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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 17 October 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:00pm - 12:30pm | 2023 FULL 18754 | Paediatric Rehabilitation - what's important to you? | Dr Jimmy Chong | Catherine Garvey & Derek Chang |
| 12:30pm – 1:00pm | 2023 FULL 18428 | Cognitive Improvement by early Restoration of cirCADian in very preterm Infants through Environmental Modification: The CIRCA DIEM Study | Dr Maria Saito-Benz | Jonathan Darby & Jade Scott |
| 1:00pm – 1:30pm | 2023 FULL 18838 | BP16-101: A Phase 1 Single-Dose Study of denosumab versus Prolia in Healthy Male Volunteers | Dr Paul Hamilton | Catherine Garvey & Sotera Catapang |
| 1:30PM – 2:00PM | 2023 FULL 17967 | Paediatric Eosinophilic Gastrointestinal Diseases Database | Prof Andrew S Day | Dianne Glenn & Andrea Forde |
|  |  | BREAK 20 MINUTES |  |  |
| 2:20pm – 2:50pm | 2023 FULL 18725 | M23-716 – UP-AA Alopecia Areata: Efficacy and Safety of Upadacitinib in Adult and Adolescent Subjects with Severe Alopecia Areata | Dr Marius Rademaker | Dianne Glenn & Sotera Catapang |
| 2:50pm – 3:20pm | 2023 FULL 18787 | EC5026-1-02: A Study to Investigate the Safety and Tolerability of Multiple Doses of EC5026 in Healthy Participants | Dr Cory Sellwood | Catherine Garvey & Jade Scott |
| 3:20pm – 3:50pm | 2023 FULL 18830 | BGE-105-004: An Open-label study to evaluate the safety of Azelaprag in older adult participants. | Dr Susanna Abigail | Jonathan Darby & Andrea Forde |
|  |  | BREAK 10 MINUTES |  |  |
| 4:00pm – 4:30pm | 2023 FULL 18844 | Streptococcus pneumoniae induced haemolytic uraemic syndrome in children | Dr Alex Humphrey | Dianne Glenn & Andrea Forde |
| 4:30pm – 5:00pm | 2023 FULL 17956 | Delivering optimal weight gain advice to pregnant women (DOT) study | Associate Professor Kirsten Coppell | Catherine Garvey & Derek Chang |

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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 | Apologies |
| 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 |
| Ms Dianne Glenn (Co-opted) | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |

## Welcome

The Chair opened the meeting at 11:40am and welcomed Committee members, noting that apologies had been received from Dr Kate Parker.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Dianne Glenn confirmed their eligibility and were co-opted by the Chair as a member of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 19 September 2023 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2023 FULL 18754** |
|  | Title: | Paediatric Rehabilitation Priority Setting Partnership |
|  | Principal Investigator: | Dr Jimmy Chong |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 05 October 2023 |

Dr Jimmy Chong and Ms Denise Taylor were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues.

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

1. The Committee clarified the data collection methods.
2. The Committee clarified that the questionnaire process and survey contain links to allow for participants to contact the research team if necessary and that the information sheet and consenting process must be completed before the survey will allow them to answer questions.
3. The Committee clarified the role of the peer reviewer as there was no signature or role specification in the peer review provided. The researcher noted this will be amended and provided to the Committee.
4. The Committee clarified how the consenting process would work for participants, including assessment of competency for young people and assenting.
5. The Committee clarified the ways in which people with disability may be provided with information and participate.
6. The Committee clarified that where possible the participants were being provided a koha.

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 provision of all advertisements and pamphlets that will be used for recruitment.
2. The Committee noted that the number of participants and nature of the data may result in participants being identifiable. Please amend the documentation to note to participants that the anonymity cannot be assured but data is de-identified.
3. The Committee requested that the protocol and the participant information sheets (PIS) cover the hui including a list of questions to be decided on that will be sent to them for prioritisation and ranking based on its importance. Please include information on the Steering Committee to the same effect and who will be facilitating the hui.
4. The Committee queried how the young people will be heard and how vulnerability may be reduced in the hui setting to ensure that their voices are heard as well as those who are slightly older, and health professionals. Please include this in the protocol and the PIS(s).
5. The Committee recommended utilising the [HDEC data management plan template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx) as there are a number of sections the HDEC require to be clarified such as access to data and data storage.

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

1. Please detail a risk management plan. This should detail how participants will be assisted and directed to care should mental distress occur.
2. Please include headers, footers, version number and page numbers.

**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).*
4. Please supply a more detailed data management plan to ensure the safety and integrity of participant data. *(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 Derek Chang and Ms Catherine Garvey.

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| **2** | **Ethics ref:** | **2023 FULL 18428** |
|  | Title: | Cognitive Improvement by early Restoration of cirCADian in very preterm Infants through Environmental Modification: The CIRCA DIEM Study |
|  | Principal Investigator: | Dr Maria Saito-Benz |
|  | Sponsor: | Telethon Kids Institute |
|  | Clock Start Date: | 05 October 2023 |

The Circa Diem study team was present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

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

**Summary of resolved ethical issues.**

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

1. The Committee clarified the reasons for the exclusion criteria and that the recruitment of participants with congenital abnormalities would be done in follow up studies to ensure that the study was statistically well-constructed.
2. The Committee clarified that the recruitment would be local in New Zealand to sites and that this would remove the need for large sums of reimbursement for travel in New Zealand.

**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 provision of the Sleep Sub study-survey, diary and easy read version of the main study brochure.
2. The Committee requested that the HDEC logo be removed from the header of documentation it appears in.
3. The Committee requested that mention of the HDEC being located in Wellington, New Zealand be removed from documentation it appears in.
4. The Committee requested that a short heading be provided to all questionnaires.
5. The Committee requested that the video include reference to New Zealand.
6. The Committee requested clarification of the accessibility of the app to video movement to all study participants.
7. The Committee requested that the Post Bayley letter only mention services available in New Zealand.
8. The Committee requested that the reference to an approving HDEC in the Protocol be amended to state that Northern A is the approving HDEC.

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

1. Please amend reimbursement wording to state “will be offered” rather than “may be”.
2. Please note that HDEC only approve the ethical aspects of studies. Please ensure that this is specified.
3. Please remove the 0800 Ethic number from the PIS as this is no longer active. The general Ministry of Health contact number from the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) may be used instead.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the 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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| **3** | **Ethics ref:** | **2023 FULL 18838** |
|  | Title: | BP16-101: A Phase 1 Single-Dose Study of denosumab versus Prolia in Healthy Male Volunteers |
|  | Principal Investigator: | Dr Paul Hamilton |
|  | Sponsor: | CuraTeQ Biologics Private Ltd |
|  | Clock Start Date: | 05 October 2023 |

Kim Huljich, Dr Paul Hamilton, and Andrea Firth 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 this bioequivalence study had been submitted to SCOTT.
2. The Committee queried why females were being excluded from the study. The Researcher noted that as this is a phase 1 study females were being excluded due to the reproductive toxicity and risk for developing foetuses. This population would likely be included in a later study.
3. The Committee clarified that in the event of an adverse event the participants would be monitored and continue to participate due to this being a single dose intervention.
4. The Committee clarified that should participants be considered at risk there would be continued monitoring after the intended day 3 discharge for up to a further 2 days as per the allowances in the protocol.
5. The Committee clarified the difference in the structure of the study intervention related to possible manufacturing differences that can occur between the EU and US approved medicines.
6. The Committee clarified that there was not considered to be a risk of reactivation of HSV, VZ or Tuberculosis with this monoclonal antibody.

**Summary of outstanding ethical issues**

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

1. Studies should not be terminated simply for reasons of commercial interest or public relations (*Ethical Guidelines for Intervention Studies* paragraph 6.65). The Committee stated their preference that this option is removed from study documentation.
2. The Committee requested provision of the Australian Peer Review document or the SCOTT letter should SCOTT review occur.
3. The Committee requested clarification as to what is meant by “a serious infection (relating to housing)” as an exclusion criteria.
4. The Committee queried the wording used in the advertisement abd requested that these be amended to fit the [HDEC advertisement guidance](https://ethics.health.govt.nz/assets/HDEC-Advertising-Guidelines-for-Clinical-Research-v1.0-23JUNE2022.docx) as currently the advertising may not meet those guidelines.
5. The Committee requested that there should be a clear pathway for participants to ensure they inform the researchers of pregnancy and to initiate follow up with separate consent should that occur.

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

1. Please specify if dietary requirements can be catered for in the case of visits.
2. Please specify the exclusion of individuals who have received a live viral vaccine within 3 months prior to participation.

**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).*
4. Please supply an independent peer review for the current version of the study protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
5. Please update the advertisements, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*

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

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| **4** | **Ethics ref:** | **2023 FULL 17967** |
|  | Title: | Paediatric Eosinophilic Gastrointestinal Diseases Database |
|  | Principal Investigator: | Professor Andrew Day |
|  | Sponsor: | Te Whatu Ora Waitaha |
|  | Clock Start Date: | 05 October 2023 |

Dr Angharad Hurley 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 about the ethnicity data and if ethnicity data is being collected as it says in the master application ethnicity data is being collected but the application indicated ethnicity data would not be collected in New Zealand. The Researcher explained that the lead site wanted the documents between Australia and New Zealand identical and the REDCap database for the study does not contain ethnicity data collection points. The Researcher agreed with the importance of ethnicity data and the need for further discussion with the study team about this.
2. The Committee asked about how many participants will be included in New Zealand. The Researcher explained a total of 100 is anticipated.

**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 ethnicity data would not be collected. Ethical Standards 9.10 and 9.20 state that all researchers conducting health research in New Zealand must collect good quality ethnicity data unless there is valid justification as to why this is not necessary. Please either ensure provision of this in the protocol, or provide justification.
2. Please ensure that Māori Consultation is complete before the study commences and that it addresses information as taonga.
3. The Committee noted the following about data management:
   1. Please include where the server is based for the cloud system.
   2. Please provide more information on how unauthorised data breaches will be managed.
   3. Please include that date of birth data will be taken, ensure consistency between the master documentation and the protocol and data management.
4. The Committee requested removal of a reason for opting out from the phone script as participants should not be required to give a reason for doing so.

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

1. Please remove any reference to "kids" in all PIS/CFs and replace with "children”.
2. Please check PIS for typos and grammar errors, in the PISs for 12-16 year olds and 16-18 year olds.
3. For the 53 data points, please include exactly what data is being collected and from where.
4. Please include how long data will be stored for.
5. Please amend the participant information child sheet to maintain simplicity; doctor looking after you, not "looking after your gut condition".
6. Please add headers and page numbers where applicable.
7. Please include an assent form for children aged 4 – 6. The assent forms can be labelled as “younger assent” and “older assent”.
8. Please include a statement that once your participants are over the age of 16, they will need to be reconsented into the database.
9. Please ensure that the New Zealand forms given to New Zealand participants are adapted from the Australian forms with parts of the form such as age of consent and reconsent are amended to better match New Zealand standards.

**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).*
4. 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 Dr Andrea Forde and Ms Dianne Glenn.

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| **5** | **Ethics ref:** | **2023 FULL 18725** |
|  | Title: | A Phase 3 randomized, placebo-controlled, double-blind program to evaluate efficacy and safety of upadacitinib in adult and adolescent subjects with severe alopecia areata. |
|  | Principal Investigator: | Dr Marius Rademaker |
|  | Sponsor: | AbbVie Ltd |
|  | Clock Start Date: | 05 October 2023 |

Dr Marius Rademaker 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 about the exclusion statements pertaining to participants aged over 65. The Researchers explained that the statement is there for participants who turn 65 during the study as these participants are allowed to stay in the study, with revised dosing guidance.
2. The Committee clarified the intentions of the study for those participants who improve on placebo, and those who do not (based on protocolised criteria).
3. The Committee asked about the reference to confounding medication that may be used during the trial. The Researcher explained the confounding medication which may influence the outcome are steroids, biologics, and methotrexates; these are not allowed in the study but may be permitted if the participant requires rescue therapy.
4. The Committee asked about the electronic questionnaires and if they are done on site and with the study ID and no other identifiers as these are shared with the Sponsor. The Researchers confirmed 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 requested amendment of section C.1 of the application form, Relevance for Māori, as there are varying statements throughout about Consultation being undertaken. If Māori are participating, please ensure at each study site in New Zealand, Māori consultation will be undertaken before the study commences, especially as there is no ability for karakia at time of destruction of human tissue.
2. The Committee requested amending the questionnaire; the interpretation of ratings must be from 1 – 5 (no 0 rating).

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

1. Please add the reason for the invitation to participate in the study in the participant information sheet and consent forms.
2. Please include the study medication dose, frequency and manner of administration.
3. On page 3 of the assent form please change the wording: “fake drug” to pretend medicine or “Dummy”.
4. On page 4 please double check for grammar errors.
5. On page 5 please review the following sentence: “If you are a girl, your study doctor may tell you about contraception methods that you must follow if you participate to the study.” This should not be a 'may' and should refer to being sexually active.
6. On page 9 referring to adolescent females please amend the wording, recommend: pregnancy or foetus etc.
7. On page 10 please review for typos and grammar errors.
8. On page 19 please amend the sentence stating the study doctor will decide if you should start birth control.
9. On page 22 there are references to genetic tests but there is no mandatory genetic testing for New Zealand participants: please remove.
10. The lifestyle restrictions identified in the protocol page 34 have not been picked up in the participant information sheet under participant responsibilities. E.g., no wigs, not shaving eyebrows. Please include.
11. Please remove all wording of 'drug' and replace with 'medicine' through the participant information sheet.
12. In each participant information sheet, towards the end, please ensure the final wording is included regarding payment from the sponsor and personal financial benefit.
13. Please review each participant information sheet for small errors and as there are many technical/medical terms, wherever possible use lay-friendly language or descriptions.
14. Perhaps a spread sheet could be added with all this information include once for clarity
15. Please remove the 0800 Ethic number from the PIS as this is no longer active. The general Ministry of Health contact number from the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) may be used instead.

**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 Dr Sotera Catapang and Ms Dianne Glenn.

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| **6** | **Ethics ref:** | **2023 FULL 18787** |
|  | Title: | EC5026-1-02: A Study to Investigate the Safety and Tolerability of Multiple Doses of EC5026 in Healthy Participants |
|  | Principal Investigator: | Dr Cory Sellwood |
|  | Sponsor: | EicOsis Human Health, Inc. |
|  | Clock Start Date: | 05 October 2023 |

Dr Cory Sellwood, Julia O’Sullivan, Holly Thirlwall, and Kayla Malate 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 mandatory requirements for genetic testing. The Researchers explained that what is mandatory is the analysis of the enzymatic target of the study medication and the future unspecified research for the samples taken that are left over that may require full genome sequencing.
2. The Committee asked about the participant information sheet and consent form cultural sections and if the study is being done in Christchurch. The Researchers explained that the Māori governance and consultation pertinent to the research team have changed title and will cover trials nationally, and an older form was submitted. The researchers have updated the forms.
3. The Committee asked if the FDA vaccine criteria for AE severity assessment will be used during this study. The Researchers confirmed the FDA vaccine criteria will be used.
4. The Committee asked about the risk of infection for the use of cannula (blood sampling) for 7-8 days. The Researchers explained that changes every 72 hours or so is usual but the ideal scenario will be the cannula placed for a long period of time. The workbooks provided to nurses ensure checks for the cannula is done safely and replaced if needed. If the cannula looks good from the nursing perspective it is best practice to leave them in as the risk of infection is at the time of insertion and does not relate to the duration that the cannula is inserted.
5. The Committee asked about the follow-up visits (Days 11, 14 & 20), and if participants will be admitted to the clinical research unit for PK blood sampling with fasting and diet restriction. The Researchers explained there is no restrictions and the visits will be no longer than 2 hours.

**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 insurance submitted expires in November, please ensure the insurance is updated and uploaded.
2. The Committee requested the data management plan is checked for typos and grammar errors under section 16.
3. The Committee recommend changing the wording of drug to medicine; however, this is not a requirement, just a future suggestion on the wording.
4. The Committee requested amendment of the mandatory genetic analysis and optional tissue Future Unspecified Research (FUR) section in the participant information sheet on left over blood samples by using lay language where possible.

**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 18830** |
|  | Title: | A Phase 1, single-dose, open-label, randomized crossover study to evaluate the pharmacokinetics and safety of azelaprag in older adult healthy volunteers |
|  | Principal Investigator: | Dr Susanna Abigail |
|  | Sponsor: | BioAge Labs, Inc. |
|  | Clock Start Date: | 05 October 2023 |

Dr Susanna Abigail, Julia O’Sullivan, Holly Thirlwall, and Kayla Malate were present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

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

**Summary of resolved ethical issues.**

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

1. The Committee queried the exclusion of prostatic cancer and the parameters used for this. The Researcher responded that this is according to the American classification system, and looking at survival data for different stages, they do not want any problems with participant survival in follow-up. The Researcher noted they can return to the Sponsor and query that further.
2. The Committee queried the timeliness of reimbursement payments based on the wording of this in the PIS. The Researchers responded that the usual ability to be flexible will be applied and will add in a statement that payment will be flexible dependent on the person’s needs. Typically, payment will be at the end of each part.

**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 data management plan refers to under 16s despite this being an older aged volunteer study.

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

1. Please clarify with an additional sentence how long between each dosing period the participants are staying for.
2. Please state that transport to the clinic can be arranged depending on the participants’ needs, and that this will be paid for.

**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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| **8** | **Ethics ref:** | **2023 FULL 18844** |
|  | Title: | Streptococcus pneumoniae induced haemolytic uraemic syndrome in Aotearoa, New Zealand (NZ) in the era of pneumococcal vaccination 14 years’ experience. |
|  | Principal Investigator: | Dr Alex Humphrey |
|  | Sponsor: |  |
|  | Clock Start Date: | 05 October 2023 |

Dr Emma Best 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 there is reference in the protocol to existing ethical approval for collection of data from the Paediatric Surveillance Unit. It is referred to as the Southern HDEC, but is institutional approval from the University of Otago. The Researcher clarified that the Paediatric Surveillance Unit database collected de-identified information about rare paediatric conditions from paediatricians around New Zealand up to December 2020.
2. The researcher clarified that they intend to seek de-identified data on case numbers from the NMDS.
3. The Committee clarified that further sources of data collection were Starship and outside practitioners where Starship does not have complete medical data, and the ESR. The Researcher further clarified after discussion that this will be accessed in identifiable form by one of the researchers and then de-identified for study purposes. The data from ESR will be provided de-identified.
4. The Committee queried how the Researcher will ascertain whether the vaccine doses were given in a complete course, whether there was a mixture of different vaccines, and also queried where this data will be obtained from. The Researcher replied that clinical records have clear records of vaccines given and they can access batch numbers if required for accuracy.

**Summary of outstanding ethical issues**

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

1. With the above clarifications, the Committee noted that the data sources and scope of data sought from each of the sources are not clearly reflected in the protocol or data management plan. Adequate documented data management and governance is a requirement for the Committee to be satisfied and grant a waiver of consent. The Committee suggested referring to the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/) for provision of an adequate data management plan.
2. The Committee requested inclusion of information regarding existing ethical approval(s) for the surveillance dataset being used.
3. The Committee requested that the researchers review their responses in the submission including as to identifiable and de-identified data, and notification to a participant’s physician.

**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 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).*
4. Please provide adequate justification and consideration for a waiver of consent. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.46-7.47).*

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

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| **9** | **Ethics ref:** | **2023 FULL 17956** |
|  | Title: | Delivering optimal weight gain advice to pregnant women (DOT): a case study |
|  | Principal Investigator: | Dr Kirsten Coppell |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 05 October 2023 |

Dr Kirsten Coppell and Dr Helen Paterson 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 with the Researcher that the component being reviewed by the Committee is the intervention by the midwives with the pregnant people in delivering optimal weight-gain advice, not the later qualitative aspect. The Committee noted the later qualitative aspect can be submitted as an amendment when it is available.
2. The Committee noted the exclusion of pregnant people aged under 18 and the researcher clarified the justification for this.
3. The Committee noted there was reference in the application that data will be collected using the EXPECT software and queried if this is common for all Lead Maternity Carer (LMCs). The Researchers responded that this was not universally used, but they had ascertained that over 90% of independent LMCs in Te Tai Tokerau Northland use this. and that the recommendation to use this system came from the midwives themselves. The Committee queried that when extracting the research data, if the midwife retrieves it and de-identifies for provision to Researchers. The Researchers responded that the EXPECT software will send encrypted data packages with unique identifier and consent and transferred to University of Otago secure data storage.
4. At least one visit of the pregnant participants will be in addition to standard of care. The Committee noted there is no budget set aside to help with travel costs currently. The Researcher responded that the midwives will likely bear the burden of cost due to going to their clients and this was the case with a previous study.
5. The Committee noted a point in the peer review, and queried what the plan is if a participating midwife is unable to provide support the participant in the study, such as they change their LMC. The Researcher responded that if they stay in the Northland area, they are still part of the study, but if the new LMC is not part of the study, then the person would still be able to choose to have data so far captured included but could not continue to participate. This should be added to the PIS.

**Summary of outstanding ethical issues**

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

1. The Committee queried how LMC midwives will be recruited and trained to assist in the study. After discussion, the Committee requested there be information regarding training in the protocol and transparency with the clients of the LMC midwives about their participation in the trial, as well as putting more information surrounding around the training and payment of the midwives in the protocol.

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

1. Please include information regarding what happens if a participant changes LMC during the course of the study.
2. Please consider including information regarding payments to LMCs for their role in the study.

**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).*

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

## General business

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

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| --- | --- |
| **Meeting date:** | 21 November 2023 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

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

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

The meeting closed at 5:00pm.