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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 07 February 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 11:30AM – 12:00PM | 2024 FULL 18979 | ALLG AML M22 | Dr Kern Chai | Alice McCarthy & Joan Pettit |
| 12:00PM – 12:30PM | 2024 FULL 19471 | A Study of ANB032 in Participants with Moderate to Severe Atopic Dermatitis (Eczema) | Dr Penelope Montgomery | Amber Parry-Strong & Ewe Leong Lim |
| 12:30PM – 1:00PM | 2024 FULL 19434 | Next Generation Automated Insulin Delivery in Children with Type 1 Diabetes | Professor Benjamin Wheeler | Kate O’Connor & Barry Taylor |
| 1:00PM – 1:30PM | 2024 FULL 19534 | Automated insulin delivery to improve current care for Māori and Pacific peoples living with type 1 diabetes | Professor Benjamin Wheeler | Kate O’Connor & Joan Pettit |
|  |  | BREAK 20 MINUTES |  |  |
| 1:50PM – 2:20PM | 2024 FULL 18851 | NZ Quit Vaping Study | Associate Professor Natalie Walker | Jonathan Darby & Barry Taylor |
| 2:20PM – 2:50PM | 2024 FULL 19443 | Psychotherapy in primary care: feasibility | Professor Marie Crowe | Barry Taylor & Ewe Leong Lim |
| 2:50PM – 3:20PM | 2024 FULL 18418 | Do synbiotics reduce infections after bowel surgery? | Dr Claudia Paterson | Jonathan Darby & Joan Pettit |
| 3:20PM – 3:50PM | 2024 EXP 18357 | Breast Screening AI | Professor Colin Simpson | Kate O’Connor & Amber Parry-Strong |
|  |  | BREAK 10 MINUTES |  |  |
| 4:00PM – 4:30PM | 2024 FULL 19303 | M22-003 - EPCORE FL-2: Follicular Lymphoma: Epcoritamab in Combination with R2 Compared to Chemoimmunotherapy in Previously Untreated Follicular Lymphoma | Dr Leanne Berkahn | Joan Pettit & Alice McCarthy |
| 4:30PM – 5:00PM | 2024 FULL 19515 | Clinical Biomarkers and Applications in Eye Tracking | Professor Helen Danesh-Meyer | Barry Taylor & Ewe Leong Lim |
| 5:00PM – 5:30PM | 2024 FULL 18792 | Examining the impact of Maternal PKU, a comparison to normative matched controls | Professor Suzanne Barker-Collo | Alice McCarthy & Amber Parry-Strong |
| 5:30PM – 6:00PM | 2024 FULL 19561 | CL-0043-1002: A Phase 1b study evaluating safety and pharmacokinetics of SZN-043 in participants with severe alcohol-associated hepatitis | Principal Investigator Edward Gane | Kate O’Connor & Barry Taylor |

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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 | Apologies |
| 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 | Present |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Present |
| 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 | Apologies |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present (CO-OP) |

## Welcome

The Chair opened the meeting at 10:30am and welcomed Committee members, noting that apologies had been received from Mrs Leesa Russell and Ms Maakere Marr.  
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mr Jonathan Darby 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 05 December 2023 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2024 FULL 18979** |
|  | Title: | The International AML Platform Consortium (IAPC) trial |
|  | Principal Investigator: | Dr Kern Chai |
|  | Sponsor: | Australasian Leukaemia and Lymphoma Group |
|  | Clock Start Date: | 25 January 2024 |

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

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The HDECs require the New Zealand co-ordinating investigator’s role to be more prominent as the person responsible for participant data in New Zealand. This role needs to be strengthened throughout the data management plan and the participant information sheet.
2. The Committee noted that future domains to the platform study will come in as appendices to the master protocol and may be presented as substantial amendments under this application number. These will be reviewed by a full Committees, and not through the expedited pathway as they are clinical trials.
3. The Committee requested clarity regarding the tissue management plan, as no tissue management is mentioned in the data management plan currently, and the application states samples will be collected. Please also mention where these samples are being analysed and if they are being destroyed or sent to a biobank.
4. In addition to the above, please amend the data management plan to better reflect its use for New Zealand according to New Zealand policy and regulation.
5. The peer review submitted doesn’t meet HDEC requirements of being independent from the study. Please provide an independent peer review for this protocol (as distinct from the platform arrangements). The [HDEC peer review template](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance/) can be used.
6. The Committee noted that a pregnant participant/partner participant information sheet/consent form should only be submitted as an amendment in the event that a pregnancy occurs so it can be fit-for-purpose. As such, these have not approved for use with the current submission.

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

1. Please amend the master screening information sheet regarding the treatment groups, please change this to investigational groups or study drug groups.
2. Please have a thorough review of the master screening information sheet and make it relevant to New Zealand participants.
3. Please remove all references to Medicare and free treatment in Australian hospitals. The PIS used in New Zealand should be fit for a New Zealand audience.
4. Please use the HDEC template for “what happens to my information section of the participant information sheets” 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.
5. Please include more detail in “what happens to my samples” section.
6. If New Zealand is taking part in the biobank, please explain why and the process.
7. Please use the New Zealand compensation statement. The HDEC’s stance on ALLG studies are that the studies are investigator led in which case ACC compensation for injury maybe applied for. However, the Committee noted that the group is holding clinical trial insurance which could also be accessed as a back-up.
8. Please note that while future domains may be clearly weighted in favour of the pharmaceutical company, the Committee are satisfied appendix 1.2 fits within the parameters of an investigator led study and would therefore be eligible for ACC compensation in the result of treatment injury.
9. Please ensure measurements for fluids are written in millilitres, not teaspoons.
10. Please include that karakia is not available at the time of tissue disposal.
11. Please include diagrams explaining the platform and the different domains.
12. Please include a diagram explaining the participant process and each step the participant will take.
13. Please ensure there is a process of referral if a participant shows distress during the trial.

**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 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).*
4. Please update the data and tissue 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, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Alice McCarthy and Ms Joan Pettit.

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| **2** | **Ethics ref:** | **2024 FULL 19471** |
|  | Title: | A Phase 2, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of ANB032 in the Treatment of  Subjects with Moderate to Severe Atopic Dermatitis |
|  | Principal Investigator: | Dr Penny Montgomery |
|  | Sponsor: | AnaptysBio, Inc. & Novotech (New Zealand) Pty LtdI |
|  | Clock Start Date: | 25 January 2024 |

Dr Penny Montgomery 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 recent purchasing of Optimal by New Zealand Clinical Research (NZCR) and explained if the processes or work has changed in any way. The Researcher explained that all work is going ahead as per usual and is sticking with the same operational procedures and has a broader spread across the country in early phase studies.
2. The Committee asked about the branded advertisements and if any will be used for this trial noting the Australian language and the advertisements lacking New Zealand on the map. The Researcher explained that no such advertisements will be used and if they are to be used, they will be amended to better suit the New Zealand population.
3. The Committee asked about the phone call referenced in the recruitment material, as it implies a cold call situation. The Researcher explained this came from the Australian site material and will not be used and clarified the New Zealand sites will never cold call potential participants.

Summary of outstanding ethical issues

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

1. For the tax compensation section, the Committee requested use of the NZCR tax statement that outlines exactly the payment, tax, when payment is shown to start etc.
2. The Committee suggest that for participants using an emollient every day that the study Researchers provide this emollient to the participant.
3. The Committee requested amendment of section C18.2 of the application form and include that travel costs will be reimbursed.
4. If any advertisements are used, please submit these as amendments and ensure they are approved by the Committee before use.

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

1. The Committee suggest using the wording of treatment groups as opposed to study groups throughout the PIS.

**Decision**

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

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

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| **3** | **Ethics ref:** | **2024 FULL 19434** |
|  | Title: | Novel Medtronic Experimental Automated Insulin Delivery System (NMX-AID) in children with type 1 diabetes - Single arm study |
|  | Principal Investigator: | Professor Benjamin Wheeler |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 25 January 2024 |

Professor Benjamin Wheeler 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.

Dr Amber Parry-Strong declared a potential conflict of interest and the Committee decided to allow the Committee member to temporarily leave the meeting while the application was discussed.

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 a previous trial where the Researchers booked a hotel for the participants to stay in while partaking in the clinical trial and how that went. The Researcher explained that the participants on that trial did not stay overnight at the hotel but more so used a hospital level facility with a local trials company and that this went well. The Researcher explained that the hotel is not acting as a locality, but are staying for 4 nights for reasons of safety as participants get accustomed to the new equipment. The locality authorisation is still the normal locality (through the hospital).
2. The Committee asked about the statement; “setting realistic expectations of the system is critical” and this may cause expectation bias with potential participants. The Researcher explained that using existing expert users for this level of study is critical and that the participants should have a good understanding of the basic parameters and functions. The Researcher clarified it is still important the participants realise the system is likely to have limitations and is something the participant cannot set and forget; the participants will be active participants in the process.
3. The Committee asked about consent process for the 16-year-olds. The Researcher confirmed there will be a true consent process for 16 years old, while a consent-assent pairing is in place for those younger.

**Summary of outstanding ethical issues**

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

1. The Committee requested a photo of the sensor attached to the arm is added to the participant information sheet.
2. Please amend the older children PIS regarding the “what happens to my information” section it is currently too abbreviated. The Committee suggest amending the wording to reflect a more adult level of language and describe the distinction between identifiable and coded data.
3. For the PIS for the adults, please add the exact days/dates the hotel stay will occur and for how long.
4. Please check for general typos and grammar errors throughout the adolescent participant information sheet.

**Decision**

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

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

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| **4** | **Ethics ref:** | **2024 FULL 19534** |
|  | Title: | Automated insulin delivery to improve current care for Māori and Pacific peoples living with type 1 diabetes. |
|  | Principal Investigator: | Professor Benjamin Wheeler |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 25 January 2024 |

Professor Benjamin Wheeler 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.

Amber Parry Strong declared a potential conflict of interest and the Committee decided to allow the Committee member to temporarily leave the meeting while the application was discussed.

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 study design and if it is for participants who would be eligible for a funded device but do not have one. The Researcher explained it is more complex than that, there are current Pharmac criteria that are restrictive and disadvantage priority populations with Māori and Pasifika populations missing out on the devices. This study would remove those barriers as the team will supply the participant the delivery system over the research period, so long as they are clinically eligible. Some of the participants would be eligible for a Pharmac funded system, but this can be a” postcode lottery”. The Researcher gave an example that in one region, patients are being refused access to the funded system due to staff shortage. The system is available if privately funded, however priority populations can face financial barriers. The Researcher explained that while some of the potential participants have been excluded from previous research, there is no reason why these participants should be, and that priority populations do well on this system. It is important to do more research on this, and this may have international impact with respect to indigenous peoples.
2. The Committee asked if participants will be patients of the investigators ‘wearing their doctor hat’. The Researcher explained this is potentially true, however at this time this is uncertain but the risks of matters such as pressure to participate are recognised, and that suitable separation between clinical and research roles will be achieved.
3. The Committee asked if there is going to be any follow up for the end of study for participants. The Researcher explained that there will be follow up, such as assistance transitioning to a funded system, and will be carried out by the research team.
4. The Committee asked about Medtronic app and what data is accessed and what is known about the participants. It was clarified that the app only sees a study ID, the glucose data goes into software for analysis which is held offshore with no names attached just a study ID. If a participant wants technical support using the 0800 number the participant uses the study ID number to receive advice. The study team holds everything internally, no data is going to Medtronic other than glucose data.

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 explained that the Researcher must be clear about what the research outcomes are since merely providing access to this system for this population is not a research question.
2. The Committee recommended that if the target population is included because of their culture and ethnicity to include a measure of whether the treatment is compatible with their cultural values. This would be measurable and adds a qualitative component to the study.
3. The Committee requested the Researcher to add two different focus groups with the participants, a Māori focus group and a Pasifika focus group, after the participants have had the intervention phase. The Committee noted that the cultural dimensions of the study are being progressed by the research team and these cultural changes will be submitted through amendments to add in the focus groups or interviews exploring the cultural dimensions of treatment.
4. The Committee requested the following changes to the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.8):*
   1. The Committee noted that Pasifika people are not indigenous to New Zealand, please amend this wording in the protocol.
   2. Please include that potential participants out of target are marked as out of target because Pharmac predict this potential participant will not do well in the trial. This statement can be used for the research team to build the case to prove that these participants will do well if given the system.
   3. Please include that the research team is taking potential participants deemed out of target by Pharmac and providing them with the technology and bringing the participants into target at the end of the trial, this furthermore adds another quantitative aspect to the study.
5. 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. Please amend the data management plan by explaining that Medtronic will be supplying the devices used.
   2. Please amend the data management plan by identifying the Māori and Pasifika clinical leads.
   3. Please amend the data management plan by further clarifying the governance structure under the Otago Research Data Policies, please seek out and name these policies and provide links to the policies.
6. The Committee recommends the researcher to go to their Research Office and find out whether clinical trials insurance would be accessible in the event of treatment injury which was declined compensation by ACC. This is because the Committee consider that there is commercial benefit for Medtronic across all these studies, even though the balance of benefit is not entirely weighted in their favour.

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

1. The Committee requested a photo of the sensor on the arm is added to the participant information sheet.
2. Please include that this study is focused on Māori and Pasifika population.
3. The Committee suggest creating a visualization representing the connection between all the software, apps, hubs etc used with the data flow in and out. There are many apps, hubs being used and may be confusing for potential participants when only explained in text.
4. Please include the ‘setting expectation’ information into the participant information sheet as an appendix.

**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 Ms Kate O’Connor and Ms Joan Pettitt.

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| **5** | **Ethics ref:** | **2024 FULL 18851** |
|  | Title: | NZ Vaping Cessation Trial (EQUIT3) |
|  | Principal Investigator: | Dr Natalie Walker |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 25 January 2024 |

Dr Natalie Walker 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 raised the comments left by SCOTT that outline SCOTT’s concerns for the application and raised that another HDEC has approved a similar study in the past however Northern B is a different committee entirely with different opinions and will review the application without bias. The Researchers explained they will have a meeting with the Chair of SCOTT to work through these issues.
2. The Committee explained it is concerned about people who believe they are not pregnant signing up to the study who have not had a pregnancy test, and those who could become pregnant during the intervention phase. In most clinical trials there are confirmations of participants not being pregnant before the intervention is supplied. It is noted that the interventional product has not been examined for safety in pregnancy.
3. The Committee raised questions about the online eligibility sheet as it seems it can be accessed without reading the information sheet first. The Researcher explained that there are multiple places to view the information sheet and within the online system a participant cannot progress unless the participant has opened/viewed each section.
4. The Committee asked if a research team member is reviewing the questions on the eligibility sheet or if randomized by a computer system. The Researcher explained there is an algorithm reviewing questions and confirming eligibility which prevents participants from 'gaming' the system.
5. The Committee asked about the courier process and what steps are taken to ensure this is as secure as possible. The Researchers explained that there are stickers on some packages that require signature indicating requirement to be over 18, however there will be under 18’s involved in this study so a parent will need to sign for them. The Researchers explained the relationship with the courier is good and can be trusted with proper handling and delivery.
6. The Committee asked about the quality-of-life questionnaires and if any adverse events are raised what systems are in place to protect participants. The Researchers explained that if the questionnaires flag any adverse events or cause for concern, this will be raised and followed-up on to ensure the affected participant is connected to assistance they require.
7. The Committee asked if there have been previous experiences with crossovers before regarding participants sharing drugs. The Researchers explained in a pragmatic trial, sharing of the medication is common and used asthma inhalers as an example. This data should be captured as it contaminates the trial.

Summary of outstanding ethical issues

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

1. Please include more safety information (including exclusion criteria) up front in the advertisements and screening phases and consider mechanisms with respect to participants consenting to be randomised to an un-approved medicine using self-report only without a clinical review. Those who are yet undiagnosed with renal problems or high blood pressure, or do not know they are pregnant, may face particular risks The Committee noted the Researchers will build in more safety with the assistance of SCOTT.
2. Greater clarity is needed with respect to looping in the participants’ GPs into study enrolment, as to whether this occurs for every sign up, or only for those participants who report eligibility questions. Since randomisation occurs by algorithm at sign-up, there doesn’t appear to be time for a GP to raise issues with respect to participant safety.
3. The Committee requested provision of the research team safety plan in the event that the follow-up visits occur in private residences.
4. Please ensure safety assurances are in place regarding courier drivers delivering unapproved medicines, and that ID’s are checked and validated.
5. The Committee requested the following changes to the protocol:
   1. Please include in the protocol a separate section that outlines the risks and how these risks are mitigated.
   2. Please include the participant safety plan into the protocol.
6. The Committee requested that the exclusion criteria is clarified in the advertisements (flyer) and provided earlier on the webpage.
7. The Committee noted that the practicing certificate uploaded is not evidence of indemnity insurance, however as the Committee accepts this study as an investigator led trial, the Committee would not need to see evidence of indemnity insurance.
8. The tapering program and behavioural booklet should be uploaded for review when the co-design is complete.

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

1. Please check the information sheet for typos and general grammar mistakes.
2. Please adjust the date for when the participant results will be available.
3. Please insert the correct Ethics approval statement as per the HDEC template and note that SCOTT is not part of MedSafe (SCOTT is part of the HRC, but their secretariat \*is\* part of MedSafe).
4. Please state that the participant’s General Practitioner (GP) will be informed of enrolment, and also in the event of clinically significant abnormal findings/concerns. Delete optional tick-box in relevant CF clause as this should be mandatory and ensure this is explained in the body of the PIS.
5. The Committee raised that the University of Auckland general liability insurance is irrelevant in the context of a clinical trial, investigator led trial or not. As this trial would be covered by ACC, please submit a different insurance statement.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms. Kate O’Connor, Mr Jonathan Darby, and Mr Barry Taylor.

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| **6** | **Ethics ref:** | **2024 FULL 19443** |
|  | Title: | Implementing psychotherapy for depression in primary care: feasibility study phase 2. |
|  | Principal Investigator: | Professor Marie Crowe |
|  | Sponsor: | Pegasus Health. |
|  | Clock Start Date: | 25 January 2024 |

Professor Marie Crowe 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 recruitment and the referral process. The Researcher explained that the process occurs standardly through Pegasus and the participants go to their health improvement practitioner (HIPs) but do not have structured therapy. The Committee noted that most HIPs in New Zealand are not clinically trained therapists and asked for justification of them delivering psychological interventions. The Researcher responded saying they are not justifying it and that the HIPs used for this study are self-selected and are also health care professionals. The Committee clarified with the Researchers that participants are not being referred for therapy but are being referred as a participant in research.
2. The Committee asked if the HIPs being used for this study can be taught to deliver the study interventions. The Researcher explained the training has begun and is being offered outside of the research as professional development.
3. The Committee asked who is providing the training and the qualifications of the trainer. The Researchers explained both study leads will be leading the training and after the training is complete the trainees are tested with rating scales to assess if they are adequately trained.
4. The Committee asked how the success of the trial will be measured. The Researchers explained they have cut back on all outcome measures and will just be using the Patient Health Questionnaire 9 (PHQ) and the clinical impression measure and are looking for improvement in the PHQ and the global clinical rating, an improvement over a series of standards.

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 considers that psychotherapy can be administered by duly qualified and registered psychotherapists only, that the use of the term ‘psychotherapy’ is misleading in this context and may not be within the safe scope-of-practices of HIPs. Please amend ‘psychotherapy’ throughout that the study documentation, including in the study title, to either therapeutic or counselling interventions.
2. The Committee noted that the University must be the study sponsor and sign off will need to be acquired through the respective research and innovation office.
3. In the data management plan please include the Otago University data policies as the governing framework.
4. Please submit a staff protocol, explaining how staff are recruited and consented, whether they are paid to train, and the assessment process. Supply the training programme undertaken by the staff volunteers.
5. The Committee requested the following changes to the protocol:
   1. Please include the training safety protocol used for trainees and include the usage of the rating scales after training is complete.
   2. Please include a safety plan and a risk mitigation plan for suicidality.
6. Please amend the data governance, it is too generic and not pertinent to this study. Use of the data management plan 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.

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

1. Please submit a separate PIS for the therapists.
2. Please make clear that if a participant does not want to take part in the research, there are other avenues for therapy available for them. Please also include if there is a waitlist between the two avenues.
3. Please add a table showing as much information as possible to allow participants to make an informed choice between the different therapy types and includes study visits and the different timeframes.
4. Please include a statement that explains the study is assessing whether mental health treatment can be made more available by training non-clinicians on how to deliver care, outline the objective of the study and how this will be achieved. Also, please amend the wording that this treatment mechanism is not proven to work and there are still unknown outcomes.
5. Please state that the participant’s General Practitioner (GP) will be informed in event of clinically significant abnormal findings/concerns. Delete optional tick-box in relevant consent form clause as this should be mandatory and ensure this is stated in the main body of the PIS.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms. Kate O’Connor, Mr Barry Taylor, and Mr Ewe Leong Lim.

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| **7** | **Ethics ref:** | **2024 FULL 18418** |
|  | Title: | Do perioperative synbiotics reduce postoperative infectious complications in patients undergoing elective colorectal resection? |
|  | Principal Investigator: | Dr Claudia Paterson |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 25 January 2024 |

Dr Andrew Hill and Dr Claudia Paterson 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 there will be co-investigators at the other sites and how the samples will be stored. The Researchers explained that for the Auckland site there is a fridge that maintains the correct temperature for the product. The Researcher will most probably require co-investigators in the future for the management of product at the other sites. The samples will be stored in a fridge at the clinics, the product will also be fine during a car ride home for the participants.

Summary of outstanding ethical issues

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

1. Please upload the sponsor sign off from the University. The Committee recommended going through the Human Ethics Office, not Head of Department.
2. Please include in the protocol a standard operating procedure for each site to follow.

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

1. Please review for typos and repeated information throughout.
2. Please amend the 4th paragraph: “after your surgery and when your surgeon says it is OK to drink fluids, you will restart the powder daily until you have reached two weeks.” to clarify this is two weeks post-surgery.
3. The Committee requested the removal of the ‘yes / no’ tick boxes from the consent form unless it is for a clause that is truly optional (i.e., the participant can answer ‘NO’ and still participate 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 participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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

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| **8** | **Ethics ref:** | **2024 EXP 18357** |
|  | Title: | Breast Cancer Screening Images and Artificial Intelligence in New Zealand. |
|  | Principal Investigator: | Professor Colin Simpson |
|  | Sponsor: | Victoria University of Wellington |
|  | Clock Start Date: | 25 January 2024 |

Professor Colin Simpson and Professor Gregor Coster 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 while algorithms to assist breast cancer detection are already in the market, these have not been trained on New Zealand data.
2. The Committee asked about the length of time taken in commencing the study. The Researchers explained the ownership of the data was held by Health Alliance which was under the Ministry of Health who gave approval to start the study. As the data swapped over under the structural changes, to Te Whatu Ora the Researchers were told to start again, hence the delay as the process has been long and difficult for them.
3. The Committee asked if it is possible to reach out to a group/clinician/Pasifika leader that screen Pasifika woman and consult about study goals. The Researchers are happy to reach out, however are not confident there is sufficient data for Pasifika woman to create an accurate algorithm and do not have the funding to do so. The committee notes the significant effort that has gone into getting Pasifika women into screening, and the higher burden of disease in Pasifika women, and encouraged consultation at an early stage of algorithm development.
4. The Committee asked how the Researchers have responded to the concerns of the peer review. The Researchers explained the main concerns was with algorithmic bias, however an advantage of using a large data base it can be split into a training set, test set and a validation set to test for algorithmic bias.
5. The Committee noted that the Researchers would have to return to HDEC to initiate later phases of the project, at this stage there are no participants involved or any pathway to clinical application.
6. The Committee asked about the data and if it is de-identified or not. The Researcher explained the data is de-identified because it carries some markers such as sex, age etc that means it is not anonymised and is de-identified.
7. The Researchers confirmed that due to the de-identification process it would not be able to re-identify individuals for whom matters of concern (e.g. a missed diagnosis) emerged.

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 following changes to the Data Management Plan (DMP):
   1. Please identify the commercial partner and explain their role in the study and how future benefits will be shared.
   2. Please explain the endpoint of the study, detailing that this is not intended for clinical setting in this phase but may have both commercial and clinical implications in later stages.
   3. In the data management plan please include a diagram that shows the AI cycle process, highlighting the checkpoint and human oversight stages in algorithm development.
   4. Please make the existing diagram with respect to data sources, storage locations and privacy considerations more lay-friendly, spelling out acronyms.
2. Please upload a response to the peer review. This does not need to be for the whole document, but a few responses to the conclusion.
3. Please reach out to Pasifika leaders or experts in the field of screening and be transparent with the study goals and endpoints to gather important insight and to share interest.
4. Please upload the social license report conducted by the Ministry of Health. The Committee noted that transparency is an important factor in social license, and it is important that New Zealanders know what is happening to their health information under a waiver of consent approved by Northern B HDEC, and what the benefits are, and to whom they accrue. Consideration should be given to developing a tool, such as a website, to assist with transparency and maintaining the social license. This might be presented through the Amendment Pathway.
5. Please create and upload an anticipated timeline of the development of the tool, and how it will be used for public/ private benefit.

**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 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 Ms. Kate O'Connor and Dr Amber Parry Strong.

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| **9** | **Ethics ref:** | **2024 FULL 19303** |
|  | Title: | A Phase 3, Multicenter, Randomized, Open-Label Trial to Evaluate the Safety and Efficacy of Epcoritamab + Rituximab and  Lenalidomide (R2) compared to Chemoimmunotherapy in Previously Untreated Follicular Lymphoma (EPCORE™FL-2) |
|  | Principal Investigator: | Dr Leanne Berkahn |
|  | Sponsor: | AbbVie Limited |
|  | Clock Start Date: | 25 January 2024 |

Dr Leanne Berkahn 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 participants have someone independent from the study to talk to if needed. The Researcher explained they encourage the participant to speak to their GP if the participant has any questions.

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 proof of indemnity for the coordinating investigator has expired. Please submit an up to date MPS certificate.

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

1. Please provide more information regarding the three study arms that a participant could be put on. This is so the participant fully understands what they are giving up by joining the research.
2. In the CF, please include exactly what test the participants will be getting, even if the participant is outside of the study while also clarifying and separating the research specific procedures from the standard of care procedures.
3. In the CF, please remove the legally authorised representative panels as they are not applicable in New Zealand.
4. On page 8 of the main PIS, please amend the generic wording of bio-marker research to make it more lay friendly.
5. In the main PIS, please refine the language around testing of samples in the future to be either drug or disease specific (rather than generic) and maintain the chosen wording throughout.

**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 Alice McCarthy and Ms Joan Pettit.

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| **10** | **Ethics ref:** | **2024 FULL 19515** |
|  | Title: | Clinical Biomarkers and Applications in Eye Tracking. |
|  | Principal Investigator: | Professor Helen Danesh-Meyer |
|  | Sponsor: | Vision Research Foundation |
|  | Clock Start Date: | 25 January 2024 |

Jackie Low 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 decided after discussion that it was best to stage the application and leave the sub-study with children out of this current review and will return to that sub-study later as working with children adds more ethical considerations which are not currently sufficiently detailed in the documentation provided.
2. The Committee asked if this is the co-investigator’s invention being validated. The Researcher confirmed this and explained that the invention is closely related to the original Ethics approved eye tracking traumatic brain injury study (for PhD). Acquiring a patent for the device is currently being progressed.

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 why the University of Auckland is not the sponsor of this study if the lead investigator is staff of the University (and the co-investigator is a student, who developed the IP as part of their study). The Researcher explained that the project is part of Vison Research Foundation and not part of the University. The Committee explained should the investigators decide to put the device and study under the governance of the University for a commercial clinical trial, the University will know how to go about doing this and can offer guidance to the investigators.
2. The Committee believe there is a conflict of interest between the co-investigator as the inventor of the device which is not acknowledged or managed. Please submit more detail around the co-ordinator, the device and who benefits from the trial as it currently lacks transparency regarding the novel device.
3. The Committee stated more information around data management is required than what is available in the study documentation to satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. 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.
4. Please amend the Koha section in the application form, any travel costs occurred by participants need to be reimbursed.
5. Please amend the Koha section by including a token of appreciation/reimbursement for the other sub-group that is also partaking in the study.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please include the study sponsor and amend the section outlining the sponsor as the submitted PIS/CF has not been edited from a different previous study.
2. Please amend the risks section and include that some participants will be drinking 3 standard drinks.
3. Please also include some mechanism that ensures the participants are safe to leave the unit, drive home etc.
4. Please amend the section regarding participants with mild TBO baseline follow up for 6 months by including a one size fits all consent form that links back to health information.
5. Please include a photo of the device being worn on all the participant information sheets.
6. Please include more detail for each information sheet – like the detail on your advertisement – around what happens at each visit.

**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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| **11** | **Ethics ref:** | **2024 FULL 18792** |
|  | Title: | Examining the impact of Maternal PKU, a comparison to normative matched controls |
|  | Principal Investigator: | Professor Suzanne Barker-Collo |
|  | Sponsor: | Starship Children’s Hospital |
|  | Clock Start Date: | 25 January 2024 |

Professor Suzanne Barker-Collo and Jade Marinkovich 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 if this study is working towards a PhD. The Researchers confirmed this and the candidature has been confirmed by the University.
2. The Committee asked if neither the parents nor children received the reports. The Researcher explained in the previous study the reports were sent via a school therapist with the data being added to the children’s file.
3. The Committee asked if there are mechanisms in place if participants have any issues arise during the study period. The Researchers explained they are both trained in clinical psychology and trained in counselling and will be there for participants if needed and can also spot the early signs of distress and refer further on if needed.
4. The Committee asked about the mechanisms in place for participants to not feel pressured to join the study. The Researcher explained that the initial letter to the participants will come from the Metabolic service, however the investigators will be doing the recruitment and are not part of the Metabolic service.
5. The Committee asked about Pasifika people with PKU and the reasoning for no Pasifika people with PKU in the study. The Researcher said it is because it is very rare. Māori and Pasifika people with PKU are exceedingly low and would be surprised if there was even 1 Māori/Pasifika participant.

Summary of outstanding ethical issues

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

1. Please amend the maternal PKU tool by putting it into a New Zealand context.
2. The peer review submitted doesn’t meet HDEC requirements of being independent from the study. 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).*
3. Please include the University as the sponsor and process and submit the University sponsor form of which is done through the University research office.
4. Reconsider the recruitment of controls as friends of the index children, due to the potential for discrimination and stigma.

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

1. Please amend the assent form by rephrasing the deficit or othering phrases. Please amend to something like “how they think”.
2. Please submit a separate assent form for the control children group.
3. The Committee requested the removal of the ‘yes / no’ tick boxes from the consent form unless it is for a clause that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study).
4. Please submit a PIS/CF for women with PKU explaining the study and a PIS/CF for 15-16 year olds who do not have PKU but are children and then assent forms for the children. The Committee agree this will limit potential participant confusion regarding being approached and expected to do. This also allows the PIS/CF’s to be more specific with the different groups.
5. Please include that individual results are not available from the tests, unless there is a concern raised with the test.
6. Please include in the consent form that if there are abnormal findings during tests that the participant GP will be informed but ensure the researcher do not disclose what group the participant belongs 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).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Amber Parry Strong and Ms Alice McCarthy.

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| **12** | **Ethics ref:** | **2024 FULL 19561** |
|  | Title: | A Phase 1b Multiple Ascending Dose Study to Assess the Safety, Tolerability, and Pharmacokinetics of SZN-043, in Participants with Severe Alcohol-Associated Hepatitis |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Surrozen Operating, Inc & Novotech (New Zealand) Limited. |
|  | Clock Start Date: | 25 January 2024 |

Professor Edward Gane 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 for a summary of the study that is being reviewed. The Researchers explained this study is a treatment for alcoholic hepatitis of which is a disease that is increasing in incidence across the world and especially in New Zealand. There is no treatment which is shown to be effective. Alcoholic hepatitis causes inflammation in the liver leading to death from liver failure. Steroids are used to improve 7 day mortality but not 30 day mortality, no long term effect on survival. The study is expected to have 4 recruits in New Zealand sites and the participants must be sick and fulfil the alcoholic hepatitis definition but cannot be comatose or septic, or unable to consent for themselves. Over a year the researchers expect to see 30-40 participants however 10% would be eligible to participant in this first study.
2. The Committee asked if these participants would receive some kind of therapeutic benefit to participating. The Researcher explained they are expecting a benefit to the dose, but do not yet know what the correct dose will be and that pre-clinical trials show at least 2 doses will be required. There will be a dose response but do not know yet what the efficacious dose will be and is too early to tell.

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 a pregnant participant/partner participant information sheet/consent form should only be submitted as an amendment if a pregnancy occurs so it can be fit-for-purpose. As such, these have not approved for use with the current submission.

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

1. Please remove all references to treatmWent and treatment groups while the study is still a study.
2. Please ensure measurements for fluids are written in millilitres, not teaspoons.

**Decision**

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

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

## General business

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

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| **Meeting date:** | 05 March 2024 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

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

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

The meeting closed at 6:00pm.