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

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12.30-1.00pm | 2023 FULL 15082 | BEAD Feasibility Study | Dr. Jordon Wimsett | Ms Catherine Garvey and Dr Andrea Forde |
| 1.00-1.30pm | 2023 FULL 13962 | Living well with dementia: Co-investigation of how does housing, daylight and views matter? | Doctor Alessandro Premier | Mr Jonathan Darby and Ms Jade Scott |
| 1.30-2.00pm | 2023 FULL 15066 | A study to test whether spesolimab helps people with a skin disease called hidradenitis suppurativa | Dr Marius Rademaker | Ms Catherine Garvey and Dr Kate Parker |
| 2.00-2.30pm | 2023 FULL 13992 | ALXN1920-HV-101: A Study to Evaluate the Safety and Tolerability of ALXN1920 in Healthy Participants | Principal Investigator Christian Schwabe | Mr Jonathan Darby and Dr Sotera Catapang |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Mr Derek Chang  | Non-lay (Intervention studies)  | 08/07/2022 | 08/07/2025 | Present  |
| Dr Kate Parker  | Non-lay (Observational studies)  | 11/02/2020  | 11/02/2023  | Present  |
| Dr Andrea Forde | Non-lay (Intervention studies)  | 22/12/2021 | 22/12/2024 | Present |
| Ms Catherine Garvey  | Lay (the Law) (Chair) | 19/03/2019  | 19/03/2022  | Present  |
| Dr Sotera Catapang  | Non-lay (Observational studies)  | 11/02/2020  | 11/02/2023  | Present  |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Dr Leonie Walker | Lay (Ethical/Moral reasoning) | 13/08/2021 | 13/08/2024 | Apology |
| Ms Jade Scott | Non-lay (Intervention/Observational studies) | 15/08/2021 | 15/08/2024 | Present |

## Welcome

The Chair opened the meeting with a karakia at 12.00pm and welcomed Committee members, noting that apologies had been received from Dr Leonie Walker.

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 22 November 2022 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 15082** |
|   | Title:  | The BEAD Feasibility Study: Baby Head Elevation device at full dilatation caesarean section |
|   | Principal Investigator:  | Dr Jordon Wimsett |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 09 January 2023 |

Dr Jordon Wimsett, Dr Lynn Sadler, and Dr Charlotte Oyston 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 need for the feasibility study. The Researcher noted that there were inconsistencies in the published results of studies into the use of the study device previously, and that the need for this trial was premised by the lack of research currently in this field. The theoretical basis for this study is to assist in deciding how to conduct a future study as to whether or not this pillow is of any actual benefit.
2. The Researchers clarified the training would be provided by the manufacturers of the pillow before use in the feasibility trial.
3. The Researchers clarified their understanding of the process for the referenced NICE review of November 2022.
4. The Researchers clarified that this pillow was not currently available at Auckland Hospital and that there would be training necessary for the surgical teams conducting the caesarean sections.
5. The Researchers clarified the situations in which this device may be used.
6. The Researchers clarified that the template for the surgical follow up would only be used for tracking of primary data points rather than the full follow up details.
7. The Committee queried the period of follow up for the mother and if this should be longer for tracking the morbidity of the mother. The Researchers noted that the 6-week period would capture almost all possible morbidities other than those that might occur at the next delivery.
8. The Committee accepted the justification for abridged consent at the time the decision to perform caesarean section is made in appropriate cases. The Researchers confirmed that the impacted fetal head was the only relevant condition for the decision to use the pillow, the use of other instruments for failed delivery would not be exclusionary factors.
9. The Committee queried the possibility of bias being built into the study given the timing of consent, and potential exclusion of women for whom it was not considered appropriate to discuss the study. The Researcher noted that this had been built into the protocol as a feasibility study.
10. The Committee clarified that support people would be able to be present during the consent.
11. The Committee clarified the ability of the surgeon to detect the foetal pillow and that it would not affect the blinding of the surgeon.

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 more information be provided in the protocol regarding the surgical staff and general staff who will be using the device and undergoing training for this study. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* *9.7).*
2. The Committee noted that the surgeons and anaesthetists are effectively participants and should be given participant information sheets (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* *7.15).*
3. The Committee requested that a written independent peer review be provided as per the requirements for HDEC review. Please refer to the [HDEC peer review template](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2021.docx) (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* *9.25-9.32).*
4. The Committee noted that the investigators had not provided evidence of indemnity.
5. The Committee confirmed the researchers were satisfied that ACC coverage would be available or assurance of some alternative cover. The researcher noted that there were no safety concerns with the study device. The Committee noted that there would be no access of the manufacturer to the study results, data or publishing and that this is an investigator-led study. The Committee noted that Medsafe should be advised of this study given the reasons for this study (*Standard Operating Procedures for Health and Disability Ethics Committees* para *144).*
6. The Committee requested an explicit statement that this is investigator led (*Standard Operating Procedures for Health and Disability Ethics Committees* para *144).*
7. The Committee requested evidence of investigator indemnity.
8. The Committee queried the intraoperative timing of consent, and whether consent could be obtained prior to failed delivery after full dilation. The plan is to disseminate information about the study to pregnant women, partners and LMC is through several online formats during the course of the pregnancy. The researcher also noted that there would be provision of training and information to midwives working in both Counties Manukau and Auckland hospitals. The Researcher noted that the consent was sought at such a late stage because of a concern to avoid indicating a caesarean may be required during earlier stages of pregnancy and labour when vaginal delivery was still possible. The researcher noted that this was being done to request the consent at the least harmful point for participants. The Researcher also noted that in the participant cohort at full dilation the surgery is not as urgent as other forms of caesarean section as there is not the same threat to the life of the mother or child, and therefore there is time for abridged discussion of the study. The Committee suggested that it be clarified in the protocol that there would be some assessment of ability/appropriateness to consent on a case-by-case basis (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* *7.18 & 9.7).*
9. The Committee noted that any videos or visual aids used for consenting would need to be submitted to the Committee for review.
10. The Committee requested that inclusion and exclusion around attempted instrumental delivery be clarified.
11. The Committee requested that it be made clear the consent for follow up data would be sought at a later date.

The Committee requested the following changes to the Abbreviated Participant Information Sheet and Consent Form (PIS/CF) in accordance with *National Ethical Standards* para *7.15*:

1. Please provide some reassurance that the health of the mother and baby would not be impacted by which group the mother was assigned to.
2. Because follow up data would be consented at a later date, any consent for that can be removed from the abridged script to keep things as simple as possible for the participants.

**Decision**

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

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| **2**   | **Ethics ref:**   | **2023 FULL 13962** |
|   | Title:  | Person-centred investigation of daylit environments for promoting dementia wellbeing while aging in place in New Zealand |
|   | Principal Investigator:  | Dr Alessandro Premier |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 09 January 2023 |

Jane Waterhouse 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 that the research team would have a caregiver/support person chosen by the participant present during the study processes.

Summary of outstanding ethical issues

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

1. The Committee queried the experience of the research team with the target population being persons living with dementia. The Researcher noted that there was no direct experience in the team but that there was some consultation being done with a suitably qualified external supervisor. The researcher noted that the consultant had advised the researcher to gain some experience with this population and those people who work with them. The Committee noted that this would be highly advised and that the protocol and participant facing documents need to be reviewed by someone with this experience (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* *9.7).*
2. The Committee noted that there needs to be a relatively detailed plan for how recruitment will occur in the protocol and how the ongoing participation may be managed.
3. The Committee queried the ability of the researcher to assess the participants’ capacity for consent and the researcher noted that any information they had around this was from literature and not from any experience. The Researcher noted that this would be done in a similar way that the external supervisor used in similar research by consulting with the participant’s caregiver in a session for this purpose at the outset. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* *9.7).*
4. The Committee requested that there be someone with experience accompany the researchers when meeting participants. This would be essential and should be built into the protocol (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* *6.2).*
5. The Committee noted that assessment of capacity would need to be ongoing, for each study visit, and noted that dementia may progress over the study period and result in differences in behaviour and the ability to participate even over a short period of time. The supervision would be necessary for the whole period of the study as a result of this. This could be a clinician or a nurse or someone with experience with these participants (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* *6.2).*
6. The Committee noted that there should be a check-in of consent prior to each session with the participants.
7. The Committee noted that the protocol and safety plan should be reviewed by the external supervisor (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* *9.7a).*
8. The Committee requested a detailed caregiver participant information sheet and a more abbreviated and simplified version for the participants with dementia. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* *6.2).*
9. The Committee noted that it needs to be abundantly clear to all possible participants what will be required of them in terms of the number and duration of study visits, the tools they will use and what they should use the tools for (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* *7.15).*
10. The Committee noted that it is desirable for research being conducted by a student researcher that their supervisors are present to support them in their application to HDEC.
11. The Committee suggested that Researchers entering participants’ homes in this study may consider it sensible to obtain a police-vet. Please also provide a safety plan/protocol for home visits. (*National Ethical Standards for Health and Disability Research and Quality Improvement*, para 11.62).

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) in accordance with *National Ethical Standards* para *7.15*:

1. The Committee noted there are missing sections of the participant information sheets in order to obtain fully informed consent. The Committee recommended the Researcher adapt the [PIS template available on the HDEC website.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
2. Please specify the number of visits, the duration of the visits, the intervals between visits, and what each visit may entail.
3. Please provide detail about the tools that will be used in the study, specifically what is involved, what will be required to use the tool and if someone else may accompany the researcher to use this. Please also provide appropriate guidance to participants about the content of images that they are asked to photograph for study purposes and allow participants to give specific consent to images being taken in the consent form.
4. Please review the PIS for the older person with dementia and simplify where possible (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.8 & 6.8a).*
5. Please amend the term “psychologically safe with” when referring to the caregivers to better reflect that the caregiver must be someone chosen by the participant with dementia and who is willing to assist in participation with the study.

**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 15066** |
|   | Title:  | Randomised, double-blind, placebo-controlled, Phase IIb/Phase III study to evaluate the efficacy and safety of spesolimab in patientswith moderate to severe hidradenitis suppurativa |
|   | Principal Investigator:  | Dr Marius Rademaker |
|   | Sponsor:  | Boehringer Ingelheim Pty Ltd |
|   | Clock Start Date:  | 09 January 2023 |

Dr Marius Rademaker and Reenu Arora 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 confirmed that only part 1 is being applied for with this application, and that part 2 will be the subject of an amendment when details for part 2 have been confirmed.
2. The Committee noted the number of optional participant information sheets (PISs) and queried which are being used in New Zealand. The Researcher stated that skin biopsies are not being done in New Zealand, and home visits if required will be by study staff not a third party.

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 justification for use of placebo was not answered fully in the application form. They queried what safety measures are in place for those who may deteriorate under placebo. The Researcher stated there was not much difference between placebo and standard of care given the inclusion criteria, but if someone deteriorates under placebo and cannot have or does not respond to rescue therapy then the investigator will withdraw them from the study. They noted that at this stage they cannot justify the design of using placebo beyond the requirement for it from the Sponsor. The Researcher noted that the rescue therapies on offer may have already been used for these patients prior but are available. The Committee requested written justification for use of placebo be provided.
2. The Committee queried how participants will be recruited. The Researcher responded that due to severity, the main recruitment avenue would be via dermatologists. Advertising will be utilized to capture those in the community, and GPs may be used. The Committee noted that the GP letter and advertisements need to be submitted to HDEC for review before they are used.
3. The Committee requested a safety plan for researchers for home visits and make it clearer in patient information on who is visiting the home and what they are doing.
4. The Committee stated that the use of photographs is quite broad, allowing identifiable pictures to be sent overseas for anything the Sponsor wants. The Committee requested this is not required of participants and the PIS is amended so that identifying images are taken. The Committee noted they were conscious of European Data Protection Act and if the participants were to be asked blanket permission for use of their photos of lesions, obligations to this Act need to be strengthened.
5. The Committee queried the mental health referral process if any issues are raised during questionnaires. The Researcher noted the elevated risk and the possibility of finding a distressed participant. If there is no immediate risk, the GP will be notified for referral. The Researcher stated that they are currently uncertain how soon the questionnaires will be reviewed, and whether they are electronic, or paper based. The Committee requested provisions are made to ensure they can be viewed as soon as possible due to the noted elevated risk in this population.
6. The Committee stated that 30 years is a long time to store samples for biobanking purposes. Please reduce the amount of time samples will be stored for or provide further justification for this length.
7. The Committee noted that in-house biobanks still must show they meet the National Ethical Standards for a given application using it. They referred the Researchers and Sponsor to Chapter 15 of the Standards, suggesting that a letter from the Sponsor on how the biobank meets the Standards (including being transparent on the name and governance structure) will aid the review.
8. The Committee requested clarification around how long the investigational medicine will be made available to participants in the open-label extension.

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

Main PIS:

1. The CF states a recognised risk of partner becoming pregnant; however, the body of the PIS contradicts this by saying male contraception is not required. Please amend for consistency.
2. CF mentions GP will be informed but this is not explained in the PIS first.
3. PIS states that samples will be sent overseas. Please include details of lab(s) they are sent to.
4. The Committee suggested an alternative to the term “palliative care” as this is colloquially associated with end-of-life care.

Biobanking PIS:

1. Make it clear this is unspecified research at the start of the PIS.
2. Please include adequate details of lab(s) samples are sent to.

**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 provide a researcher safety plan addressing the concerns raised by the Committee (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62*).

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

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| **4**   | **Ethics ref:**   | **2023 FULL 13992** |
|   | Title:  | A Phase 1, Randomized, Double-blind, Placebo-controlled, Single Ascending Dose Study of Subcutaneously and IntravenouslyAdministered ALXN1920 in Healthy Adult Participants |
|   | Principal Investigator:  | Dr Christian Schwabe |
|   | Sponsor:  | Alexion Pharmaceuticals, Inc. |
|   | Clock Start Date:  | 09 January 2023 |

Dr Christian Schwabe, Courtney Rowse and Julia O’Sullivan were present via videoconference for discussion of this application.

Potential conflicts of interest

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

Dr Andrea Forde raised a potential conflict. This was discussed at the beginning of the meeting and considered minimal, and Dr Forde was able to remain as part of the discussion.

Summary of resolved ethical issues

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

1. The Committee requested further clarity around the Japanese cohort. The Researcher explained that this is typically to satisfy Japanese health authorities when planning clinical trial programs by obtaining data for Japanese participants at an early stage.

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 asked how identity of ethnic Koreans, historically resident in Japan, will not be protected.
2. The Committee queried the reason for excluding prior Neisseria diseases, and if the diseases are excluded, why not vaccination also.
3. The Committee noted that the advertising was largely acceptable however there were issues identified in the radio script minimising the potential risks with involvement in a clinical trial. Please remove language which equates involvement to being recreational and ensure that advertising is not misleading by avoiding reference to potential risks. Please also remove reference to numbers of participants in the radio ad as this is not trial specific.
4. C.5 of application form refers to Karakia being available at collection of samples and when samples are sent overseas but the participant information sheet (PIS) does not. Please ensure the PIS reflects what is proceeding in the study.

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

1. The PIS specifies certain live vaccines for exclusion of participants, but the protocol information is broader. The Committee also noted that some of the vaccines in the PIS are paediatric vaccinations so the exclusion of participants who have received them 2 weeks prior is contradictory. Please ensure the PIS accurately reflects the exclusion criteria and requirements around vaccinations.
2. The Committee noted to review the COVID-19 statement. As this is a restricted facility, the Committee recommended that the Researchers consider following the current recommendations of local health authorities for vaccination.

**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 noted the resignation of Dr Leonie Walker and the Committee passed on their comments and well wishes to the Chair to pass on to Dr Walker.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting:

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| **Meeting date:** | 21 March 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 2.30pm with a karakia.