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| **Committee:** | HDEC Health and Disability Ethics Committee |
| **Meeting date:** | 16 July 2024 |
| **Zoom details:** | 96507589841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12.30-1.00pm | 2024 FULL 20593 | BJT-628-001: A Study to Evaluate BJT-628 in Single and Multiple Doses in Healthy Participants and in Participants with Chronic Hepatitis B (CHB) and Chronic Hepatitis D (CHD) Infection. | Professor Edward Gane | Ms Catherine Garvey and Ms Jade Scott |
| 1.00-1.30pm | 2024 FULL 19729 | GuiDIng energy provision using indiREct CalorimeTry - DIRECT trial | Ms Varsha Asrani | Mr Jonathan Darby and Dr Kate Parker |
| 1.30-2.00pm | 2024 FULL 20663 | Safety and Efficacy of balloon dilation for Improvement of Swallowing in Patients with Upper Esophageal Sphincter obstruction | Associate Professor Jacqui Allen | Ms Catherine Garvey and Dr Sotera Catapang |
|  | *Break (10 mins)* |  |  |  |
| 2.10-2.40pm | 2024 FULL 20602 | NEU-111-UC101: A Study to Evaluate NEU-111 in Healthy Participants | Dr Leanne Barnett | Mr Jonathan Darby and Dr Andrea Forde |
| 2.40-3.10pm | 2024 FULL 20152 | Natural History Study of Exocrine Pancreatic Function in Infants With CF (VX24-445-130) | Dr Samuel Dalton | Ms Catherine Garvey and Ms Jade Scott |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Kate Parker | Non-lay (Observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Dr Andrea Forde | Non-lay (Intervention studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Catherine Garvey | Lay (the Law) (Chair) | 11/08/2021 | 11/08/2024 | Present |
| Dr Sotera Catapang | Non-lay (Observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Ms Jade Scott | Non-lay (Intervention/Observational studies) | 15/08/2021 | 15/08/2024 | Present |

## Welcome

The Chair opened the meeting at 12:00pm 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 18 June 2024 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2024 FULL 20593** |
|  | Title: | BJT-628-001: A Phase 1a/b, Randomized, Double-blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Antiviral Activity of BJT-628 in Healthy Volunteers and in Subjects with Chronic Hepatitis B Infection, Including Subjects with Chronic Hepatitis D Infection. |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | Bluejay Therapeutics, Inc. |
|  | Clock Start Date: | 04 July 2024 |

Professor Edward Gane, Ms Kayla Malate, Ms Lucy Druzianic, Ms Julia O’Sullivan, Ms Maria Yamet and Ms Rebecca Hall 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 confirmed that Parts B, C and D dosing will be determined once Part A (then B) is complete.

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 responsiveness to psychological care as a result of participation should be built into the study, including details of who participants are referred to, cost of this if any, and timeliness. The Researcher confirmed that any care would be covered by the study and referred to private assistance. The Committee noted that in the participant information sheet (PIS) that in relation to the reference to Lifeline it is clear that regardless of where the participant seeks help, the study team must be notified.

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

General:

1. The Committee noted that the Medicines New Zealand (MNZ) reference from template that states “some sponsors may-” and to be specific if the Study sponsor has committed to the MNZ guidelines or to otherwise appropriately rephrase to reflect the Sponsor’s position.
2. Notification to GP should be mandatory and not an optional component.

Part A PIS/CF:

1. Table on page 3 with the details of dosing group, refer to ‘LGT-305. Please amend.

Part C & D PIS/CF:

1. Table on page 7 mentions that participants will continue on current standard of care. Please ensure this information is included near the beginning of the document.

**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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| **2** | **Ethics ref:** | **2024 FULL 19729** |
|  | Title: | GuiDIng energy provision using indiREct CalorimeTry: a pilot feasibility randomised controlled trial in critically ill adults with obesity. |
|  | Principal Investigator: | Ms Varsha Asrani |
|  | Sponsor: | Te Whatu Ora To Toka Tumai |
|  | Clock Start Date: | 04 July 2024 |

Ms Varsha Asrani 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 raised the following queries arising from the application form answers:
   1. Inconsistent answers that note participant numbers are expected to be 50 in New Zealand, then later states 15. The Researcher clarified that the feasibility study will recruit 15 participants. The Committee requested to ensure there is only reference to these 15.
   2. The Committee noted if feasibility is proven in this study a new ethics application for a further study is required.
   3. Kaupapa Māori methodology is indicated, however this is not demonstrated. Kaupapa Māori methodology is ‘by Māori, with Māori for Māori’. Please correct this in the application form.
   4. D12 answer does not explain why it is most appropriate to conduct this study with non-consenting participants rather than those who are able to provide informed consent. While the study has an intended application for participants who cannot consent, for pilot purposes / a feasibility study, better explanation is required as to why the participants cannot be drawn from a group able to consent.
   5. D14 which asks how best interests will be ascertained has not been answered, and the process of determining best interests for an individual participant needs to be thoroughly documented in the protocol.
2. All researchers should collect good quality ethnicity data unless there is a particular justification for not doing so. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.20)*.
3. The Committee requested an additional comprehensive [peer review](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance) is undertaken.
4. The Committee requested an update to the protocol to include an argument for how participation will be in each participant’s best interest and how this will be assessed. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.70).*
5. The Committee noted a staff acceptability survey in the protocol appendix and advised if staff will be given a questionnaire this will make them study participants and they will need a brief information sheet and consent form.
6. The Committee queried whether a patient acceptability survey is necessary as participants would be unconscious and unaware of the intervention.
7. The Committee requested the data management plan is completed from a New Zealand perspective and data governance is included. Please correct any references to anonymised data as data will not be anonymous. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
8. Please ensure the correct start date is entered on the resubmission.
9. The Committee requested an update to the protocol to include a reference to the [National Ethical Standards for Health and Disability Research](https://neac.health.govt.nz/national-ethical-standards) in section 1.18. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
10. The Committee queried the rationale for excluding pregnant women after feasibility. The Committee noted ensuring someone who is pregnant has adequate calorie intake is important. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.15).*

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).*:

Adult providing own consent PIS/CF:

1. Please adjust to rephrase that this is consent to continue participation.
2. Please revise the first paragraph to correct the tense and improve the reference to the NZ Code. Please include an explanation of what the Code is.
3. Please include a statement advising this is a pilot study.
4. Please include the “best interests” justification for enrolling a participant without consent and explain why it was considered to be in their best interests to do so. Please make it clear they were enrolled without consent and a family member did not provide consent on their behalf.
5. Please revise the ‘what will my participation involve’ section to explain what participants will be required to do by participating in the follow-up research (e.g., answer questionnaires) and remove ‘do nothing’.
6. Please revise the benefits section to explain participants are unlikely to benefit from the study directly.
7. Please remove the ‘can I have other treatments’ section as this will not be relevant to participants.
8. Please revise the statement that data will be kept to ensure that this is optional so participants who do not wish to continue to participate may have their data removed.
9. Please state that data will be kept for 10 years and not indefinitely.
10. Please adapt relevant prompts from the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates) and ensure any references to laws and regulation are specific to New Zealand and not Australia.
11. Please include the compensation clause from the HDEC template.
12. Please adapt the consent form from the template.

Person responsible information sheet:

1. Please refer to this as a consultation form and not a consent form.
2. Please revise the title so it is not ‘person responsible’ and state next-of-kin or whānau.
3. Please revise the reference to the New Zealand code as above.
4. Please revise the sheet so it does not state it will help the person decide whether the participant takes part and instead asks whether the person thinks the participant would likely wish to participate if they were capable of giving consent.
5. Please revise asking next-of-kin to provide information about the participant as this will make them participants too and require an additional consent form.
6. Please include missing information as per the HDEC template.

**Decision**

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

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| **3** | **Ethics ref:** | **2024 FULL 20663** |
|  | Title: | Safety and Efficacy of balloon dilation for Improvement of Swallowing in Patients with Upper Esophageal Sphincter obstruction |
|  | Principal Investigator: | Associate Professor Jacqui Allen |
|  | Sponsor: | Te Whatu Ora Waitemata |
|  | Clock Start Date: | 04 July 2024 |

Associate Professor Jacqui Allen was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the randomisation had been removed to empower the participants as these participants would likely have very little autonomy at the stage of treatment they are at.
2. The Committee clarified how the Principal Investigator (PI) would avoid coercion and “white-coat” bias and the possibility of someone who may have experience in this field being available to discuss the study with potential participants. The PI discussed that the process for participation in the study would be a long one with plenty of time for support and consultation with other parties. The Researcher noted that there was unlikely to be another person who would consistently be able to take this role on (given changes in registrars) but that they would try and make an effort for people to consult another physician, as well as other members of the study team.
3. The Committee clarified the reasoning for choice between general or local anaesthetic.

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 role of the speech therapist be clarified in the protocol and the participant information sheet/consent form (PIS/CF).
2. The Committee requested that the protocol note that the fluoroscopy be explained as standard of care (SoC) and not a part of this study itself but that if data is to be included from this that it is noted in the protocol and clarified in the data management plan (DMP).
3. The Committee queried the provision for repeat dilation and what balloon would be used at that stage (that is, the investigational or standard of care device). The researcher clarified that the balloon used would be up to the participants. Please clarify this in the protocol and the PIS.
4. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP):
   1. Please review for template information that had been left in the document.
   2. Please ensure that the sponsor is just the locality as the local sponsor as this is an investigator-initiated study.
   3. Please include any organisational privacy policies per the localities in this study, specifically where the data will be held/stored/how it will be managed.

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

1. Please include more information about the number of people who may have received the study intervention and that it has been undertaken in humans prior to this study (as available).
2. Please clarify early in the PIS that this is the first time that this balloon is being used in New Zealand.
3. Please provide more information around the UC Davis results to assist participants to understand the aim and expectations of this study.
4. Please clarify if this device has been approved in the US or other places internationally.
5. Please ensure that the visits are consistent with the protocol and which of these visits are additional to those already being undertaken by the participants as part of SoC.
6. Please review and amend repetitious information.
7. Please replace the old Ethics 0800 number with the general inquiries number for the Ministry of Health. The correct contact can be found in the [HDEC templates.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
8. Please clarify what camera and telescope will be used and under what conditions this will be done for the study procedure.
9. Please use the same terminology throughout for the swallow videography.
10. Please be clear with the terminology for the questionnaires throughout.
11. Please include adverse event review in the table of assessments.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the data and tissue management plan (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a; 14.16).*
4. Please update the study protocol, taking into account the feedback provided by the Committee. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7*).

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

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| **4** | **Ethics ref:** | **2024 FULL 20602** |
|  | Title: | A Phase 1 Study of NEU-111 Administered Orally to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics in Healthy Volunteers |
|  | Principal Investigator: | Dr Leanne Barnett |
|  | Sponsor: | Neuron23, Inc. |
|  | Clock Start Date: | 04 July 2024 |

Dr Leanne Barnett, Ms Julia O’Sullivan, Ms Lucy Druzianic and Ms Kayla Malate were present present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee queried if the insurance was ACC equivalent as it was labelled product liability insurance and not clinical trial insurance. The Researcher agreed to confirm with the Sponsor that all ACC equivalent entitlements would be available to participants.
2. The Committee requested the Researchers discuss licensure in New Zealand with the Sponsor if the drug is shown to be effective.
3. The Committee noted recent evidence linked JAK inhibitors with an increased risk of herpes zoster reactivation and recommended the researchers consult with the Sponsor.

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

1. Please include a suggestion that all male participants use condoms regardless of the sex of their partner to limit exposure to the investigational product in semen.
2. Please refer to medicine and not drug.
3. Please state data will be kept on servers located in Australia and New Zealand.

**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 discuss insurance, licensure and JAK inhibitors with the Sponsor.

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| **5** | **Ethics ref:** | **2024 FULL 20152** |
|  | Title: | A Natural History Study of Exocrine Pancreatic Function in Infants With Cystic Fibrosis Less Than 12 Months of Age (VX24-445-130) |
|  | Principal Investigator: | Dr Samuel Dalton |
|  | Sponsor: | Vertex Pharmaceuticals Australia Pty Ltd |
|  | Clock Start Date: | 04 July 2024 |

Dr Samuel Dalton and Dr Malina Storer 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 noted New Zealand law allows participants to request any data held about them not just if it is clinically relevant. Please amend documentation to reflect this.
2. The Committee discussed the amount paid per sample and concluded it was fair for the effort and inconvenience required. The Researcher clarified this was the same rate paid globally. The Researcher confirmed it would not be used as an inducement during recruiting. The Committee noted there may be tax implications for this amount of payment over time and requested participant-facing documentation is updated to address this.
3. The Committee requested the data management plan is updated so data will be kept for 10 years after the youngest participant turns 16.
4. The Committee requested the Researcher amend the informed consent process document to remove the ‘You or your child’s insurance will need to pay’ line and ensure the content is appropriate for a New Zealand context.
5. The Committee requested the protocol, participant information sheet and tissue management plan are updated to include how long blood samples will be stored for before they are destroyed.
6. The Committee suggested section 7.1 of the protocol is amended to state parent or guardian rather than legally appointed or authorised representative.

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

1. Please revise the recommendation on page 3 to reflect that the study team will inform the GP.
2. Please remove the requirement on page 6 for participants to provide receipts for reimbursement.
3. Please include a statement in the optional sub study sheet saying the ethical aspects of the study have been approved by the Northern A HDEC. Please add appropriate contact prompts from the [HDEC template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates)
4. Please make it clear which of the additional samples are not routine and only taken for the optional sub study.
5. Please refer to publicly funded healthcare and not ‘public health’.
6. Please revise the information on page 8 about the doctor usually replacing the child’s name as study data will be collected deidentified.
7. Please replace any references of diaper to nappy. Please include another step to ensure the baby is changed and is safe before taking the sample.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the data and tissue management plan (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a; 14.16).*

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

## General business

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

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| **Meeting date:** | 20 August 2024 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

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

The meeting closed at 3:25pm with a karakia.