting date:** | 13 May 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 10:00 - 10:30am |  | *Committee Welcome* |  |  |
| 10:30 – 11:00am | 2025 FULL 22521 | Study on Felzartamab in Adults with immunoglobulin A Nephropathy | Dr Kalpa Jayanatha | Jonathan / Geoff |
| 11:00 – 11:30am | 2025 FULL 22346 | ACCESS-AID Study – Accelerating Care, Capacity & Equity in AID Systems for New Zealanders with Type 1 Diabetes | Professor Benjamin Wheeler | Dominic / Amy |
| 11:30am – 12:00pm | 2025 FULL 21491 | Animal Assisted Treatment with Children | Mrs Joanne Hona | Dianne / Joan |
| 12:00 – 12:30pm | 2025 FULL 22673 | A Study Evaluating the Efficacy and Safety of ALG-000184 Compared with Tenofovir Disoproxil Fumarate in Patients with Chronic Hepatitis B | Professor Edward Gane | Maree / Amy |
| 12:30 - 1:00pm |  | *Break (30 mins)* |  |  |
| 1:00 – 1:30pm | 2025 FULL 22612 | CDX0159-13 A Phase 3 Study of Barzolvolimab in Patients With Chronic Spontaneous Urticaria (EMBARQ – CSU2) | Dr Claire Thurlow | Dominic / Geoff |
| 1:30 – 2:00pm | 2025 FULL 22295 | LeAAPS Trial | Dr Zachary DeBoard | Dianne / Amy |
| 2:00 – 2:30pm | 2025 FULL 22605 | Comparative efficacy of 0.15 grams/kg glucose treatment in Children and Teenagers using Automated Insulin Delivery Pumps vs 0.3 grams/kg of glucose for managing hypoglycaemia episodes. | Mr Lindsay McTavish | Jonathan / Joan |
| 2:30 – 3:00pm | 2025 FULL 22856 | CT-388-104: A Study to Evaluate How Safe, Well Tolerated and Effective CT-388 is in People Who are Overweight or Obese with Type 2 Diabetes | Dr Rinki Murphy | Maree / Geoff |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mr Dominic Fitchett | Lay (the Law) | 05/07/2019 | 05/07/2022 | Present |
| Dr Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Ms Joan Pettit | Non-Lay (Intervention Studies) (Chair) | 08/07/2022 | 08/07/2025 | Present |
| Ms Dianne Glenn | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Dr Geoff Noller | Non-Lay | 03/03/2025 | 02/03/2029 | Present |

## Welcome

The Chair opened the meeting at 10:00am and welcomed Committee members, noting that apologies had been received from Dr Nicola Swain and Ms Neta Tomokino.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Joan Pettit and Mr Jonathan Darby confirmed their eligibility and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 8 April 2025 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2025 FULL 22521** |
|  | Title: | A Phase 3, Randomized, Double-blind, Placebo-controlled Study of Felzartamab in Adults With IgA Nephropathy (PREVAIL) |
|  | Principal Investigator: | Dr Kalpa Jayanatha |
|  | Sponsor: | Biogen, Inc. |
|  | Clock Start Date: | 1 May 2025 |

Dr Kalpa Jayanatha, Amy Tong 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 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 Data Management Plan (DMP) include any institutional policies that will be followed in addition to references to relevant laws.
2. The Committee requested governance of data be described more carefully, especially with information being sent overseas,
3. The Committee requested clarification about what is involved for participants who are recruited into the exploratory cohort. The Researcher indicated that the procedures are the same in the exploratory cohort as the main study so the same Participant Information Sheet (PIS) would be used but would seek clarification with the sponsor and adjust documentation as necessary.
4. The Committee requested that the study ensure that it collects New Zealand relevant ethnicity data.

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

1. Please revise PIS for readability, revising technical into Lay language where possible.
2. Please ensure General Practitioner (GP) notification is mandatory.
3. Please include more detailed explanation of ‘Scout Clinical’ as a service based overseas and how participant information will be protected overseas.
4. Please include information about the risk factors and restrictions on participants who undergo kidney biopsy during the study.
5. Please add "access your medical record" to the list of procedures.
6. Please describe how samples will be used in "non-optional" ways for the 25 years under the description of how samples will be retained. Specify whether the use is limited to the development of this drug or if it is broader.
7. Please add a description of the kinds of topics the questionnaires will address.
8. Please revise wording from accessing "hospital" records to accessing "medical records".
9. Please describe what the ‘non-optional’ uses of samples is.
10. Please provide more detail in the PIS for Genetic/Genomic research. This should include descriptions of what kind of research will be done, any risks to the participant and their families, and provision of any incidental findings to the participant.

**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 management plan, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Jonathan Darby and Dr Geoff Noller.

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| **2** | **Ethics ref:** | **2025 FULL 22346** |
|  | Title: | Advanced Diabetes Technology – A New Model of Care for Faster and More Equitable Access |
|  | Principal Investigator: | Professor Benjamin Wheeler |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 1 May 2025 |

Professor Benjamin Wheeler and Jennifer Gale 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 the intervention in this study is the ‘model of care’ and the devices and technology used in this study are all standard of care.
2. The Researchers confirmed that this study has been registered to clinical trials registry.
3. The Researchers clarified that they would aim to have parents involved in all consenting processes for participants under 16, however ensuring that the child is aware that have agency in the process.
4. Researchers clarified that there is theoretically no age range for this study, however the referral forms with all the inclusion criteria would still need to be completed.
5. Researchers clarified that the reason for including wording “…make sure the participants healthcare providers are able to continue their care after enrolment in the study” in the PIS as opposed to mandatory GP notification is due to a region in New Zealand which refuses to see patients who have seen a different provider.

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 this is an ‘implementation’ research project where the research is changing the mode of delivery, not care itself. As such, the protocol is unclear whether components being measured are part of standard care or part of the assessment of the new method being trialled to make the broader impact on the population. The Committee therefore requested that the Protocol and PIS documents reflect specifically what is part of the study.
2. The Committee noted, for future reference, that not all participants will give informed consent, as children are being consented by their parent or guardian.
3. The Committee noted that the content for the adolescent PIS is very close to the full PIS. As such, the adolescent PIS can be removed, and guidance can be sought from parents or guardians on which PIS form would be appropriate for their child.
4. The Committee noted that quality of life questionnaires that cover mental health issues are being used in this study and were concerned about the length of time it would take for review of these questionnaires to take place, as the submission indicates that they will be reviewed at the time of data entry. The inclusion of this questionnaire in the study means researchers take on duty of care and therefore is role of researchers to provide safety plan to address anything that arises from asking those questions. The Committee requested that the solution raised by the Researchers be carried out, where a particular question of interest within the survey can be screened and flagged for real time assessment if concerns are raised. This will also protect researchers as it indicates that they have acted on something of concern appropriately.

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

1. Please revise risks section to focus on the risks that apply to the new ‘model of care’ being tested. Risks involved with the device and disease can be briefly outlined, however clarifying that its use is standard of care and not part of the study.
2. Please explain that medical tests outlined are standard of care and that these tests will be performed through the study if they had not been done recently by GP.
3. Please revise wording “destruction” of tissue to “disposal” of tissue, and consider including this information under its own section rather than under “study enrolment”.
4. Please ensure that it is clear that HDECS approve only ethical aspects of the study.
5. Please ensure page numbers are accurate.
6. Please ensure that it is clear in the parent and guardian PIS that, while the parent may participate in some capacity, the child is the primary participant in the study.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Dr Amy Henry.

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| **3** | **Ethics ref:** | **2025 FULL 21491** |
|  | Title: | Evaluating the Effectiveness of Dog Presence on Comfort and Distress Indicators Among Children Receiving Therapy who are Living in Whānau or Out-of-Home Care. |
|  | Principal Investigator: | Mrs Joanne Hona |
|  | Sponsor: | University of Canterbury |
|  | Clock Start Date: | 1 May 2025 |

Mrs Joanne Hona and Sarah Whitcombe-Dobbs 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 there are guidelines around informed consent with children and young people from the psychologists board in place where, if asking for consent from the parent would increase the risk to a child in any way, a psychologist can provide a rationale as to why the particular legal guardian will not be contacted.
2. The Researchers confirmed that disabled children would not be excluded from the study.
3. The Researchers clarified that the vouchers that will be given to children are warehouse vouchers.
4. Researchers confirmed that, while for some of these children Oranga Tamariki will have additional or sole guardianship of the children, consultation will still need to be done with the family.
5. The Researchers confirmed that there are other psychologists are available for children to see if participants decide to withdraw from the research.

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 Protocol be revised to address each of the requirements laid out by the *National Ethical Standards for Health and Disability Research and Quality Improvement*, para 9.7 and 9.8.
2. The Committee requested that the Protocol and PIS documents clearly state which procedures are specifically study related and which procedures are part of standard of care. As, in the context of the study, consent is being sought to participate in procedures unique to the study as opposed to standard of care procedures *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8, 7.15-7.17)*.
3. The Committee requested that the questions raised in the peer review document around randomisation and burden be addressed and provided.
4. The Committee requested further detail about the consent process is conducted in a way that ensures the safety of the child and the navigation of gaining legal informed consent on behalf of children from parents. Please outline how the Assent process is integrated with the consent process *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.26, 9.7-9.8)*.
5. The Committee requested that the location or possible locations at which this research will or could take place be provided *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
6. The Committee requested that information is provided describing how privacy is maintained for participants when sessions with the dog are taking place.
7. The Committee requested that the processes around the home visits, where initial contact is made, is provided in more detail, and that a researcher safety plan for these visits is provided *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62)*.
8. The Committee requested that, as this is an intervention study, it be registered with a World Health Organisation (WHO) approved trial registry.
9. The Committee noted that an assent form for young Tamariki has been provided, however a more comprehensive assent form for older children which provides more information on what would be involved in the study should also be provided *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.27)*.
10. The Committee requested that the Māori consultation form from the University of Canterbury be provided with responses as indicated by the Researcher.
11. The Committee noted that consultation had taken place with Ngai Tahu, however this is a South Island Iwi and research is taking place in far north. The Committee requested that documentation from consultation with Ngāpuhi, which the Researcher indicated has also taken place, be provided *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.3, 3.5)*.
12. The Committee noted that the Ministry for Pacific peoples were contacted and directed the Researcher to an on-line resource (Yavu-Booklet) and requested that information be provided in the protocol that outlines how learnings from this module will be applied if Pacific children are included in the study *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 4.4)*.
13. The Committee requested that the pictures that are shown to young people at the beginning and end of sessions to evaluate conscious feelings of calm be provided *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*.
14. The Committee requested that more detail is provided in the protocol around the consenting process for children who will be consenting for themselves and how they will be assessed for capacity to provide fully informed consent. Rationale should also be provided as to why consent is being sought from this age group *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.22, 6.26, 9.7-9.8)*.
15. The Committee queried whether someone else is available to be involved in the consenting process who is not directly involved in the research so as to avoid any undue influence *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.17-6.18)*.
16. The Committee requested information be provided describing duty of care if, over the course of the study, there are concerns around blood pressure and heart rate recordings carried out during the study *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.48)*.
17. The Committee noted that the current trauma framework shows little evidence of the ongoing therapeutic oversight for each participant during or after the trial. Safety planning for distress arising from the removal of animal assisted therapy when the study ends needs to be considered. Evidence of psychological debriefing or emotional planning to prevent retraumatisation in this case needs to be provided, as after 10 sessions the child may have formed an attachment to the dog. As such, the removal of interactions with the dog simulates loss and could be traumatic for the child. The Committee requested that the study design be revised to include clinical wraparound support if there is any exposure to loss or withdrawal and suggested that pre and post study support for up to 12 months be provided *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8, 11.25)*.
18. The Committee requested that cultural safeguards be revised to be more robust, including integration of tikanga, Kaupapa Māori, and mana enhancing practice for tamariki into the framework of the study *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 2.2)*.
19. The Committee requested that a trauma informed cultural response of care framework be included in the study and include independent child advocacy input into study design, or evidence of this, to reduce risk to child’s wellbeing *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.1-8.3*.

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 amend the PIS to use more objective, neutral, language. When potential participants are making their decision to consent the choice needs to be made without any undue influence or persuasion.
2. Please revise the mandated language from “you will need to…” to “the study involves.”
3. Please state at the beginning of the PIS that an interpreter is available as many potential participants will have te reo Māori as their first language.
4. Please remove tick boxes unless truly optional

**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:** | **2025 FULL 22673** |
|  | Title: | A Randomized, Double-Blind, Active-Controlled Multicenter Phase 2 Study Evaluating the Efficacy and Safety of ALG-000184 Compared with Tenofovir Disoproxil Fumarate in Untreated HBeAg-Positive and HBeAg-Negative Adult Subjects with Chronic Hepatitis B Virus Infection (B-SUPREME) |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Aligos Therapeutics |
|  | Clock Start Date: | 1 May 2025 |

Professor Edward Gane and Manish Patel 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 commended the Researchers on the quality of their submission.

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 Data and Tissue Management Plan and the Participant Information Sheet be revised to provide consistent information about whether Future Unspecified Research will be done.
2. The Committee requested that the study be registered with a clinical trials registry prior to commencement.

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

1. Please ensure that it is clear to participants that participation in the sub study is optional, and that inclusion in Future Unspecified Research is also optional.
2. Please clearly explain that for those that participate in the sub study the PBMC collection is mandatory, but for those who are not participating in the sub study it is optional.
3. Please clarify that TDF is available as standard of care in New Zealand, so the potential participant can understand how the research would differ from standard of care.
4. Please remove the word Addendum when describing the sub study and explain why the biopsies are being done.

**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 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).*

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| **5** | **Ethics ref:** | **2025 FULL 22612** |
|  | Title: | CDX0159-13 A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Barzolvolimab in Patients with Chronic Spontaneous Urticaria Who Remain Symptomatic Despite H1 Antihistamine Treatment (EMBARQ – CSU2) |
|  | Principal Investigator: | Dr Claire Thurlow |
|  | Sponsor: | Celldex Therapeutics, Inc. |
|  | Clock Start Date: | 1 May 2025 |

Dr Claire Thurlow, Charlene Botha, Jo van Zyl, Monika Nagpal, Nicole Sinclair, Alan Mendelsohn and Steven Greenberg were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. Please ensure that, once the levels of compensation have been determined, the relevant information be provided.
2. Please revise PIS to refer to the study medicine instead of the investigational and check the document for typos and repetition.
3. Please specify city and country where samples will be sent to match DTMP.
4. Please remove the yes/no tick boxes post withdrawal in the photo PIS as this is not optional.
5. Please provide further detail on the potential benefits of participating in the study are. Outline how more frequent checkups could be a benefit of participation. Describe clearly what would be available as standard of care, and what the participant will have access to as part of the study.

**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 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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| **6** | **Ethics ref:** | **2025 FULL 22295** |
|  | Title: | Left Atrial Appendage Exclusion for Prophylactic Stroke Reduction Trial |
|  | Principal Investigator: | Dr Zachary DeBoard |
|  | Sponsor: | ATRICURE, INC |
|  | Clock Start Date: | 1 May 2025 |

Dr Zachary DeBroad, Rebecca Ikura, and Kelly Henderson 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 ‘clip’ described in the study is routinely used in New Zealand and is a class one recommendation worldwide.
2. Researchers described the recruitment process, identifying that patients are contacted as soon they are identified for surgery, so they will have the maximum amount of time with the Information sheets. Typically, patients would receive the PIS 2-10 days before the beginning of the study.
3. Researchers clarified that there is no koha for participants in recognition of their time and contribution to the study.
4. The Researchers confirmed that there was understanding that there will be limited blinding, as people who are directly involved in surgery, MRI and other follow up procedures will not be blinded, however, those looking at the study data will remain blinded.
5. Please provide the above information in the PIS, alternatives fail, there is robust history of integrity of device over time, and there may also be other benefits as flow on effects as this option.
6. The Researchers clarified that the need for premenopausal women to have pregnancy testing is a routine laboratory evaluation for patients undergoing a surgical intervention. This is not done as automatic standard lab testing but after discussion with patients to understand if they would have this test done. The aim of this pregnancy testing is to avoid any risks for the pregnant individual and foetus associated with cardiac surgery.

Summary of outstanding ethical issues

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

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

1. Please include information in the PIS describing the left atrial appendage in more detail and the impacts that the blood clots it is associated with it can have. Highlight the history of studies looking at how the removal, sealing, or sewing of this appendage and how these procedures can reduce the associated risks.
2. Please include information about how previous procedures, such as sewing, stapling, partial removal, or total removal of the appendage had variable success rates, indicating that 30% - 70% of these procedures fail, and that the clips proposed to be used in this study have been shown to have 100% success rate, within defined parameters, for follow up periods of 3 to 6 months. Highlight that there is robust history of the integrity of the clip device and there have been no indications that the clips would come undone or fail for those that have had this procedure.
3. Please include detailed description of the blinding process and the limitations for this study. Explain that people directly involved in surgery, or seeing MRI or x ray follow ups will not be blinded. While researchers looking at study data will be blinded. Clearly identify that the blinding will not affect the participants standard of care.
4. Please revise the statement that says that participants, for the duration of the clinical trial, may only undergo treatment after consultation with study doctors. As this is currently too broad and would capture a variety of treatments that participants should not need to seek permission from study doctors to undergo.
5. Please revise wording in PIS to indicate that the HDEC approves ‘ethical standards’ of the study, not the entirety of the study.

**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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| **7** | **Ethics ref:** | **2025 FULL 22605** |
|  | Title: | Comparative efficacy of 0.15 grams/kg glucose treatment in Children and Teenagers using Automated Insulin Delivery Pumps vs 0.3 grams/kg of glucose for managing hypoglycaemia episodes at the 2026 National Diabetes Camp. |
|  | Principal Investigator: | Mr Lindsay McTavish |
|  | Sponsor: | Te Whatu Ora Capital, Coast and Hutt Valley |
|  | Clock Start Date: | 1 May 2025 |

Mr Lindsay McTavish 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 Researcher explained that current statistics indicate that approximately 60-70% of children are using automated insulin delivery (AID) pumps, and by 2026 expect 90% of the same cohort to be using AID.

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 Researchers confirmed that the control group is receiving the standard dose for a hypoglycaemic event and that having participants act as their own control removes bias for any outstanding variables. The Committee wasn’t entirely clear on the rationale and would like further explanation.
2. The Committee requested that a cover letter be developed for parents with the assurance that this, along with consent and assent forms, do not look like they are associated with the camp but that they are from the clinical research team.
3. The Committee noted that there are still outstanding issues from the previous decline letter that need to be addressed in the protocol. The current consent process, where PIS letters are sent to camp attendees with their acceptance letters and only allows for email correspondence needs to be revised. The consent and assent process needs to be outlined or revised so that the children are aware that they have the right to say no, as they are taking on the risks associated with participation before parents are involved. An option for the consent process could be to set up phone contact with the family where the child is spoken to first, where they are given the opportunity to ask any questions they may have, and then the consent process is finalised at the camp in person *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.20, 9.7-9.8)*.
4. The Committee requested that a procedure section be provided in the protocol describing what the Researcher has outlined regarding what will happen in the event of any participant having a hypoglycaemic episode. This section should clearly set out the research procedures and how they differ from the standard of care procedure. Explaining that the standard protocol at the camp for any child having such an episode is for the treatment to be given, and for a group leader to stay with the child until the episode is resolved. If after 15 minutes the episode is not resolved another dose is given and the group leader continues to stay with the child until the episode is resolved. Clearly identifying that this process would be the same for children who are randomised into the lower dose group *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
5. The Committee requested that specific sections of the protocol be provided that clearly outline the background rationale, methodology, procedures, the defined population and what product is being delivered and how it is known to be safe. Risks and benefits to participation in the study should also be included. This can be aided by diagrams for ease of understanding *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8)*.
6. The Committee noted that of the protocol requirements laid out by the [*National Ethical Standards for Health and Disability Research and Quality Improvement*, para 9.7 and 9.8](https://neac.health.govt.nz/national-ethical-standards/part-two/9-research-development-and-design/#_ftn5) provide a list of what should be included in a research protocol.
7. The Committee noted that a number of points from the previous decline letter have been addressed in the response letter or during the meeting, however these responses need to be reflected in the study documents, particularly the protocol.
8. The Committee requested that where the DMP states that all participants will provide informed consent be revised, as some participants will be providing assent *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*.

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 ensure that it is clear to participants, what any differences are between attending the camp and not participating in the research compared to attending the camp and also participating in the research.
2. Please revise the 16 years and over PIS to remove any reference to parents as participants 16 years and older do not have the need for parental consent.
3. Please ensure that the PIS and protocol documents are consistent. Currently the 16 years and over PIS indicates that that all participants will be on automated pumps, however the protocol suggests that some pumps may not be automated.
4. Please revise the assent forms to explain why you are doing the study, and what the risks and benefits are for participation.
5. Please address what procedures are in place if the dose given does not effectively manage the hypo event in both Assent and Parent/Over 16 PIS.
6. Please include an "Alternatives" section in both the Assent and Parent/Over 16 PIS that will explain that not participating will not affect the childs standard care, as currently the documents indicate that the hope is that all 50-60 children will participate in the study. This intention gives concern as people may not feel comfortable declining participation.
7. Please remove yes/no tick boxes from consent form unless truly optional.

**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 22856** |
|  | Title: | A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-center Phase 2 Study to Evaluate the Efficacy, Safety, and Tolerability of Once-Weekly CT-388 Administered Subcutaneously for 48 Weeks to Participants who are Overweight or Obese with Type 2 Diabetes Mellitus |
|  | Principal Investigator: | Dr Rinki Murphy |
|  | Sponsor: | Carmot Therapeutics Inc. |
|  | Clock Start Date: | 1 May 2025 |

Dr Rinki Murphy, Julia O’Sullivan, Lucy Druzianic, Kayla Malate, and Kaylyn Zhang was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researchers clarified that the exclusion for cannabis or cannabinoid related products specifically for this study is because of way that these products can increase appetite which could directly aspects of the study looking into appetite.
2. The Researchers clarified that tissues and deidentified data are kept for standard lengths of time in accordance with what is applicable to each type of information or sample.
3. The Researchers confirmed that consultation with Māori and pacific people has taken place along with HDEC application and follows usual processes in accordance with the level of consultation required.
4. The Researchers confirmed that anyone who enters the study who needs additional assistance will have it provided, and iterated that in person conversations and assistance are tailored to each individual participant.
5. The Researchers clarified that that the contraceptive requirements outlined are standard for an early phase study, however noting that the requirement for abstinence is unnecessary.
6. The Researchers clarified that there are no questions asked on sexual activity, only a yes/no question that includes a reference to sexual activity, which is necessary for accurate interpretation of menstrual chart.
7. The Researchers confirmed that there is a safety plan in place for any participants who indicate distress during the course of 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 queried whether there have been considerations to over sample Māori and pacific people and indicated that advertisements and recruitment strategies should encourage these groups to participate. Current advertising materials are pakeha oriented and may not facilitate high recruitment for Māori and Pacific people.
2. The Committee noted concern regarding the 3 month wash out period with the intention of helping enrolment and requested assurance that any decisions for people to come off their mental health drugs or medication is made completely outside of the study. The Committee want to ensure that people are not going off their mental health drugs specifically to be eligible for this weight loss drug and then not have appropriate care for their mental health.
3. The Committee requested that the advertising materials be revised to identify that the HDEC are responsible for approving ethical aspects of the study only.

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

1. Please proofread and review for typos, consider changing reference to CT388 to ‘study medicine’ for readability throughout the document.
2. Please revise moral terminology “history of drug abuse” in the exclusion criteria, up to date terminology such as “substance abuse disorders” or specifying “substance abuse in the last 12 months” could be implemented. Use of the word ‘abuse’ may result in people feel they are being labelled, which in turn may not facilitate recruitment. This would also extend to ‘drug abuse testing’ which could be changed to ‘non-prescribed use of drugs’.
3. Please revise wording from opiates to opioids so that it encompasses the entire class of drugs.
4. Please ensure that it is clear that both non-prescribed and prescribed use of cannabis would mean that people would be excluded for this study.
5. Please revise wording for medical emergencies including participants experience a severe allergic reaction after leaving the study site, currently the only options listed are to call 111 or to visit the ED. Include provision for contacting study clinicians.
6. Please revise document limiting descriptors and adjectives to improve layperson readability.
7. Please remove ‘reasonable’ from the wording indicating that participants will be reimbursed for reasonable travel costs for pre-screening visit.
8. Please revise wording ‘ill effects’ versus ‘injured’ from pre-screening for clarity.
9. Please ensure that is clear that GPs will be notified if there are any concerning results from pre-screening, however there is not mandatory notification of GPs for participants in the pre-screening phase.
10. Please revise wording around reimbursement for optional MRI for clarity. Explain whether the reimbursement for the MRI includes travel expenses or if there are separate reimbursements for the MRI itself and any travel cost.
11. Please ensure that it is clear to participants that they cannot self-administer the study drug.
12. Please include that GP notification is mandatory

**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 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).*

## General business

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

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| --- | --- |
| **Meeting date:** | 10 June 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. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 3:00pm.