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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 20 September 2022 |
| **Zoom details:** | 965 0758 9841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 12.30-1.00pm | 2022 FULL 13295 | ABI-4334-101: A Study to Assess Single and Multiple Doses of ABI-4334 in Healthy Participants | Prof. Edward Gane | Mr Jonathan Darby & Dr Kate Parker |
| 1.00-1.30pm | 2022 FULL 12486 | ASCEND Study | Dr Jane Yeojeong So | Dr Leonie Walker & Dr Sotera Catapang |
| 1.30-2.00pm | 2022 FULL 13500 | Examining Access to Food Among Emergency Department Patients | Dr Stephanie Richling | Ms Kate O'Connor & Mr Derek Chang |
| 2.00-2.30pm | 2022 FULL 13517 | Neonatal CPAP Comparison Study | Dr Bronwyn Dixon | Mr Jonathan Darby & Ms Jade Scott |
|  |  | Break |  |  |
| 2.45-3.15pm | 2022 FULL 12729 | Comarison of methylprednisolone ointment and Advantan® ointment applied to the skin. | Dr Noelyn Hung | Dr Leonie Walker & Dr Sotera Catapang |
| 3.15-3.45pm | 2022 FULL 13452 | D5244C00001 - Efficacy and Safety of Tezepelumab in Patients with Eosinophilic Esophagitis (CROSSING) | Dr Benjamin Griffiths | Ms Kate O'Connor & Dr Kate Parker |
| 3.45-4.15pm | 2022 FULL 12899 | SER150 vs placebo in diabetic kidney disease | Dr Michael Williams | Ms Kate O'Connor & Ms Jade Scott |

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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 | Apology |
| Ms Catherine Garvey | Lay (the Law) (Chair) | 19/03/2019 | 19/03/2022 | Apology |
| 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 |
| Dr Leonie Walker | Lay (Ethical/Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Ms Jade Scott | Non-lay (Intervention/Observational studies) | 15/08/2021 | 15/08/2024 | Present |
| Ms Kate O’Connor | Lay (Ethical/Moral reasoning) (Chair) | 13/08/2021 | 16/08/2024 | Present |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Ms Catherine Garvey and Dr Andrea Forde.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Kate O’Connor, Chair of Northern B confirmed their eligibility, and was co-opted as a member and Chair 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 16 August 2022 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2022 FULL 13295** |
|  | Title: | A Phase 1, Blinded, Placebo-controlled Study of the Safety, Tolerability, and Pharmacokinetics of Single- and Multiple-Ascending Doses of ABI-4334 in Healthy Subjects |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Assembly Biosciences, Inc |
|  | Clock Start Date: | 08 September 2022 |

Professor Edward Gane, Holly Thirlwall 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.

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

Summary of resolved ethical issues

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

1. The Committee clarified that online participant information paper alternatives would be provided. There was also clarification around the fact that group and private consent sessions would be available.
2. The Committee clarified that the menu provided for participants would be standardised and would be communicated to participants. There is no difference between the caloric intake across participants.
3. The Committee noted the dosage was tripling each time between groups and that this correlated with the animal studies but that this seems to be quite high. The Researcher noted that in terms of exposures this was standard but that this would be reviewed after each cohort by the dosage review Committee.
4. The Committee clarified that Race would be self-identified and is a request from the Sponsor and would be handled by NZCR to prevent any offence on the part of the participants.
5. The Committee clarified that clinical trials site units would be used to identify participants.
6. The Committee clarified that there would be no future unspecified research.
7. The Committee clarified that participants on the 11-night stay would be permitted visitors, but this would be dependent on nursing staffing.

**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 in the protocol that Participants should be encouraged to notify their general practitioner (GP) of participation, however this was not consistent with the Participant Information Sheet which detailed that GPs would be notified by the study co-ordinators. The researcher noted that NZCR would be notifying GPs for healthy participants. Please correct this in the Protocol.
2. The Committee clarified that the reimbursement would be commensurate with the time spent in the unit and the ICF and advertising would be amended with the correct information.
3. The Committee requested that the messaging around “grabbing your friends” in the advertisement would be removed.

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

1. Please define Hepatitis B Virus (HBV) the first time it is used.
2. The Committee noted that the numbering in the bullet points would be fixed.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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| **2** | **Ethics ref:** | **2022 FULL 12486** |
|  | Title: | A Randomised, double-blinded phase II study of gemcitabine and nab‐paclitaxel with CEND‐1 or placebo in patients with untreated  metastatic pancreatic ductal adenocarcinoma |
|  | Principal Investigator: | Dr Jane Yeojeong So |
|  | Sponsor: | Australasian Gastro-Intestinal Trials Group |
|  | Clock Start Date: | 08 September 2022 |

Dr Jane Yeojeong So and Sophie Goodger 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 participants randomised to the placebo arm were benefitting in that they would be given access to an expensive chemotherapeutic drug as a result of inclusion into the study.
2. The Committee noted that this was not a commercially sponsored study and that injury compensation would be covered by ACC.
3. The Committee clarified that the study drug was an adjunct therapy intended to aid standard of care. This study will not be changing standard of care.
4. The Committee clarified that the archived tissue would be new as these participants are almost all recently diagnosed.
5. The Committee clarified that a high-resolution CT scan would be taken and is standard of care for these patients.
6. The Committee clarified the handling of distress in participants given this is a terminal cancer would also be standard of care.
7. The Committee clarified the recruitment approach would be done by someone who is not the treating clinician.
8. The Committee noted that there would be no reimbursement of travel costs outside of the parking fee coverage as is standard.
9. The Researcher clarified how serious medical or psychiatric conditions that might limit the ability of the person to comply with the protocol would be assessed and the reasons for exclusion on this basis were to prevent data issues arising from seriously mentally unwell participants who may not be able to comply with the parameters of the study design.

Summary of outstanding ethical issues

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

1. The Committee requested that a copy of the University of Sydney’s liability coverage certificate be provided, naming this study specifically.

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

1. Please note that on page 2 there is exclusion of women who could become pregnant. Remove this as it is not accurate given the details for contraception etc as detailed later in the document.
2. Please remove the brief mention of storage for future genetic research from the main PIS and include it only in the Future Unspecified Research PIS.
3. Please include limits around the storage period of tissue, as “indefinite” is not specific enough.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Leonie Walker and Dr Sotera Catapang.

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| **3** | **Ethics ref:** | **2022 FULL 13500** |
|  | Title: | Examining Food Insecurity in a Regional New Zealand Emergency Department |
|  | Principal Investigator: | Dr Stephanie Richling |
|  | Sponsor: | Te Whatu Ora - Whangarei Hospital |
|  | Clock Start Date: | 08 September 2022 |

Dr Stephanie Richling 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 that this was a feasibility study to attempt to ensure access to resources to participants who need it. The Researcher noted that they wanted to specifically investigate this in the Emergency Department (ED) settings.
2. The Researcher clarified that the face-to-face nature of the study was to attempt to promote conversation and give more context to the importance of the study to participants.
3. The Committee noted that Right 7(4) of the Code of Rights was not relevant where adults could not consent, as this survey is not in the best interest of the participants.
4. The Committee noted that children would not be approached with the study and that given the adult is answering the survey for the household, there is no need to receive the permission of the children of that household. As such the Committee noted that the request from the previous Committee was void as the child would not be the participant. No separate participant information sheets would be needed for younger people.
5. The Committee clarified that management of the participants potential mood etc would begin with a consultation between the research team and the treating clinicians. The researcher noted that there was exclusion of unstable patients and that this would include emotionally unstable individuals as well physically unstable.
6. The Committee clarified that overwhelming of ED clinicians with this additional study burden will not occur as the research team would be separate from the treating clinicians.
7. The researchers notes that there was no way of removing participants from the survey once the survey was completed. Withdrawal would need to be during the survey.
8. The Committee clarified that it was incredibly difficult for the deprivation index to be calculated without the provision of the address of individuals participating.
9. The Committee clarified the ways in which the Intervention stage of the study will function. Including how the Participant’s information will be able to be shared with the social worker and they will keep information as to the intervention provided as follow up for the study.
10. The Committee clarified that through contact with the social worker, there would be enough capacity for the study but if there was intention for the study practice to become standard in that department there would need to be further funding.
11. The Committee clarified the check in periods following the study as well as during the intervention.

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 considered that the answering of a survey in the ED would not be appropriate and that they may respond with anger or feelings of coercion.
2. The Committee queried the use of the number of the street. This is an identifier and therefore the study is not anonymous.
3. The Committee requested clarification of whether the sample size had taken into account the withdrawal and dropout rates from follow up sessions.
4. The Committee suggested reworking the Participant Information Sheets to be briefer for the purpose of this study. Simplification of this form is requested.
5. The Committee requested that there be a simplified recruitment and consenting process addressed to adults with some additional materials for easy socialisation and the ability for supported decision making in younger people and people who are severely unwell.

**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 Kate O’Connor and Mr Dereck Chang.

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| **4** | **Ethics ref:** | **2022 FULL 13517** |
|  | Title: | A single-centre, controlled, within-patient, multi-period study to assess the non-inferiority and safety of the Airvo 3 Junior device to  deliver variable-flow CPAP to premature infants requiring respiratory support. |
|  | Principal Investigator: | Dr Bronwyn Dixon |
|  | Sponsor: | Fisher & Paykel Healthcare |
|  | Clock Start Date: | 08 September 2022 |

Dr Bronwyn Dixon, Claire Mellick and Caitlin Chatfield were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified the care that would be provided for the participants was not lacking by nature of the change in device.
2. The Committee clarified that the initial approach for recruitment would be by someone not on the study team and removed from the clinician.
3. The Committee clarified that Fisher and Paykel staff would not be attending all clinical sessions but just the first one.
4. The Committee clarified that this firmware has not been used in humans previously.
5. The Committee clarified the congenital abnormalities that would be excluded from the study.

Summary of outstanding ethical issues

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

1. The Committee requested that there be no identifiable information sent to the sponsor and that any cases where there is mention of data be de-identified by the sponsor be replaced with “Study data will be de-identified prior to being sent to the sponsor.”
2. The Committee noted that there were errors in the protocol regarding the randomisation that need to be removed. Particularly referring to the envelopes and their use in randomisation.

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

1. Please review for lay language and simplify technical information.
2. Please note that the first paragraph should read "it won't affect the care your baby receives”.
3. Please consider changing the language around withdrawal to "withdraw your baby from the study..."
4. Please communicate the change-over process simply for parents.
5. Please include information that Fisher and Paykel staff will attend the first study session.
6. Please include the First-In-Human (FIH) box at the top of the form to ensure participants are aware that parts of the new study device are FIH.
7. Please state what swapping the device for testing will involve and the interruptions that may occur to treatment as a result of this.
8. Please remove all reference to Canterbury District Health Board (DHB).
9. Please include the risks associated with Continuous Positive Airway Pressure (CPAP) therapy or note that there are the same risks as with any Flow-drive treatment.
10. Please remove the repeated mention of participants not receiving reimbursement.

**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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| **5** | **Ethics ref:** | **2022 FULL 12729** |
|  | Title: | A pivotal in vivo bioequivalence study comparing methylprednisolone aceponate ointment (Nova Chem, Australia) to Advantan® ointment (Leo Pharma Pty Ltd, Australia), using the ED50 for Advantan® ointment calculated from the pilot dose duration-response study and using 90 responders with the expectation to have 40-60 subjects who meet the responder and detector criteria (“evaluable”) |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Nova Chem Australasia Pty Ltd. |
|  | Clock Start Date: | 08 September 2022 |

Dr Noelyn Hung and Linda Folland were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee noted that study documentation states that participants are to be discouraged from cleansing the skin, however the participant information states that the arm should be free of dirt. The Researchers clarified that the skin will be cleansed by the study team on arrival. The Committee requested that this is clarified in the participant information and protocol.

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

1. The Committee noted that the statement referring to allowing different product to market and be available for consumer choice can go under benefit.
2. Regarding the restriction of over-the-counter medications, please clarify that participants should check first before taking these or advise the study team of any medications taken if required.
3. Provide examples of “substances” like including food.
4. Please specify what the 0 hour under evaluation is.
5. Please mention that karakia is not available at time of tissue disposal.

**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:** | **2022 FULL 13452** |
|  | Title: | A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Phase III Efficacy and Safety Study of Tezepelumab in Patients with Eosinophilic Esophagitis (CROSSING) |
|  | Principal Investigator: | Dr Benjamin Griffiths |
|  | Sponsor: | AstraZeneca Pty Ltd |
|  | Clock Start Date: | 08 September 2022 |

Dr Benjamin Griffiths, Richard Coleman, April Dano, and William Rae 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 was satisfied that the risk was minimal for affecting waiting lists for biopsies and procedures for the trials will be invoiced to the Sponsor.
2. The Researcher confirmed that the patient support materials will not be used for every New Zealand site and will not replace conversation with the Researcher or the submiited PIS / CF and would only be used in as additional supporting information.
3. The Committee queried how the Researcher would avoid the risk of coercion when inviting their own patients to participate in the study. The Researcher stated that they would make it very clear that participation is optional and will also provide access to study co-ordinators to consent the participants.

Summary of outstanding ethical issues

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

1. Please confirm if the US-based helpdesk for is free to call or provide a local support number.
2. The study protocol has options for home-visits, but there was no safety procedures for these home visits for the participant or for members of the study team.
3. The Committee requested that if home-visits are planned in New Zealand, a researcher and participant safety plan/standard operating procedure is required. This can be submitted as an amendment if this is intended.
4. The Committee noted that a pregnant participant/partner participant information sheet/consent form should only be submitted as an amendment in the event that a pregnancy occurs so it can be fit-for-purpose. As such, these have not approved for use with the current submission.

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

1. Please remove reference to home visits in the PIS. If these become available for New Zealand participants, this can be updated via an amendment.
2. State that the study device must be given back at the end of the study.
3. Mention what access participants would have to the investigational product after the study.
4. The Committee noted that a study cannot be stopped for commercial reasons only. Please clarify.
5. Notification of participation to the GP is mandatory for participation, please remove the optional tickbox in the CF.

**Decision**

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

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

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| **7** | **Ethics ref:** | **2022 FULL 12899** |
|  | Title: | Randomized, double-blind, placebo-controlled, parallel groups, multicenter pivotal study assessing the efficacy and safety of 15 mg twice a day (BID) of SER150 in well-controlled type 2 diabetic patients with diabetic kidney disease and macroalbuminuria in treatment with an angiotensin converting enzyme inhibitor or an angiotensin receptor antagonist |
|  | Principal Investigator: | Dr Michael Williams |
|  | Sponsor: | Serodus (Aus) Pty Ltd |
|  | Clock Start Date: | 08 September 2022 |

Dr Michael Williams 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 use of tissue in the protocol, "Research samples will be retained for possible future analyses of exploratory biomarkers, which may include but is not limited to, TNFR1, brain natriuretic peptide and KIM-1". The Committee stated that this isn’t specific enough as underlined. Please define what answers the study question and what would answer other questions, and state all that would be explored. If there is future unspecified, this would need a separate consent.
2. Please further define ‘overtly healthy’ under the inclusion criteria.
3. The Committee requested the following changes to the advertising:
   1. Use “potential” in front of treatment.
   2. State participant will receive investigational product or placebo.
   3. Please include ethics reference.
   4. Please add name of study funder.

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

1. Please add the expected timeframe for receiving results at the end of the study.
2. On page 14, please remove reference to “hospital” and amend accordingly.
3. The Committee noted that a study cannot be stopped for commercial reasons only.
4. Please clarify when alcohol and caffeine has to be avoided.

**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 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).
3. 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 Kate O’Connor and Ms Jade Scott.

## General business

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

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| **Meeting date:** | 18 October 2022 |
| **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 4.00pm