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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 04 April 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:00pm-12:30pm | 2023 EXP 15318 | The Gold Studies: Myocarditis and Pericarditis Association Study | Associate Professor Helen Petousis Harris | Ms Kate O'Connor and Mrs Leesa Russell |
| 12:30pm-1:00pm | 2023 FULL 15546 | What sorts of cognitive tasks do men find easier than others within Ara Poutama? | Professor Alice Theadom | Ms Alice McCarthy and Mr Barry Taylor |
| 1:00pm-1:30pm | 2023 FULL 15290 | A Study Comparing Treatment Preference Between Oral Decitabine/Cedazuridine and Azacitidine in Myelodysplastic Syndrome, Low-Blast Acute Myeloid Leukemia, or Chronic Myelomonocytic Leukemia | Dr Anna Elinder-Camburn | Mr Ewe Leong Lim and Dr Amber Parry-Strong |
| 1:50pm-2:20pm | 2023 FULL 15451 | A Phase 2 Study Evaluating INCB099280 in Participants With Advanced Cutaneous Squamous Cell Carcinoma | Associate Professor Michael Jameson | Ms Kate O'Connor and Dr Amber Parry-Strong |
| 2:20pm-2:50pm | 2023 FULL 15089 | An extension study to evaluate the efficacy of Olezarsen (ISIS 678354) among patients with elevated levels of triglyceride | Dr Jocelyne Benatar | Ms Alice McCarthy and Mr Barry Taylor |
| 2:50pm-3:20pm | 2023 FULL 15336 | A Study comparing Vixarelimab with Placebo in Participants with Fibrotic Lung Diseases | Dr Henry Gallagher | Mr Ewe Leong Lim and Mr Barry Taylor |
| 3:20pm-3:50pm | 2023 FULL 15373 | Anakinra Pilot | Dr Gergely Toldi | Ms Maakere Marr and Mrs Leesa Russell |
| 11:30am-12:00pm | 2023 FULL 13948 | DECRESCENDO: de-escalation of adjuvant chemotherapy in HER2-positive, early breast cancer patients who achieved pathological complete response after neoadjuvant treatment. | Dr David Porter | Ms Maakere Marr and Dr Amber Parry-Strong |
| 4:00pm-4:30pm | 2023 FULL 13740 | ALLAY-HF Study | Professor Gerard Thomas Wilkins | Ms Alice McCarthy and Dr Amber Parry Strong |
| 4:30pm-5:00pm | 2023 FULL 15544 | Co-creating a research proposal to explore the role of domestic soundscapes in dementia friendly housing | Professor Vanessa Burholt | Ms Maakere Marr and Mr Barry Taylor |
| 5:00pm-5:30pm | 2023 FULL 15547 | The SMILEY Study | Professor Clare Wall | Mr Ewe Leong Lim and Mrs Leesa Russell |
| 5:30pm-6:00pm | 2023 EXP 15600 | Nutritional response to chyme reinfusion in intestinal failure - a pilot study | Professor Rozanne Kruger | Mrs Kate O'Connor and Mrs Leesa Russell |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Ms Kate O’Connor  | Lay (Ethical/Moral reasoning) (Chair) | 13/08/2021 | 16/08/2024 | Present |
| Mrs Leesa Russell | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present  |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Ms Alice McCarthy | Lay (the Law) | 22/12/2021 | 22/12/2024 | Apologies |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Apologies |
| Dr Amber Parry-Strong | Non-Lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Mr Ewe Leong Lim | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |

## Welcome

The Chair opened the meeting at 11.00am and welcomed Committee members, noting that apologies had been received from Ms Alice McCarthy and Ms Joan Petit.

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 07 March 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | 2023 FULL 13948 |
|   | Title:  | De-Escalation of adjuvant ChemotheRapy in HER2-positive, EStrogen reCEptor-negative, Node-negative early breast cancer patients who achieved pathological complete response after neoadjuvant chemotherapy and Dual HER2 blOckade |
|   | Principal Investigator:  | Dr David Porter |
|   | Sponsor:  | Breast Cancer Trials (BCT) |
|   | Clock Start Date:  | 23 March 2023 |

Dr David Porter 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 asked about the recruitment strategy. The Researcher explained there is a study nurse who is independent from the direct clinical team who participants can talk to.
2. The Committee asked about the optional sub study agreement and its content. The Researcher explained that it would be a separate HDEC amendment submission and is not made just yet.
3. The Committee asked about the mandatory genetic testing with the option of testing the background genes. The Researcher explained that this is used to look at the subset of breast cancer and will be used to identify if there is a group who benefit more from the study and is typically standard of care.

Summary of outstanding ethical issues

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

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

1. Please include a graph or table explaining the standard of care and what the differences that will cover the differences for standard of care and make it easier for participants to understand.
2. Please clarify whether any tissue will be sent overseas and include the location of the lab(s) if so.

**Decision**

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

* 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 EXP 15318 |
|   | Title:  | Myocarditis and pericarditis association studies. Observational studies to assess the risk of adverse events of special interest following COVID-19, and mpox (smallpox), vaccines in Aotearoa New Zealand – A gold standard approach. |
|   | Principal Investigator:  | Professor Helen Harris |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 23 March 2023 |

Professor Helen Harris and Lisbeth Alley 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 asked about the Sponsor and if the CDC is sponsoring this study. The Researcher explained that the CDC is sponsoring the study and that New Zealand is a site for the study.
2. The Researcher clarified that Te Whatu Ora’s involvement is the overall body rather than an individual district.
3. The Committee queried the line in a letter from Te Whatu Ora "the scientific data and conclusions of the final report are not to be altered for this suitability". The Researcher clarified that this was Te Whatu Ora providing assurance on their end and was not a restriction being imposed.

**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 after discussion that they acknowledge that the Researchers have a good understanding of the protocol, but this has not been clearly explained in the study documentation. The particulars are outlined below.
2. The Committee noted that what is being asked to approve is the use of administrative data and the cases for a subset of the programme, not about the genomic study which is in the global protocol. Please supply more specification on what HDEC is being asked to approve, separating out what is required from New Zealand from the global protocol and have the data management plan pertain to that component. It would be useful to have governance documentation around the programme as well as terms of reference around the community advisory and data groups that should satisfy the requirements for good governance to have identifiable administrative data under a waiver of consent *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.28-12.30).*
3. The Committee queried the scope of the administrative data. After discussion, the Researchers clarified that the dataset they have is one they already obtained and use for other projects. Within this encrypted data collection, they identify cases of interest, send them to the Ministry of Health (the Ministry) for de-encryption where a team of clinicians will audit the clinical notes to validate whether they are a case of interest. This is then re-encrypted by the Ministry before being sent to analysts. The Committee noted that the source of the large administrative dataset they already have and how these approvals and governance structures work for that dataset need to be detailed to the Committee in documentation. They were comfortable with what was described, but this needed to be separated out from the global protocol for the global program, making it also clear that the data will not leave the country and only aggregate bottom line data will be contributed to the rest of the program. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8).*
4. The Committee asked about how the Researcher will deal with identification through inference. The Researcher explained that it will only be clinicians who will see the deidentified data, and individual cases won’t be able to be identified from the data sets, however they have acknowledged this is a sensitive subject and will take extra care when dealing with this.
5. Regarding how this application was structured with local and global sponsor, the Committee noted that someone within the team cannot sign off as the local sponsor for the institution, such as academic head or research office. The Committee noted to check with the university’s human ethics office.
6. The Committee recommended not using the term administrative data as it has a specific meaning for classifications of data, which is contradictory to the kind of data this is as this is considered health data such as ICD-10 codes with an identifier *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.1)*.
7. Throughout the application and documentation, the Committee requested clarity and consistency about retention periods of all data. This includes big data set used for multiple applications, and the data used specifically for this study, and is not only just the local study team and their institution, but also the overseas collaborators who are ending up with an aggregate set. If this is a study with significant scientific benefit, 6 years as noted in part of the application would not be long enough *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.13)*.
8. The Committee asked about if the Researchers need live data which is in the protocol for the i-39 inclusion. The Researcher explained that there is only retrospective health data and is not identifiable data for i-39 as these would be de-identified by Te Whatu Ora. The Committee noted that the protocol currently reads as having live data for the i-39 inclusion review and that this could be identifiable. The Researcher confirmed that no identifiable data will be used. The Committee requested this is outlined in the New-Zealand specific protocol.
9. The peer review submitted doesn’t meet HDEC requirements of being independent from the study, and the Committee requested an independent review of the distinguished protocol requested above. Please provide an independent peer review. The [HDEC peer review template](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance/) can be used *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
10. The Committee raised the following about the application form:
	1. B.4.1. currently suggests there might be on-sharing of data, but is unclear who has governance and when that might occur. Please review that section and make sure it is clearer in the next submission.
	2. Date of birth (DOB) is considered an identifier, so if DOB is in the dataset, that is an identifiable dataset. References to de-identified sets with DOB is incorrect. Please be direct that this is identifiable data and be clear which sets are now needing to be identifiable
	3. It is not clear what the ‘administrative’ data set contains, please be clear what is identifiable within it.
11. The Committee requested the following changes to the Data Management Plan (DMP) (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a*):
	1. The Committee noted per the DMP that assertion to follow laws around Māori data sovereignty is incorrect as New Zealand doesn’t have specific laws surrounding it currently. Please refer to guidelines available instead that the study will adhere to.
	2. Please be very clear about what data the study is using, and reference to the larger dataset being used for this, clarifying that the study is only using what you need and that this is not fishing for other information, and the purpose is clear and specific.
	3. Please password protect all excels spreadsheets.
	4. The Committee referred the Researchers to the HDEC DMP template for guidance and use and would be helpful for isolating the New Zealand portion of the study. Use of the HDEC template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/) is not mandatory but is encouraged to be adapted or used as a guide/starting point.

**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 15546 |
|   | Title:  | What are the cognitive characteristics of men within the prison population? |
|   | Principal Investigator:  | Professor Alice Theadom |
|   | Sponsor:  | Auckland University of Technology |
|   | Clock Start Date:  | 23 March 2023 |

Professor Alice Theadom, Marliyn Farmer, Te Kanu Kingi and Nicola Starkey were present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

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

**Summary of resolved ethical issues**

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

1. The Committee commended the Researchers on the quality of their application and the careful consideration that had been undertaken in putting the study together.
2. The Committee asked about the return of results and the recruitment for Researchers on contract and will they be qualified enough to give a quick summary of the results. The Researcher explained that the Researcher at the time will not be scoring the participant in front of them, all the scores will be checked by a qualified neuropsychologist, and they will provide a brief overview for the Researcher to feed back.

**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 consent form for the simplified participant information sheet was not included. Please submit this.
2. The simpler participant information sheet has been framed as a supported decision-making sheet. This is a misapplication of this term as capacity is not being assessed for this determination.
3. In the questionnaire regarding drugs and alcohol, please remove the “drugs, alcohol etc in the last 3 months” question as this has wider implications.
4. The data management plan it should be explicit about the data that is being shared with the prison.

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

1. Please include a contact for Māori cultural support.
2. Please ensure information provided here is clear that participants are entitled to request their results and explain how the study team will go about providing these to them, as well as other options available to them for how this can be documented.
3. Please provide more information about types of tasks, such as matching symbols or getting through a maze.

**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 Barry Taylor and Ms Kate O'Connor.

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| **4**   | **Ethics ref:**   | 2023 FULL 15290 |
|   | Title:  | A Phase 3b, Randomized, Open-Label, Double Crossover Study Comparing Treatment Preference Between Oral Decitabine/Cedazuridine and Azacitidine in Adult Patients with IPSS-R Intermediate Myelodysplastic Syndrome, Low-Blast Acute Myeloid Leukemia, IPSS Intermediate-2 or High-Risk Myelodysplastic Syndrome or Chronic Myelomonocytic Leukemia |
|   | Principal Investigator:  | Dr Anna Elinder-Camburn |
|   | Sponsor:  | Otsuka Australia Pharmaceutical Pty Ltd |
|   | Clock Start Date:  | 23 March 2023 |

Dr Francisca Reed 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 asked if vouchers will be handed out every visit. The Researcher explained that they do usually provide vouchers for every visit, including travel expenses, etc.
2. The Committee asked if the median age of diagnosis is 70, do all females need a pregnancy test. The Researcher explained that all participants will need to have a pregnancy test regardless of age as this is common practice and noted that there can be some participants of child-bearing age.

**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 amend the “how much would you pay” question and reiterate to the participant they do not have to pay themselves. Further, in the context of asking them this, asking them to be realistic of their own circumstance. The Committee recommended outlining to participants in the participant information sheet that you are asking them in a round-about way about other personal information and amending the item in the consent form about accessing medical records ‘and other personal information’.
2. The Committee noted that insurance cover for period of study is 1 Sept 2022 - 31 July 2023. The proposed period of study the subject of the application is outside the insured period of study. The insurance period of study needs to be extended to cover the New Zealand study and should be submitted to the Committee when a new insurance certificate is acquired.
3. The Committee noted minor concerns about responses to the application form to consider for response/future applications
	1. In section C4 of the application please do not cite the Treaty of Waitangi in this section. Instead, please talk about rates of this condition in Māori and what is known about Māori experience with this condition instead.
	2. Please amend section C5 of the application it currently states that blood and urine is going overseas but then in section F2/3 states it will not be, please clarify and amend if needed.
4. The Committee requested that paper copies of the electronic questionnaires are provided in case. Given the age of this population, some might struggle with interaction with a digital device.

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

1. Please include that travel expenses for participants will be covered.
2. Please amend the koha section to include petrol vouchers for patients who drive themselves (or a support person does) or taxi vouchers.
3. On page 8, please remove the sentence “social situations that your study doctor believes may not make the study suitable for you”.
4. Please make sure the sheet mentions the caregiver statement and reassure that they can take part even the participant does not have a caregiver, or if the caregiver declines to take part.

**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 Ewe Leong Lim and Dr Amber Parry Strong.

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| **5**   | **Ethics ref:**   | 2023 FULL 15451 |
|   | Title:  | A Phase 2 Study Evaluating INCB099280 in Participants With Advanced Cutaneous Squamous Cell Carcinoma |
|   | Principal Investigator:  | Professor Michael Jameson |
|   | Sponsor:  | Pharmaceutical Company - Incyte Corporation |
|   | Clock Start Date:  | 23 March 2023 |

Claudia Romano, Sandra Hargrove, and Dr Edbert Wong 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 is only being done at Waikato at this stage.
2. The Committee asked about if participants are getting continued dosing. The Researcher explained that part 2 is there for statistical inclusion and not the participation rolling over into part 2 for more treatment. They are not getting continued dosing in part 2.
3. The Committee asked about recruitment and power imbalance being mitigated. The Researcher explained that the participants will come through the tumour board meeting, the surgeon informs the participant of their options and will let them know there is a clinical trial available and someone in the research team will send through the potential participant consent forms etc., to be enrolled into this study if the potential participant wishes to join. The Committee was satisfied with this.
4. The Committee asked if paper copies of the online medical diary is available for participants for parts of the population not quite caught up with digital advancements. The Researcher explained that it is available, however they are encouraged to use the digital diaries for easier data input and tracing for the research team.
5. The Committee asked about participant reimbursement. The Researcher explained that they work out the distance a participant must travel, and they are reimbursed 83 cents a kilometre as per IRD standards. Meals and parking are also covered if needed.

**Summary of outstanding ethical issues**

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

1. The Committee noted that this study does require locality authorisation through the hospital research office. The application form currently indicated it was not required, rather than it was required but will be obtained later.

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

Main PIS/CF:

1. Please amend the other treatment options to be in line with the progression PIS.
2. Please explain parts 1 and 2 in more detail, highlighting exactly what will happen at each stage of the study, including time frames and procedures.
3. On page 8, please distinguish between the tumour and the human cells as the protocol talks about circulating tumour DNA however this section seems broader. Please ensure this is specific to this study only.
4. On page 13 in the contraception section, please remove references to the NuvaRing as it is not available in New Zealand.
5. Please amend the consent form and make future unspecified research an opt-in choice, not opt-out.

**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 Kate O’Connor and Dr Amber Parry-Strong.

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| **6**   | **Ethics ref:**   | 2023 FULL 15089 |
|   | Title:  | An Open-Label Extension Study of Olezarsen (ISIS 678354) Administered Subcutaneously to Patients with Severe Hypertriglyceridemia (SHTG) |
|   | Principal Investigator:  | Dr Jocelyne Benatar |
|   | Sponsor:  | Ionis Pharmaceuticals, Inc. USA |
|   | Clock Start Date:  | 23 March 2023 |

No one from the research team was present via videoconference for discussion of this application who gave their apologies ahead of time.

**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.

**Decision**

This application was *approved* by consensus, noting no ethical concerns to be addressed.

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| **7**   | **Ethics ref:**   | 2023 FULL 15336 |
|   | Title:  | A Two-cohort, Phase II, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study Evaluating the Efficacy and Safety of Vixarelimab compared with Placebo in Patients with Idiopathic Pulmonary Fibrosis and in Patients with System SclerosisAssociated Interstitial Lung Disease |
|   | Principal Investigator:  | Dr Henry Gallagher |
|   | Sponsor:  | Genentech Inc |
|   | Clock Start Date:  | 23 March 2023 |

Christine Tuffery and Dr Rebekah Anstey 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 recruitment is managed for these patients given the power imbalance between them and clinicians. After discussion, the Committee was assured they had opportunity to discuss participation with someone independent of their clinical care and had plenty of time to consider.

**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 answer to F4.1 in the application form regarding genome sequencing currently raises significant cultural issues for Māori and may be excluding participants which is deemed unfair to them. If this is not answering the main study questions, the Committee’s preference is that this is transferred into the optional research information sheet that already exists. The Committee are prepared to approve the study so long as it’s not made mandatory and whole genome sequencing could be included in the optional participant information sheet (PIS).
2. The Committee stated that the optional home visit nursing information sheet could be folded into the main PIS, with an option on the Consent Form.
3. The Committee noted that the CI’s MPS membership expires/has expired and will need to be renewed.
4. In the data management plan, please remove template comments at beginning of document and account for personal identifiers being sent to the home visit nurses.

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

1. On page 4 of Main PIS, please amend "You should not join another research study" change to clinical trial.
2. On page 12 of Main PIS, please remove exclusion "The costs are not paid for by your medical insurance" as the Sponsor will be liable for any costs.
3. Please amend the open label extension participant information sheet, when referencing the main participant information sheet, add 'compensation for study related injury' to "All conditions, risks, and privacy information described there, also please apply to the open-label extension period.”

**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 Ewe Leong Lim and Mr Barry Taylor.

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| **8**   | **Ethics ref:**   | 2023 FULL 15373 |
|   | Title:  | Advancing Interleukin 1 Receptor Antagonist to Prevent Inflammatory Disease in Preterm Infants |
|   | Principal Investigator:  | Dr Gergely Toldi |
|   | Sponsor:  | Monash University. |
|   | Clock Start Date:  | 23 March 2023 |

Dr Gergely Toldi and Professor Marcel Nold 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 pre- and post- birth consent process and deemed that 6 participants would be a feasible number for the study. The Researcher noted that the post-consent process would not be used unless necessary due to the increased stress this could put on parents.
2. The Committee clarified that the cut-off for a pre-birth approach for recruitment would be the point at which labour began.
3. The Committee noted that the information and consent forms were focused on the gestational parent only. The Researcher explained that the samples collected from the gestational parent was the primary reason for this, however, there would be a strong emphasis made by the research staff for parents to include whoever they sought in determining whether participation was right for them.
4. The Committee clarified that there was some indication that this study drug could be of great benefit to young babies, for which currently there is only a steroid-based treatment that comes with several side effects.
5. The Committee queried if Māori and Pasifika will be specifically targeted. The Researcher clarified that these will be recruited as part of the population given the incidence of pre-term births.

**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 separate post-birth consent be sought for the collection of the baby’s data due to the way legal personhood is given upon birth. Confirmation of consent would not be sufficient in this case.
2. The Committee queried how the Researcher would approach potential discussions with parents should the baby die during the study. After discussion, they requested documentation of what the Researcher will do.
3. The Committee requested making notification to GP of adverse events mandatory.
4. The Committee noted that an assent form would be required for when the child is older, but that can come through as an Amendment to the Committee for review and approval when it is required.
5. The Committee requested to see the outcome of cultural consultation once it has been received.
6. The Committee noted that the indemnity certificate for the CI is missing from the submission and is required in this case.

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

1. The Committee noted that there is not much information on what is happening at the future study visits. Please tell participants as much information about the future activities as much as possible as it is currently open ended and vague and may not be assuring. An amendment can be submitted to the Committee in future if these visits change.
2. Please provide more information around what development testing involves.
3. The Committee noted that the data for the baby must be signed after birth. Please adjust the consent form for this, and this could be signed by either parent post-birth.
4. Please note that at later ages, the child can provide their own assent for continued participation.
5. Please review for lay-language and simplify where possible.
6. On page 3, it isn’t clear if the study is requesting to access the mother’s medical notes for 12 years. Please clarify that this is accessing the medical information for pregnancy and birth.
7. Please include overall blood amount being taken.
8. The Committee clarified that a koha is a gift, money for travel is reimbursement. Covering travel expenses is reimbursement, and a koha would be in addition to that.
9. Page 6, it says samples will be stored and tested in future using techniques not available now. Please clarify this is not future unspecified research (FUR) for this study. This needs to be reworded, as consent for future use needs a different PIS. Currently the wording implies open-ended future use of samples.

**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 Maakere Marr and Mrs Leesa Russell.

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| **9**   | **Ethics ref:**   | 2023 FULL 13740 |
|   | Title:  | Safety and Efficacy of the Alleviant System for No-Implant Interatrial Shunt Creation in Patients with Chronic Heart Failure. |
|   | Principal Investigator:  | Professor Gerard Wilkins |
|   | Sponsor:  | Alleviant Medical, Inc. |
|   | Clock Start Date:  | 23 March 2023 |

Professor Gerard Wilkins and Mary Blok 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 the sham procedure and requested justification for putting participants through that stress of not having a proper procedure. The Researcher responded that whether a participant receives the study intervention, all will receive closer care and additional clinical oversight they would not otherwise receive. In addition, all will undergo invasive testing not usually performed that is beneficial to understand their specific haemodynamic problems. Further, the Researcher confirmed that those who do not receive the intervention can be crossed over in 2 years if the intervention demonstrates benefit.
2. The Researcher confirmed equity of opportunity for participation of public versus private as recruitment will largely be drawn from public admissions.
3. The Researcher confirmed that all surgery would be paid for by the Sponsor and would not burden the public health system.

**Summary of outstanding ethical issues**

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

1. The Committee requested that the data management plan (DMP) be redone in HDEC-expected format. The submitted appendix from protocol in its current place can be reformatted using the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/) or using it as guidance so that the standards can be specifically checked
2. The advertisement describes it as a non-surgical treatment but may be overstating it as many people would regard the catheter procedure as a surgery. The Committee recommended adjusting the wording to be a bit clearer.

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

1. Please edit description in Section 3 of the sham treatment to be in more lay-friendly terms
2. Sections 8 and 9 talk about risks and benefits of the intervention, but please also add risks and benefits of the control group.
3. Please add a section about data and tissue going overseas, as well as a cultural section. The [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) has example statements to use for guidance.

**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 more detailed data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(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 Ms Kate O’Connor and Dr Amber Parry-Strong.

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| **10**   | **Ethics ref:**   | 2023 FULL 15544 |
|   | Title:  | Co-creating a research proposal to explore the role of domestic soundscapes in dementia friendly housing |
|   | Principal Investigator:  | Professor Vanessa Burholt |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 23 March 2023 |

Professor Vanessa Burholt 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 people living with dementia are included in the study, however noted after discussion with the Researcher that these are all participants who will have been assessed to have capacity to consent with supported decision making and ongoing consent check-in. The Committee determined that they do not consider these participants vulnerable with these measures in place related to the relative risk of participation of the study. This study is early-stage and currently does not appear to be health-research, and the Committee recommended submitting this project through the University of Auckland’s ethics committee.

**Decision**

After discussion, this application was determined to be out of scope by consensus as it does not relate to health and disability-related research. This letter can be used as evidence that HDEC review is not required.

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| **11**   | **Ethics ref:**   | 2023 FULL 15547 |
|   | Title:  | Sheep and Cow milk Complementary Food Effects on Gut Microbial Diversity SMILEY Pilot Study |
|   | Principal Investigator:  | Professor Clare Wall |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 23 March 2023 |

Professor Clare Wall was present via videoconference for discussion of this application.

**Potential conflicts of interest**

Dr Amber Parry-Strong declared a potential conflict of interest and excused herself from the discussion.

**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 Sponsor sign-off for the University should go through the human ethics office. This can be re-signed before resubmitting the form for the provisional approval response.
2. The Committee noted that the advertisements before they are used should be submitted as an Amendment if not included in the response to provisional approval.
3. The Committee noted the statement about seeking prior approval about future unspecified research (FUR) on samples. This leaves the option for extended storage for FUR open. The Committee recommended getting consent for that extended storage from the beginning rather than contact at a later date or remove entirely if samples cannot be stored for continued use.
4. The Committee confirmed that the shipping of the product and samples between the research team and participants will be paid for, however noted that the Researcher must account for data safety with respect to the courier in the data management plan, as they are seeing identifiable information in association with the study.
5. G2 of the application form appears to state that the Researcher is planning to store data in identifiable format. It is not currently clear if it is some for a purpose, and only place this is references. After discussion, the Committee recommended using the ID on both datasets and linking the IDs, removing the names and identifiers on a separate list.

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

1. Consent form contains typo of ‘1050’ babies, please correct.
2. Correct Māori health support to Māori cultural support
3. Please make it clearer what is the mother’s data versus baby’s data.
4. The “for your own protection” statement suggests there may be something someone needs to be protected from and could be alarming. Please soften this.
5. A statement under “what will I be paid?” has reference to an old study. Please amend.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Ewe Leong Lim and Mrs Leesa Russell.

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| **12**   | **Ethics ref:**   | 2023 EXP 15600 |
|   | Title:  | Investigation into the nutritional response to chyme reinfusion in patients with Type 2 Intestinal Failure - a pilot study |
|   | Principal Investigator:  | Professor Rozanne Kruger |
|   | Sponsor:  | Massey University |
|   | Clock Start Date:  | 23 March 2023 |

Professor Rozanne Kruger and Professor Gil Hardy 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.

Mr Ewe Leong Lim declared a potential conflict of interest and was recused from discussion by the Chair.

**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 due to a declared conflict of interest and attendance, the membership was not quorum to make a decision. Upon agreement with the Researcher, they proceeded with discussion and would give a preliminary decision, with the formal decision communicated via letter following review by an absent member of the issues raised and recommendation of the rest of the Committee.
2. The Committee commended the Researchers on addressing issues raised as part of the previous Decline decision.
3. The Committee confirmed with the Researchers that patients approached for participation will have adequate time to consider their participation and were satisfied with the healthy controls being recruited by age-matching the patient group.
4. The Committee noted that Māori consultation is well considered but noted the idea of how tissue samples remain the “property” of the donor, which is not the case for the donation. The Committee stated it is likely a semantic term but could be changed to be consistent with the nature of the donation.

**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 Researchers to check and amend for consistency for information on storage of tissue samples in the Data and Tissue Management Plan and Healthy Participant Information Sheet.

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

1. The Main and Healthy Volunteer CF should have the optional tickbox removed for sending abnormal results to the GP as this should be mandatory.
2. The Future Unspecified Research (FUR) document mentions tissue samples for FUR in the consent form first, and not in the main body of the PIS. Please amend.
3. The FUR PIS is also unclear on what happens if someone withdraws. The Committee recommended in discussion with the Researchers that due to the sample size, make it clear that if they withdraw, there can be an attempt to withdraw samples or data it if it hasn’t already been used, but this cannot be guaranteed. The Committee referred the researcher to the [FUR template on HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) and advised to ensure data is included if it is adapted.

**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).*

## General business

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

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| **Meeting date:** | 02 May 2023 |
| **Zoom details:** | To be determined |

 The following members tendered apologies for this meeting.

* Ms Joan Petit
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 6.00pm