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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 22 August 2023 |
| **Zoom details:** | 973 875 6003 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:00 - 12:30pm | 2023 FULL 18299 | Setting the research agenda for paediatric rehabilitation | Dr Jimmy Chong | Cordelia / Albany |
| 12:30 - 1:00pm | 2023 FULL 18257 | The ears are doorways to the brain. | Dr Andrew Wood | Sandy / Patricia |
| 1:00 - 1:30pm | 2023 FULL 18534 | The real world evaluation of the STEPS-A DBT in schools programme | Dr Liesje Donkin | Helen / Patries |
| 1:30 - 2:00pm | 2023 FULL 16776 | A study to investigate the effect of a new nasal mask on breathing and comfort while using non-invasive ventilation in adults with chronic respiratory failure. | Dr Julie Cook | Jessie / Andrea |
| 2:00 - 2:20pm |  | Break (20 mins) |  |  |
| 2:20 - 2:50pm | 2023 EXP 18439 | Behavioural Activation Therapy for Mood Disorders in Aotearoa | Associate Professor Katie Douglas | Sandy / Patricia |
| 2:50 - 3:20pm | 2023 FULL 12903 | Non-Invasive Measurement of Gastric Function | Dr Stefan Calder | Cordelia / Albany |
| 3:20 - 3:50pm | 2023 FULL 18176 | Ketamine and Behavioural Activation Therapy study | Dr Ben Beaglehole | Helen / Patries |
| 3:50 - 4:20pm | 2023 FULL 13989 | Pilot Study- Assessment of FAPI PETCT in Neuroendocrine tumours with discordant disease at FDG PETCT | Dr Andrew Henderson | Jessie / Andrea |
| 4:20 - 4:40pm |  | Break (20 mins) |  |  |
| 4:40 - 5:10pm | 2023 FULL 18297 | LTG-001-001: Phase 1 Single and Multiple Ascending Dose Study of LTG-001 in Healthy Participants | Dr Alexandra Cole | Sandy / Andrea |
| 5:10 - 5:40pm | 2023 FULL 18371 | ARODUX4-1001: A Study to Investigate the Safety and Tolerability of ARO-DUX4 in Participants with Facioscapulohumeral Muscular Dystrophy | Associate Professor Richard Roxburgh | Jessie / Albany |
| 5:40 - 6:10pm | 2023 FULL 18352 | ITL-2001-CL-301: A Study to Investigate NTLA-2001 in Participants with Transthyretin Amyloidosis with Cardiomyopathy (ATTR-CM) | Dr Timothy Sutton | Cordelia / Patries |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Mrs Helen Walker  | Lay (Consumer/Community perspectives) (Chair) | 22/12/2020  | 22/12/2024 | 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)  | 22/12/2020  | 22/12/2024 | 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 | Apologies |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Present |
| Dr Andrea Forde | Non-lay (Intervention studies)  | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members, noting that apologies had been received from Mx Albany Lucas.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Andrea Forde confirmed her eligibility and was co-opted by the Chair as a member 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 25 July 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 18299** |
|   | Title:  | Setting the research agenda for tertiary paediatric rehabilitation in Aotearoa New Zealand using a Priority Setting Partnership process |
|   | Principal Investigator:  | Dr Jimmy Chong |
|   | Sponsor:  | Auckland University of Technology |
|   | Clock Start Date:  | 10 August 2023 |

Dr Jimmy Chong and Professor Denise Taylor 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 Researcher for the responses acknowledging cultural issues in the application.
2. The Committee queried who would be on the steering group. The Researcher stated it consists of the study team, a social worker and occupational therapist as well as community and iwi representatives who would oversee the different stages of the research.
3. The Committee queried why the hui would not be recorded. The Researcher stated this was not part of the JLA process and engagement with Māori and Pacific collaborators revealed recording the hui was not supported as it was felt this may impair the conversation.

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 several changes requested in the previous decline letter had not been incorporated such as footers in the information sheet which are important for document control and consenting participants onto the correct sheet.
2. The Committee noted the information sheet states “only written verified questions will be saved” but further down states gender, ethnicity, area and connection to The Wilson Centre. The Committee noted these datapoints may lead to an individual being potentially identifiable and advised the Researcher to be careful in how this is written up and to clarify the PIS to avoid this apparent contradiction.
3. The Committee advised written informed consent to participate in research is required by the [Code of Health and Disability Services Consumers’ Rights](https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/) (the Code). However it noted that this research may not be covered by the Code as there is no health or disability service being provided as part of the research. The Committee advised that in any event if verbal consent was obtained over the phone this could be written by the Researcher as the Code does not specify the writing must come from the participant. The Committee requested the Researcher update the participant information sheet to include a space for participants to write their consent to participate in the research. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.1 – 7.2 ).*
4. The Committee noted it would be difficult to obtain informed consent for the workshop at the beginning of the study. The Committee suggested a separate information sheet for the workshop could be submitted at a later date as an amendment once the study has progressed.
5. The Committee advised that participants under 16 should give their assent and a parent/guardian must give proxy consent on their behalf. Although they are able to consent for themselves if competent that would involve individual competence assessments. The Committee advised suitable information sheets for different levels of comprehension are necessary and suggested the Researcher develop an older and younger assent form. The Committee recommended adapting the [assent templates available on the HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/). *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.22 – 6.23; 6.27).*
6. The Committee advised any participants over 16 could consent for themselves but the Researcher must be satisfied they are competent to do so. The Committee advised if a participant was 17 or 18 and did not have capacity to provide their own informed consent this could be given by a parent/guardian but the Researcher must do a competency assessment to establish this first.
7. The Committee advised any participants under 16 who are enrolled under parental consent will require a re-consent for themselves when they turn 16. The Committee requested the Researcher develop an information sheet advising that participants were enrolled by their parent/guardian and now they are 16 the study is seeking their consent for ongoing participation / use of data. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.26).*

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. The Committee requested a proof-read to correct any misuse of apostrophes.
2. The Committee requested “Once consented” is changed to “Once you have given informed consent” on page 3 of the PIS.
3. The Committee requested the Researcher add a statement requiring participants to respect the confidentiality of the hui and not to repeat what others have said.
4. The Committee advised that koha is not reimbursement of expenses and should be in addition as recognition and thanks. The Committee requested the Researcher revise this section of the PIS to separate the two.
5. The Committee requested the inclusion of the ACC statement available on the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc).

**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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| **2**   | **Ethics ref:**   | **2023 FULL 18257** |
|   | Title:  | Using codesign to create an early-life hearing health service which meets the needs of teenage parents. |
|   | Principal Investigator:  | Dr Andrew Wood |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 10 August 2023 |

Mrs Genevieve Choi, Professor Suzanne Purdy and Associate Professor Holly Teagle 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 advised that a 14- or 15-year-old parent is likely to have capacity to provide their own informed consent and the Gillick test could be applied to enrol them into the study without parental consent if the Researcher is confident they understand the study and have capacity to provide informed consent.

Summary of outstanding ethical issues

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

1. The Committee queried the structure of the brainstorming sessions and what questions they would involve. The Researcher stated they do not want to have it pre-planned in advance before engaging with the group. The Committee advised adaptations can be made via the amendment pathway once approval is given but it would require detail of the proposed process and ideas of topics and subjects to be discussed in order to grant an initial approval.
2. The Researcher clarified the hearing test is not a research component of the study and will be offered as koha to participants who request it. The Committee requested information in the sheet advising participants that if they choose this option the result will be reported to their GP or other health care provider (e.g. Plunket).
3. The Committee queried whether fathers would be excluded as participants as the documentation seemed to infer this. The Researcher stated this was unintentional and would revise the documentation for clarity.
4. The Committee queried whether the lead teacher would be a research participant and if data would be collected from them. The Researcher stated they would be an influencing part of the study. The Committee requested an information sheet and consent form for the lead teacher to consent them into the study.
5. The Committee queried the risk about time in the information sheet and whether it was appropriate to use learning time for research activities. The Researcher stated they would likely take place during lunch hours and could make this more explicit in the sheet.
6. The Committee requested the Researcher investigate whether a $100 Prezzy card would have tax implications for participants.
7. The Committee advised that health data must be stored for a minimum of 10 years and requested an update to the data management plan.
8. The Committee noted participants require enough information on what the study involves and how it would be done in order to provide informed consent to participate and requested additional detail on what the study involves, why it is being done and how it will be achieved in all sheets. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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. The Committee requested the information sheets include what information is available at the outset of what the brainstorming sessions will involve for participants.
2. The Committee requested information on the koha options be added to the information sheet.
3. The Committee requested information on cultural issues for Māori and recommended inserting the information from the application and protocol into the information sheets.
4. The Committee requested a plain language review to simplify the language into shorter sentences.
5. The Committee recommended rephrasing the statement “will advise services around New Zealand” to be less definitive as this cannot be guaranteed. The Committee suggested “the findings of the study may help to improve audiology services”.
6. The Committee requested inclusion of the ACC statement available on the [HDEC information sheet template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc)

**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:**   | **2023 FULL 18534** |
|   | Title:  | An exploration of the effectivess, feasability and acceptability of a DBT in schools (STEPS-A) programme in Aotearoa New Zealand |
|   | Principal Investigator:  | Dr Liesje Donkin |
|   | Sponsor:  | Te Whatu Ora Waitematā  |
|   | Clock Start Date:  | 10 August 2023 |

Dr Liesje Donkin 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 noted the Researcher would not see the raw data of the psychometric questionnaires. The Researcher stated they would receive the scores from Te Whatu Ora Waitematā. The Researcher confirmed they would be reviewed by clinical staff at Te Whatu Ora soon after completion so a participant indicating distress would be identified.
2. The Committee advised written informed consent to participate in research is required by the [Code of Health and Disability Services Consumers’ Rights](https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/) (the Code). The Committee advised that oral consent could be recorded by the Researcher in writing as the Code does not specify the writing must be by the participant.
3. The Committee noted the exclusion criteria contained people not fluent in English and those who do not have technology access which raises equity issues. The Researcher stated they would not anticipate English being a barrier to most participants who have already engaged with the conversational programme but acknowledged it may be difficult for some of their whānau. The Researcher stated the digital divide was an issue and whānau could either come into the clinic or do the interview via telephone.
4. The Committee commended the Researcher for the responses acknowledging cultural issues in the application.

Summary of outstanding ethical issues

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

1. The Committee noted the date of the peer review precedes the protocol version submitted. The Researcher stated the peer review had been on a previous version and agreed to get an updated peer review. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
2. The Committee requested the Researcher adapt the HDEC [data management plan template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
3. The Committee advised that health data is required to be stored for a minimum of 10 years and not 6.
4. The Committee queried how the study would manage a referral for distress if the participant did not have a GP. The Researcher stated their preference would be if someone reports distress to obtain their consent for Marinoto Child and Youth Mental Health Services to follow them up directly. The Committee requested the Researcher develop a safety plan to detail what action will be taken and to include information regarding this in the information sheet.*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4).*

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. The Committee requested the Researcher adapt the [HDEC information sheet and consent form template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc)
2. The Committee advised that different stakeholders should receive different information sheets with specific information for that group (e.g. a more age-friendly sheet for rangatahi).
3. The Committee advised a parent / guardian is the only person who can give consent on behalf of a minor and requested removal of the word whānau.
4. The Committee requested removal of the “I agree to my child or children taking part” bulletpoints in the assent form.
5. The Committee requested a general proof-read to correct errors (e.g. “you school”).
6. The Committee requested a phone number for the Māori cultural contact in the information sheet.
7. The Committee queried whether consent would be sought from rangatahi for their parents to give information about them to the study. The Researcher stated this has not been planned. The Committee requested the Researcher add an option in for rangatahi to indicate they do not want their parents to give information about them to the study.
8. The Committee requested inclusion of a cultural statement acknowledging that information is a taonga and to acknowledge that whakamā may be present.
9. The Committee requested “health and disabilities ethics committee” be corrected to “health and disability ethics committee”.

**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 Mrs Helen Walker and Dr Patries Herst.

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| **4**   | **Ethics ref:**   | **2023 FULL 16776** |
|   | Title:  | The effect of a novel nasal mask on minute ventilation in adults with chronic respiratory failure: A pilot randomised cross-over trial. |
|   | Principal Investigator:  | Dr Julie Cook |
|   | Sponsor:  | Fisher & Paykel Healthcare |
|   | Clock Start Date:  | 10 August 2023 |

Dr Julie Cook, Dr Louis Kirton and Professor Richard Beasley were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried the exclusion of pregnant women. The Researcher stated the use of non-invasive ventilation can sometimes over-distend the stomach and have an impact of the cardiovascular system so it may be inappropriate for pregnant women to undergo that stress. The Researcher stated it would be unlikely for a pregnant participant to meet the other inclusion criteria such as low oxygen saturation below 90% and did not anticipate pregnant participants. The Committee noted there may be circumstances where a pregnant woman may require non-invasive ventilation and invited the Researcher to reconsider this. The Researcher stated it would be preferable to enrol pregnant participants in a phase 3 study and not a first-in-human trial due to safety concerns.
2. The Committee noted publication may be delayed as determined by commercial interests at the time and queried what this meant. The Researcher stated the mask was in its developmental phase and there may be a delay of months before publication but confirmed it would be published before the device was brought to market.

Summary of outstanding ethical issues

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

1. The Committee noted the exclusion criteria contained bacterial infection but not other possible infectious agents, for example, aspergillosis. The Researcher stated this had not been considered and would be added as an exclusion.
2. The Committee queried who the medical monitor would be. The Researcher stated the planned medical monitor is a respiratory physician that has a part time appointment at MRINZ as a monitor. The Researcher confirmed the monitor would not be directly involved in any study procedures. The Committee requested a safety charter for the monitor to manage adverse events and what role the monitor would play. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*
3. The Committee noted section 9.3 of the protocol and advised that a Sponsor may not terminate a study solely for commercial reasons in New Zealand and requested a revision to address this. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.37).*
4. The Committee acknowledged the device was commercially sensitive and in development but requested the Researcher add some description or image of the mask into the information sheet so participants are aware of what it will involve. The Researcher stated they would consult with the Sponsor on what they can make available in the PIS. The Researcher suggested the mask could be shown to potential participants during the consenting process in person.
5. The Committee suggested adding a clause in the consent form for participants to agree not to photograph or share information about the device if the research team deems it necessary.

**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).*
* Please provide the safety charter *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*

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| **5** | **Ethics ref:**   | **2023 EXP 18439** |
|   | Title:  | The BeAT-MD Feasibility Trial: Behavioural Activation Therapy for Mood Disorders in Aotearoa |
|   | Principal Investigator:  | Associate Professor Katie Douglas |
|   | Sponsor:  | University of Otago  |
|   | Clock Start Date:  | 10 August 2023 |

Associate Professor Katie Douglas 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 queried whether the research team could approach potential participants instead of their clinical team. The Researcher stated the plan was for the clinical team to offer a study pamphlet and if they were interested, they could contact the research team.
2. The Committee queried whether the study had capacity to offer a koha for time in addition to expenses. The Researcher stated at the moment $20 would be available but the study funding could not cover more than this. The Researcher stated the main benefit for participants would be a six-month course of psychological therapy without cost.
3. The Committee queried how quickly the psychometric assessments would be assessed after completion. The Researcher clarified clinical assessment occurs at the same time as the research assessment so any risks would be identified when they questionnaires were being completed.

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 the justification for excluding pregnant women. The Researcher stated it was due to the cognitive assessments done at baseline and six months to determine how the treatment affects cognitive function. The Researcher stated pregnancy could affect these results so was an exclusion to reduce the variables. The Committee requested the study advertisements include pregnancy as an exclusion so potential participants are aware. The Committee invited the Researcher to reconsider the exclusion. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.15).*
2. The Committee requested the Researcher review the information sheet for correct spelling of Te Reo Māori words and to undertake a general simplification for plain language.
3. The Committee advised the Researcher to be aware of whakamā that may be present in Māori participants.
4. The Committee requested a copy of peer review comments and any rebuttals from the research team

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. The Researcher confirmed bloods would be taken as part of standard of care during the study. The Committee requested inclusion of the cultural tissue statement available on the [HDEC template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc)
2. The Committee recommended increasing the font size.
3. The Committee requested an explanation of how much time the therapy homework would involve.

**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 Mrs Patricia Mitchell.

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| **6**   | **Ethics ref:**   | **2023 FULL 12903** |
|   | Title:  | Body Surface Gastric Mapping to Evaluate Patients with Gastrointestinal Symptoms and Controls |
|   | Principal Investigator:  | Dr Stefan Calder |
|   | Sponsor:  | Alimetry Ltd |
|   | Clock Start Date:  | 10 August 2023 |

Dr Stefan Calder 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.

Ms Jessie Lenagh-Glue declared a conflict of interest and recused herself from the discussion.

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 the exclusion of pregnant and lactating women from the study. The Researcher stated they have a separate study for pregnant women via the University. The Researcher stated lactation is known to affect gastric function but this has not been thoroughly studied yet. The Committee invited the Researcher to reconsider the routine exclusion in this under-researched group. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.15).*
2. The Committee noted D9 stated participants aged 14-16 will sign the standard consent form then further down states participant under 16 require parental consent and minor assent. The Researcher confirmed parents will provide consent and minors assent.

Summary of outstanding ethical issues

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

1. The Committee noted the study planned to send a letter to participants if suicidal ideation was identified and advised this would not be adequate. The Committee advised if a study involves quality of life questionnaires that collect information mental health the researchers have an ethical obligation to have a safety plan to act on any information they receive that indicates a participant is experiencing severe distress or suicidal ideation. The Committee requested the Researcher develop a safety plan to immediately respond to any participants in distress (e.g., appropriate referral) and to include information about this in the participant information sheet. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4).*
2. The Committee requested the Researcher adapt the [HDEC Data Management Plan template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
3. The Committee noted the information sheet states 30% of the population has a GI disorder and the application stated 40%. The Committee requested a revision to the sheet if required.
4. The Committee requested a description of the study in the advertisements to inform participants there are two groups participating, one with gastric issues and one without as some people may not understand what healthy volunteer / control group means.
5. The Committee advised any participants under 16 that turn 16 during the study will require a reconsent for ongoing participation and use of their data. The Committee suggested adapting the main PIS for this purpose (e.g., “Your parents signed this on your behalf when you were under 16 and now you need to give consent for us to continue using your data”). *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.26a).*
6. The Committee requested a copy of the HRC review comments and any rebuttals from the research team.

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. The Committee requested the Researcher adapt any missing [information prompts from the HDEC information sheet template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc)
2. The Committee requested the Researcher revise the parental information sheet to be clear when the sheet is referring to the child (e.g., it currently reads as if the parent would consent to photographs of them when it should read “your child”).
3. The Committee recommended splitting the assent form into older and younger versions based on level of understanding and not strictly age. The Committee advised the younger version can be more picture-based and the older version more verbal and the study team can give an individual which sheet they would understand best.
4. The Committee suggested the older assent form could contain additional information about the study.
5. The Committee requested the older assent form contain a cultural statement.
6. The Committee noted the assent declaration does not include an agreement for photographs to be taken of the children and requested this is added in.
7. The Committee requested changing the word ‘happy’ on the assent form to ‘I agree’.
8. The Committee recommended including more pictures or diagrams in the younger sheet.
9. The Committee requested the term ‘tummy stickers’ be replaced.
10. The Committee requested the study’s explanation of identified and coded data in the data management plan be transferred into the information sheet.
11. The Committee requested an explanation of what data the Sponsor will receive in the participant information sheet and the older assent sheet.
12. The Committee requested correction of the typo on page 2 “pregnant of lactating”.
13. The Committee requested removal of ‘individual with known cognitive impairment’ from the vulnerable group description as an individual with mild impairment may be capable of giving informed consent.
14. The Committee requested removal of the word ‘institutionalised’.
15. The Committee suggested simplifying some of the language in the sheet (e.g., “eat a meal” instead of “complete a meal”).
16. The Committee requested “skin prep” be revised to state “preparation” for clarity.
17. The Committee requested inclusion of a cultural statement to acknowledge that information is a taonga and the study involves touching peoples’ bodies and the removal of clothing.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please provide a safety plan for managing participant distress *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4).*
4. Please update the data management plan *(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 Dr Cordelia Thomas and Dr Patries Herst.

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| **7**  | **Ethics ref:**   | **2023 FULL 18176** |
|   | Title:  | Ketamine versus Ketamine plus Behavioural Activation Therapy for Adults with Treatment Resistant Depression |
|   | Principal Investigator:  | Dr Ben Beaglehole |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 10 August 2023 |

Dr Ben Beaglehole 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.

Ms Jessie Lenagh-Glue declared a conflict of interest and recused herself from the discussion.

Summary of resolved ethical issues

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

1. The Committee requested more detail in the information sheet about the qualitative interview and what it involves (e.g. what sort of questions are asked, where it will take place, how long it will take, who will conduct the interview, who will transcribe it, will participants be able to see the transcript and make corrections). The Committee suggested this could be a separate optional form.
2. The Committee queried why the HADS was removed from the protocol. The Researcher stated the study had an entry criterion based on the Hamilton depression rating scale and there was concern that self-reported scales in clinical trials may result in participants inflating their baseline to gain entry which would generate less-accurate data.
3. The Committee queried the purpose of the interviews and who would be selected for them. The Researcher stated they were interested in the experience of ketamine combined with behavioural activation therapy. The Researcher stated they were particularly interested in whether the combination is a suitable treatment for Māori. The Researcher stated there is likely to be a saturation point of about 10 – 15 participants. The Committee queried how Māori would be recruited. The Researcher stated they would draw upon existing relationships with Māori health workers to recruit through their connections as well as the general population of patients with depression.

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 advised the Researcher to consider whakamā when completing the cultural section on future applications as some people do not come forward when they need help due to feelings of shame.
2. The Committee requested a copy of the HRC peer review comments and any rebuttals from the research team.
3. The Researcher confirmed the psychometric questionnaires for depression would be assessed within half an hour of completion. The Researcher confirmed potential participants returning high scores would not be included in the study and the study team would address the risk of whether emergency psychiatric support was needed. The Committee requested information explaining this process be included in the information sheet so potential participants are aware.

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. The Committee requested inclusion of the cultural tissue statement available on the [HDEC template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc)
2. The Committee noted the preventing pregnancy section repeats, once for females and once for males which contains the same information and suggested condensing the section.
3. The Committee advised that NuvaRing is no longer available in New Zealand and requested its removal.
4. The Committee requested removing “(for females)” after the reference to pregnancy on page 3.
5. The Committee requested an explanation of ECT on page 3.
6. The Committee noted some information repeats (e.g., mixing ketamine with orange juice) and suggested condensing the information.
7. The Committee requested the Researcher amend the benefit section to state research has indicated ketamine is likely to improve mood for a short term but the combination with therapy is unknown and some people do not have an improvement.

**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 supply a copy of the HRC peer review comments.

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Dr Patries Herst.

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| **8**   | **Ethics ref:**   | **2023 FULL 13989** |
|   | Title:  | Pilot Study- Assessment of FAPI PETCT in Neuroendocrine tumours with discordant disease at FDG PETCT |
|   | Principal Investigator:  | Dr Andrew Henderson |
|   | Sponsor:  | Mercy Radiology |
|   | Clock Start Date:  | 10 August 2023 |

Dr Andrew Henderson 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.

Dr Andrea Forde declared a potential conflict of interest as she is a member of the Hazardous Substances and New Organisms Committee. The Committee deemed this minor and Dr Forde was allowed to participate in the discussion.

Summary of resolved ethical issues

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

1. The Researcher clarified that Mercy Radiology would be providing the machines, gallium and staff for the study pro bono. The Researcher clarified that Sofie Biosciences provided the FAPI agent but was not sponsoring this investigator-initiated trial.
2. The Committee noted the application stated ethnicity data would not be collected from participants but the information sheet referred to it. The Researcher confirmed ethnicity data would be collected.

Summary of outstanding ethical issues

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

1. The Committee noted the investigator brochure referred to pancreatic ductal adenocarcinoma whereas the study is on neuroendocrine tumours. The Researcher stated it was likely referring to earlier investigations of the agent and most of the information about safety with FAPI was learned through trials on adenocarcinoma. The Researcher stated there was not much information on neuroendocrine tumours in the brochure as not much work has been done on them yet. The Committee queried whether a half page summary on the risks and benefits on the agent for neuroendocrine tumours could be provided.
2. The Committee noted Mercy’s privacy policy refers to the Privacy Act 1994 and suggested this should be updated to the Privacy Act 2020.
3. The Committee queried how data from the study will be incorporated into a future study of the agent. The Researcher stated it may be appropriate to share the deidentified dataset with Sofie and would revise the sheet to state coded information will be shared with the manufacturer.

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

1. The Committee noted the ‘Who is funding the study’ section contains a lot of information but does not state who the funder is. The Researcher confirmed the funder is Mercy and would clarify the section.
2. The Committee requested removal of Nuvaring from the contraception section as this was no longer available in New Zealand.
3. The Committee requested a simplification of the ‘What is the purpose of the study’ section to use lay-friendly language.
4. The Committee requested ‘study drug’ be corrected to ‘study agent’ under the risks to the unborn child section.
5. The Committee requested removal of references to overseas ethics committees and government agencies.
6. The Committee requested consistency between terms for the participants doctor, noting the sheet currently switches between “usual doctor”, “GP” and “current provider”.

**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 provide a brief summary, in place of a completed Investigator Brochure to document what is known and unknown in terms of the potential risk benefit of FAPI in neuroendocrine tumours.

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| **9**   | **Ethics ref:**   | **2023 FULL 18297** |
|   | Title:  | A Sequential, Randomized, Double-Blind, Placebo-Controlled, Phase 1 Single and Multiple Ascending Dose Study of LTG-001 Administered Orally to Evaluate the Safety, Tolerability, and Pharmacokinetics in Healthy Male and Female Participants 18 to 55 Years of Age |
|   | Principal Investigator:  | Dr Alexandra Cole |
|   | Sponsor:  | Latigo Biotherapeutics, Inc. and PPD, Part of Thermo Fisher Scientific |
|   | Clock Start Date:  | 10 August 2023 |

Dr Chris Wynne, Julia O’Sullivan and Courtney Rowse 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.

Dr Andrea Forde declared a potential conflict of interest as she is a member of the Hazardous Substances and New Organisms Committee. The Committee deemed this minor and Dr Forde was allowed to participate in the discussion.

Summary of resolved ethical issues

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

1. The Committee recommended reviewing the pandemic statement as the WHO has declared an end to the Public Health Emergency of International Concern.
2. The Committee commended the Researcher for the comprehensive cultural paragraphs in the information sheet.
3. The Committee noted animal models showed no genotoxicity of the drug and queried whether reproductive toxicity has been established. The Researcher confirmed genotoxicity and reproductive toxicity studies would be completed before the study moved to Phase 2.

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 a missing word on page 2 of the study advertising (“The study a 3-night”).
2. The Committee requested “help advance medical science” and “help advance global health” are not used in promotional material and suggested using 11, 12, 13, 15, 19, 37 or 42 instead.

**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 study advertisements *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12)*

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| **10**   | **Ethics ref:**   | **2023 FULL 18371** |
|   | Title:  | Phase 1/2a Dose-Escalating Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ARO-DUX4 in Adult Patients with Facioscapulohumeral Muscular Dystrophy Type 1 |
|   | Principal Investigator:  | Associate Professor Richard Roxburgh |
|   | Sponsor:  | Arrowhead Pharmaceuticals Inc. and Novotech (New Zealand) Limited |
|   | Clock Start Date:  | 10 August 2023 |

Associate Professor Richard Roxburgh, Holly Thirlwall and Julia O’Sullivan 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.

Dr Andrea Forde declared a potential conflict of interest as she is a member of the Hazardous Substances and New Organisms Committee. The Committee deemed this minor and Dr Forde was allowed to participate in the discussion.

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 the insurance certificate would expire in December. The Researcher confirmed it would be updated.
2. The Committee suggested condensing the separate reproductive paragraphs into one section. The Researcher stated having separate sections for males and females was useful during the consenting process. The Researcher stated they will look at condensing the section.
3. The Researcher confirmed genetic test results will be returned to individuals who undergo testing but are ineligible for participation.

Summary of outstanding ethical issues

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

1. The Researcher confirmed undergoing MRI was a compulsory part of participation. The Committee requested metal implants such as pacemakers be added to the exclusion criteria so participants with metal implants will know they are ineligible to participate.
2. The Committee queried whether $150 less tax was an appropriate amount for two muscle biopsies as they can be uncomfortable with a long recovery period. The Researcher agreed to increase the amount offered.
3. The Committee noted participants would be between 18-70 years old and the data management plan referred to under 16s. The Researcher agreed to revise the data management plan.

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

1. The Committee requested information advising that identifying features such as tattoos or birthmarks captured in the photograph of the infusion site will be blocked out.
2. The Committee requested removal of the ‘yes/no’ boxes on the consent form for any items which are not truly optional (i.e. the participant can answer ‘no’ and still participate).

**Decision**

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

* Please address all outstanding ethical issues raised by the Committee
* Please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please update the data management plan *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*

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| **11**   | **Ethics ref:**   | **2023 FULL 18352** |
|   | Title:  | A Phase 3, Multinational, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of NTLA-2001 in Participants with Transthyretin Amyloidosis with Cardiomyopathy (ATTR-CM) |
|   | Principal Investigator:  | Dr Timothy Sutton |
|   | Sponsor:  | Intellia Therapeutics, Inc. and CARSL Consulting (Clinical and Regulatory Services limited) |
|   | Clock Start Date:  | 10 August 2023 |

Dr Tim Sutton, Professor Ed Gane, Holly Thirlwall and Julia O’Sullivan were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researcher confirmed the study was submitted to the Gene Technology Advisory Committee.
2. The Researcher confirmed the Sponsor is planning an open-label extension participants in the placebo arm would be invited to if the treatment is effective.
3. The Committee noted mention of the protein being formed in ovaries and queried implications for fertility. The Researcher stated this was unknown as it was new technology. The Researcher stated the population with transthyretin amyloidosis is almost uniquely male with a 10:1 ratio and most patients are in their 60s, 70s and 80s. The Researcher stated female patients are usually beyond child-bearing age by the time their heart is affected by the disease. The Researcher stated a previous study showed no uptake of the lipid nanoparticle in testicular or ovarian tissue.
4. The Researcher confirmed the quality-of-life questionnaires would be reviewed within 24 hours of completion.
5. The Researcher confirmed the $10,000 deductible for an insurance claim would be covered by the Sponsor.
6. The Researcher confirmed Medpace’s service would be available to participants in the study.
7. The Committee commended the Researcher for the tikanga Māori perspective in the application and information sheet.

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 Researcher supply the charter for the data monitoring committee (DMC).
2. The Committee noted the data management plan referred to participants under 16 and suggested this be corrected.
3. The Committee queried the 15 year follow-up for health information. The Researcher stated this was an FDA requirement for gene technologies. The Committee requested a statement in the sheet advising that this is due to a requirement by a regulator and to include a clause on the consent form for this.
4. The Committee queried what Vitamin A products the study would supply if the available products on the market changed. The Committee queried if participants would receive the best available Vitamin A product, as the duration of follow up was prolonged. Product availability should be aligned with the newer/better products if they were available during this timeframe of follow up.

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

Main PIS:

1. The Committee requested the Researcher amend the eye examination paragraph on page 5 to state lack of vitamin A can lead to general blindness not just night-blindness and to correct ‘eye-site’.
2. The Committee requested an explanation of wild and hereditary types on page 5.
3. The Committee noted a difference between the table and text on pages 16-17 for how long paper records are stored (15 versus 25 years). The Researcher confirmed 25 years is correct and would update the sheet.
4. The Committee advised that the trial cannot be terminated for commercial reasons and noted the wording on page 18 may be ambiguous.

Future Unspecified Research PIS:

1. The Committee requested the word “handle” on page 3 be amended to “affected by”.
2. The Committee noted information on a participant’s right to access and correct information about them is under the “Ownership Rights” section and should be moved to its own privacy section.
3. Page 4 under ownership rights – privacy part doesn’t belong under ownership heading. Can amend that and template.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* please update the data management plan *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*
* please supply the charter for the DMC *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25)*

## General business

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

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| **Meeting date:** | 26 September 2023 |
| **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**

The Committee noted Mrs Patricia Mitchell left the meeting to attend other business at 3:50pm and was not present for applications 8 – 11. Quorum was maintained.

1. **Other business**
2. **Other business for information**
3. **Any other business**

The meeting closed at 6:00pm.