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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 21 November 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 12.30-1.00pm | 2023 FULL 19025 | A study of ALXN2220 versus Placebo in Adults with ATTR-CM | Doctor Timothy Sutton | Ms Catherine Garvey and Dr Sotera Catapang |
| 1.00-1.30pm | 2023 FULL 18139 | A feasibility study of respiratory-gated non-invasive auricular vagus nerve stimulation in people with rheumatoid arthritis | Mr Ankit Parimal Parikh | Mr Jonathan Darby and Dr Kate Parker |
| 1.30-2.00pm | 2023 FULL 18359 | PRACTICAL - IMV | Associate Professor Rachael Parke | Ms Catherine Garvey and Dr Andrea Forde |
|  | *Break (10)* |  |  |  |
| 2.10-2.40pm | 2023 FULL 18327 | HOME BRAIN PRESSURE study | Dr Sarah-Jane Guild | Mr Jonathan Darby and Mr Derek Chang |
| 2.40-3.10pm | 2023 FULL 18705 | (Equator) Study of Itolizumab in Combination with Corticosteroids for the Treatment of Acute Graft Versus Host Disease | Dr Clinton Lewis | Ms Catherine Garvey and Ms Jade Scott |
| 3.10-3.40pm | 2023 FULL 18720 | Hearing for pēpi | Dr Andrew Wood | Mr Jonathan Darby and Dr Kate Parker |
|  | *Break (30)* |  |  |  |
| 4.10-4.40pm | 2023 FULL 18645 | Small drop administration of phenylephrine and cyclopentolate in preterm infants (Nano-ROP) | Dr Lisa Kremer | Ms Catherine Garvey and Dr Andrea Forde |
| 4.40-5.10pm | 2023 FULL 18387 | Comparing the effect of two medications (angiotensin and noradrenaline) used for support blood pressure after cardiac surgery on recovery | Dr Daniel Frei | Mr Jonathan Darby and Ms Jade Scott |
| 5.10-5.40pm | 2023 FULL 18497 | Exclusive Enteral Nutrition (EEN) therapy in active luminal paediatric Crohn's disease: do specific additional foods affect therapy response? | Mrs Stephanie Brown | Ms Catherine Garvey and Dr Andrea Forde |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Mr Derek Chang  | Non-lay (Intervention studies)  | 08/07/2022 | 08/07/2025 | Present  |
| 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) | 19/03/2019  | 19/03/2022  | 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 meeting was opened at 12.00pm with a karakia, and the Chair 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 17 October 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 19025** |
|   | Title:  | A Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy and Safety of Amyloid Depleter ALXN2220 in Adult Participants with Transthyretin Amyloid Cardiomyopathy (ATTR-CM) |
|   | Principal Investigator:  | Dr Timothy Sutton |
|   | Sponsor:  | AstraZeneca Pty Ltd |
|   | Clock Start Date:  | 16 November 2023 |

Dr Timothy Sutton, Duncan Hui, Peter Kahr, Gustavo Buchele, and Teena Sebastian 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 standard treatment is an expensive, self-funded medication not commonly used in New Zealand. There is no standard medication used in New Zealand that is funded. A person who is taking that medication is not excluded from participation. The Committee noted that the protocol states that participants in both treatment arms will receive standard therapy. It was clarified through discussion that the study drug is versus the placebo.
2. The Researchers noted that they do not see any potential interactions with viral infections such as hepatitis and the investigational medicine.

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 most recruitment will be from identifying potential participants within clinics. The researcher clarified that cardiologists around the country will be notified of the enrolment criteria and can review the eligibility criteria and refer participants to avoid screen-fails with unnecessary travel. The Committee noted that there should be greater clarity upfront around reimbursement for out-of-town travel and what assistance can be given, as well as the likely duration of the main study before any long-term extension. (The Sponsor indicated that NZ participants were likely to be some of the first enrolled into the study).
2. The Committee requested to review the letter that would be sent to recruiting physicians.
3. The Committee queried the exclusion of those who are pregnant, or breastfeeding given the poor prognosis of potential participants. The Researcher responded that the likelihood of disease in young females meant that this cohort was very unlikely to be available to be enrolled. The Committee noted that it is unlikely to happen, but if it did, ensure there are options for inclusion and advice regarding egg freezing prior to commencing the study drug.

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

1. On page 7 of the Master PIS, please amend the minor typo to state Hepatitis B “and” HCV, not “or”.
2. Please do not use tablespoons/teaspoons for blood or other fluid measurements as this can produce a comparison to food – please use millilitres.

**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:**   | **2023 FULL 18139** |
|   | Title:  | A feasibility study of respiratory-gated non-invasive auricular vagus nerve stimulation in people with rheumatoid arthritis |
|   | Principal Investigator:  | Mr Ankit Parimal Parikh |
|   | Sponsor:  | Exsurgo Ltd |
|   | Clock Start Date:  | 16 November 2023 |

Ankit Parikh and Associate Professor Gwyn Lewis 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 commended the Researchers on the amount of work that had been done in response to the previous decline.
2. The Committee queried if it would be possible for a research nurse to consent participants and the Researcher confirmed this would be the case.

Summary of outstanding ethical issues

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

1. In the participant-facing documentation, please ensure the Northern A HDEC is named as the approving ethics committee.
2. The Committee noted there is some commercial benefit to the primary sponsor. Any references to ACC compensation will need to be replaced. It is likely that this study will have access to AUT insurance which will be adequate, but this should be clarified as the company are getting study data and will benefit from this study. The Committee requested provision of ACC-equivalent cover in the event of an injury.
3. The Committee noted the following about the data and tissue management plan:
	1. It currently states that samples will go to landfill. Please instead state that samples will be destroyed according to standard lab procedures.
	2. There is a statement that de-identified data will not be made available to anyone else, but in the participant information sheet (PIS), participants are asked for permission to share that data with other researchers. Please decide which one is correct and alter documents accordingly. If data will be made available overseas, please ensure it is outlined how this will be done.

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

1. The Committee noted that the 0800 4 ETHICS number is no longer current. The appropriate contact can be found under the latest [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
2. The Committee suggested that given the limited number of devices available for use in the trial, please consider providing participants with information about how to care for these in person and include this information in the PIS.
3. The Committee queried how the researchers monitor whether the device is being used as planned. The Researcher responded that they are aware when a participant has logged in and partially or fully completed the intervention, and this is checked every day. The CI also gets notified to follow up. The Committee asked that this information be included in the PIS.
4. On page 7, there is clarification further down that participant can withdraw from the study if they have extreme pain. But at the top of the page, it states that there can be no adjustment of drugs during the course of the study. Please add after that sentence that if their pain is unmanageable, they of course are able to withdraw from the study.
5. On page 8, please remove the reference to the New Zealand Medicine Industry guidelines. These do not apply to devices.

**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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| **3**   | **Ethics ref:**   | **2023 FULL 18359** |
|   | Title:  | Platform of Randomised Adaptive Clinical Trials in Critical Illness (PRACTICAL) Randomised Controlled Trial |
|   | Principal Investigator:  | Associate Professor Rachael Parke |
|   | Sponsor:  | University Health Network and Te Whatu Ora Te Toka Tumai Auckland |
|   | Clock Start Date:  | 16 November 2023 |

Dr Eileen Gilder was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee confirmed with the Researcher that appropriate Māori consultation will be undertaken as part of locality authorisation. The Committee noted that consumer-representation consultation may be beneficial for ICU-related studies particularly where participants are enrolled on a ‘best interests’ basis.
2. The Researcher confirmed that New Zealand is not part of the optional biomarker study.
3. The Committee highlighted that the submitted questionnaires are labelled Canadian version and queried how these will be used in New Zealand. The Researcher clarified that these are universally validated tools that will be the same questionnaire regardless of country, and are labelled this way due to licensing requirements.
4. The Committee queried what psychiatric support may be available after ICU discharge. The Researcher responded that current practice across New Zealand does not have formal psychiatric reviews post ICU discharge. Because there is longer-term follow up for this research, both the research nurses interacting with the patient and also through the use of questionnaires, the need for psychiatric follow up post ICU is one of the study measures that can address this.

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 the domain-specific appendix that is referred to in the protocol was not included in the submission. Please provide this.
2. There is reference to Māori data sovereignty in the data management plan, but this is not referenced in the participant information sheet. Please amend.
3. The Committee queried if any consultation was undertaken with First Nations people in Canada. The Researcher responded that they can seek clarification around this.
4. The Committee requested provision of the Data Safety Monitoring Board (DSMB) charter for their records.

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

1. The Committee noted that the 0800 4 ETHICS number is no longer current. The appropriate contact can be found under the latest [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
2. In the Relatives PIS under ‘what are your rights’, add in information about the HDC advocacy service. A contact for them can be found in our HDEC 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).*

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| **4**   | **Ethics ref:**   | **2023 FULL 18327** |
|   | Title:  | Wireless HOME monitoring of intracranial (BRAIN) PRESSURE - HOME BRAIN PRESSURE study |
|   | Principal Investigator:  | Dr Sarah-Jane Guild |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 16 November 2023 |

Dr Sarah-Jane Guild and a number of the study team were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that these are patients who are quite unwell, with implications for informed consent. The researchers noted that there will be a range of groups that will have various capacity for consent, and there will be no attempt to recruit those to the study that clearly cannot consent for themselves. A research nurse will also walk through the consent process with a potential participant, i.e. one who is currently well, but may in future need replacement of a shunt. The Committee suggested an easy-read version of the participant information sheet to assist comprehension but was otherwise satisfied with the approach and consideration of the Researchers.
2. After demonstration of the device, it was clarified that information would not be pre-emptively used to diagnose and treat the patient, but the information obtained will be available should they present to hospital. Readings will be monitored and if these indicate there is an increase in intracranial pressure, the participants will be asked to come back for an evaluation. The study will provide a phone for the app to be installed on to ensure accessibility.
3. The Researchers clarified that if the participant wished to withdraw and also have the device removed, they would be referred for a consultation to discuss the risks and will have the option for it to be removed at the same time as a future shunt revision.
4. The Researchers confirmed that there are plans in place to accommodate additional support requests.
5. The Committee queried if there would be any interaction with another activated implant. It was clarified that the device itself doesn’t have a battery, it requires the wand to be activated and would otherwise be inert. The decision to exclude those with other active implants is because it is beyond the scope of the study to test whether the wand has any interaction with those. It was agreed that for this study, it was best to minimise any potential interaction issues.

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 the advertisements and other documentation do not need to specify that the HDEC have approved the study for 5 years. It can state that the Northern A HDEC have approved the ethical aspects of the study.
2. The Committee requested clarification of the University of Auckland’s insurance coverage.

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

1. Please include that the animal studies were performed on sheep and for how long.
2. Please provide an MRI-related risks/impact statement.
3. Please make it clear that the wand is the only potential interaction with other devices, the implant itself is otherwise inactive.
4. Please make it clear that if participants choose to continue to use the wand beyond the 3 month formal study period that this also means that the research team will continue to collect data from those participants, and explain how this will be used.

**Decision**

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

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

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

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| **5**   | **Ethics ref:**   | **2023 FULL 18705** |
|   | Title:  | A Phase 3, Randomized, Double-Blind, Placebo-Controlled Multicenter Study of Itolizumab in Combination with Corticosteroids for the Initial Treatment of Acute Graft Versus Host Disease |
|   | Principal Investigator:  | Dr Clinton Lewis |
|   | Sponsor:  | Equillium, Inc |
|   | Clock Start Date:  | 16 November 2023 |

Dr Clinton Lewis and Dr Nel Peiris 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 how the short screening period of 3 days will be managed. The Researcher clarified that this disease has a very rapid onset, so because of this there is a medical indication to treat urgently. The 3 days is a balance of trying to give time for pre-screening and getting treatment. There are study nurses available to support the decision-making process.

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 the CI’s indemnity has expired. Please upload the updated document.
2. The Committee queried the exclusion criteria around HIV, HBV, HCV and TB. The Researcher responded that some of those diseases are relative contraindications to getting the transplant in the first place and explained that this is standardized internationally. As this is immunosuppressive therapy, the Researchers said there is a concern for viral reactivation worsening and drug interaction with other treatment. The Committee recommended this is clarified for participants.

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

1. Under identifiable data, please remove reference to the Sponsor and people and companies working for the Sponsor having access to identifiable data for the purpose of the study.
2. Section 14 refers to the cost of treatment and a participant’s insurance. Please remove.
3. Section 16 states ‘as required by US law’ which can be removed.
4. Please refer to Northern A HDEC in the Assent form.
5. Please include contraception information in the Assent form.
6. The committee queried the wording of “can bad things happen” and “these bad things are called risks”. This is not entirely accurate, and phrasing might be off-putting. The Committee suggested explaining that there are side-effects or potential risks instead.
7. Please note in the PIS that a karakia will not be available at tissue destruction.

**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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| **6**   | **Ethics ref:**   | **2023 FULL 18720** |
|   | Title:  | How do teenage parents view hearing in early life? |
|   | Principal Investigator:  | Dr Andrew Wood |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 16 November 2023 |

Genevieve Choi and Professor Suzanne Purdy were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that application form says the researchers are not collecting ethnicity data. The Researcher responded that if participants would like to share this information, they can, but the study is being influenced by having them taking ownership of their voice and their story. The Committee noted that it is a requirement to record ethnicity where possible and justify if not.
2. The Researchers clarified that the participant has time to take away the information sheet to consider their participation.
3. The Researchers clarified that support people for disabilities can be provided if required and have grant money set aside for accessing these.

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 to explicitly clarify to participants a code of conduct for the focus groups, such as confidentiality expectations. Please clarify what will happen to the audio recordings of the focus groups including transcription, what the recordings and transcripts will be used for and their subsequent storage and destruction.
2. The Committee noted that ethical approval had been stated as time limited in documentation, but this can be removed. Please refer to the fact that HDECs approve only the ethical aspects of the study.
3. The Committee recommended developing a safety plan for the Researcher and participants given the duration of contact and close involvement with the parents and children.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee.

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| **7**   | **Ethics ref:**   | **2023 FULL 18645** |
|   | Title:  | Pilot randomised controlled trial for small drop administration of phenylephrine and cyclopentolate in preterm infants for retinopathy of prematurity eye examinations |
|   | Principal Investigator:  | Dr Lisa Kremer |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 16 November 2023 |

Dr Lisa Kremer 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 request for a closed meeting but outlined that this discussion and the Minutes will not reveal any commercially sensitive information, or information that will not otherwise be publicly available. No observers were present. The Researchers were satisfied to proceed with an open meeting.
2. The Committee clarified with the Researcher that this device is not new but is being trialled for a new indication to be used on premature babies.
3. The Committee queried how the Researchers will manage any infection or contamination of the dropper bottle. The Researchers responded that each baby will have their own bottle and device prepared by the pharmacy under GMP, and they have sterility data about the use of the device with the bottle in combination.
4. The Researcher outlined the consenting approach, which involved whānau being approached to have their baby involved in the study. They will also be asked if they would be happy to be involved in a survey. The other group to be asked to participate are nurses who will be administering the eye drops using the study device.

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 involvement of the device company in the protocol design and in receiving de-identified study data and likely membership on the data monitoring committee. The Committee queried if the company has any say in the publication of the results as currently there is ambiguity in the documentation as to the extent of their involvement. The University of Otago should be able to provide insurance as Sponsor which should resolve some of the concerns in whether participants would have access to ACC in the event they require it from their involvement in the study.
2. Please clarify across documentation to make it clear that all study data will only be relayed in de-identified manner to the device company. The Committee recommended referring to the DMP template to ensure these matters are all addressed in the data section of the Protocol.
3. The Committee noted that the data monitoring committee is also a safety monitoring committee and that there ought to be an independent review of safety. The Committee also indicated a charter for the SRC would be helpful.
4. The Committee noted the FDA approval of the device should be provided to participants, outlining what indications it is currently approved for,

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

1. Recommended rephrasing “the silicone device” to be “the device we are investigating” and in addition elaborating on its current regulatory status.
2. The Committee noted that the 0800 4 ETHICS number is no longer current. The appropriate contact can be found under the latest [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).

**Decision**

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

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

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

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| **8**   | **Ethics ref:**   | **2023 FULL 18387** |
|   | Title:  | A Prospective angiOtensin vs. noRadrenaline Trial for Hypotension management to reduce length Of hospital stay in Cardiac Surgery(The PORTHOS study) |
|   | Principal Investigator:  | Dr Daniel Frei |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 16 November 2023 |

No researcher was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee noted that one medicine has been available since 1941.
2. The Committee noted that the ethical review by Australia would be helpful for extra assurance in lieu of any review by SCOTT.
3. The Committee noted that this is funded by a US company but the European SmPC has been provided for consideration, so it is unclear whether e the product is coming from the US manufacturing site or the European. Please clarify.
4. The Committee queried whether recruitment and other aspects of the study would be impacted by potential participants being seen acutely in private hospitals as overflow patients from the public system.
5. The Committee queried the routine exclusion of pregnant/breastfeeding people from the study given they would not be excluded from cardiac surgery if it was needed, and noradrenaline is not a new medicine.
6. Please clarify whether ethnicity data will be collected as the application form says this is not, but the participant information sheet says it will be; the Committee noted the expectation that ethnicity data will be collected.
7. Please confirm registration of the study.
8. The Committee noted the one-month post-operative contraception requirement despite the fact the study medication is short-acting. Please clarify the rationale behind this.
9. The Sponsor needs to be added to the Data and Tissue Management Plan to describe the involvement and interaction they have with data and tissue.

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

1. Please review for typos and errors with page numbers.
2. Some sentences could be simplified and shortened. Please review.
3. Alternatives to taking part should be worded to make clear that those who choose not to participate will receive standard of care rather than ‘you will do your best’.
4. The Committee noted that the 0800 4 ETHICS number is no longer current. The appropriate contact can be found under the latest [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
5. Optional notification to GP in CF but PIS says they will. Either its optional or mandatory, remove yes/no option if mandatory.
6. Blood sample collection is optional in CF. Confirm whether its optional or mandatory and amend accordingly.

**Decision**

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

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

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

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| **9**   | **Ethics ref:**   | **2023 FULL 18497** |
|   | Title:  | Exclusive Enteral Nutrition (EEN) therapy in active luminal paediatric Crohn's disease: do specific additional foods affect therapy response? |
|   | Principal Investigator:  | Mrs Stephanie Brown |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 16 November 2023 |

No researcher was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. Please confirm that the control sites are providing standard of care and what that entails.
2. The documentation appears to have been almost entirely taken from the Australian sites and therefore is not adequate for the New Zealand sites:
	1. Please provide copies of PIS/assent forms that are prepared either using the HDEC template or modify the existing (submitted) PIS to be appropriate for a New Zealand audience and include all relevant matters from the template. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
	2. Please refer to HDEC approval rather than the statement “Study is conducted under the ethics board.”
	3. The Committee raised concern around whether Māori consultation is current and relates to the most recent version of the study protocol and documentation as it is dated 2017. The Committee suggested updated consultation be undertaken and evidence provided. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.3, 3.6, 3.7).*
3. Given this is an international study, inclusion of the master protocol in place of a data and tissue management plan is not sufficient to ensure the requirements under Chapter 12 and 14 of the National Ethical Standards. The Committee suggested use of the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/) to ensure there is New Zealand-specific information that is clear and outlined around data and tissue.
4. Please check that the protocol is up to date. It currently refers to DHBs instead of Te Whatu Ora.
5. The Committee noted there are two PIs in Auckland and queried if this study will be conducted in both Christchurch and Auckland or just Christchurch. There were no CVs provided for the additional PI(s).
6. The use of Kaupapa Māori methodology is indicated in application form but not demonstrated in submission. Please clarify. *(National Ethical Standards for Health and Disability Research and Quality Improvement, Chapter 3).*
7. There is reference in the submission (D4, E4) to participant recruitment being undertaken by male paediatric gastroenterologists using exclusively he/him pronouns. The Committee did not agree with this assumption and suggested ensuring all rewording.
8. It is not clear how psychiatric and mental health issues identified during the study will be flagged and addressed. In particular, the time frames were not addressed. Please provide this information. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4).*
9. The Committee wondered if it was clear to participants that consenting to the taking of clinical specimens was separate to the taking of samples for research, or to the subsequent consent to the use of clinical samples in research. Please clarify this, as all tissue sampling is referred to in the past-tense in the documentation. *(National Ethical Standards for Health and Disability Research and Quality Improvement, Chapter 14).*
10. Questionnaires do not appear to be age appropriate. Please ensure all questionnaires used are suitable.

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 revision of the PIS to make sure it is fit for the New Zealand-context. The [HDEC PIS template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) can be used as a guide.
2. More information is required around study visits, information being collected, expectations around assessments to be done, etc. Level of detail is outlined in the template as an example.
3. Assent forms are required for those under 16.

**Decision**

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

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 23 January 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 5.30pm