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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 18 October 2022 |
| **Zoom details:** | 965 0758 9841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 12.30-1.00pm | 2022 FULL 12742 | PREschool Children's Anti-inflammatory REliever (PRECARE) study | Professor Stuart Dalziel | Dr Leonie Walker & Dr Kate Parker |
| 1.00-1.30pm | 2022 FULL 12101 | Digital Drawing App (iTui) Trial in Paediatic Gateway Clinic | Mr Jonathan Lee | Ms Catherine Garvey & Mr Derek Chang |
| 1.30-2.00pm | 2022 FULL 13195 | Equitable Hearing Project | Dr Angelique Nairn | Ms Catherine Garvey & Ms Jade Scott |
| 2.00-2.30pm | 2022 FULL 13450 | Airvo 3 NIV Comparison Study | Dr Louis Kirton | Dr Leonie Walker & Dr Andrea Forde |
| 3.00-3.30pm | 2022 FULL 13229 | Study to Assess Oral BRN-002 in Adult Participants with Coronary Artery Disease. | Dr Richard Stubbs | Ms Catherine Garvey & Dr Sotera Catapang |
| 3.30-4.00pm | 2022 FULL 11919 | The aspergillus antigen study (ASPAG) | Professor Stephen Chambers | Ms Catherine Garvey & Ms Jade Scott |
| 4.00-4.30pm | 2022 FULL 13331 | INFORM ASTHMA Trial | Professor Richard Beasley | Ms Catherine Garvey & Dr Kate Parker |
| 4.30-5.00pm | 2022 FULL 13504 | GS-US-642-5670: A Study to Evaluate GS-2829 and/or GS6779 in Healthy Participants and Patients with Chronic Hepatitis B | Professor Edward Gane | Dr Leonie Walker & Dr Andrea Forde |

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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 | Apology |
| Dr Leonie Walker | Lay (Ethical/Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Ms Jade Scott | Non-lay (Intervention/Observational studies) | 15/08/2021 | 15/08/2024 | Present |

## Welcome

Ms Jade Scott opened the meeting with a karakia at 12.00pm and welcomed Committee members, noting that apologies had been received from Mr Jonathan Darby.

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 20 September 2022 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2022 FULL 12742** |
|  | Title: | PRECARE: An open-label Randomised Controlled Trial of as-needed budesonide-formoterol vs salbutamol reliever therapy in  preschool children with mild asthma/recurrent wheeze. |
|  | Principal Investigator: | Professor Stuart Dalziel |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 06 October 2022 |

Professor Stewart Dalziel and Libby Haskell 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 the approved use of the drug in Australia is limited and in older children for a different use than is being researched in New Zealand.
2. The Committee clarified the databases in use for recruitment would be comprised of data from Starship and other hospital admittance. The families would not know that they are on these databases but there was a large focus on ensuring the participants know where their details were collected and the use of these by named researchers solely to approach potentially eligible participants.
3. The Committee clarified that the sponsorship documents naming Professor Stuart Dalziel was necessary due to university sponsorship arrangements, and appropriate given Dr Dalziel’s role with the research.
4. The Committee clarified that the dosing would be clarified with participants upon consultation with the study team to prevent daily use where not necessary.
5. The Committee clarified that there was no increased risk of any side effects on the children from the steroid use as opposed to the adult cases, that the safety in young children had been quantified and that there were no safety concerns for this age-group.
6. The Committee queried the inclusion of certain economic questions that parents would be asked. The Researcher noted that thus far in other studies collecting this information there had not yet been any notable issues raised and no pushback from parents and that this question was included for its perceived value and for the sake of consistent data across cohorts.
7. The Committee queried the accuracy of asthma diagnoses and the validity of this in the group under study, which the Researcher clarified was the reason for this study as there is a need to identify asthma in this age group.
8. The Researcher confirmed the registry the clinical trial would be registered with.

Summary of outstanding ethical issues

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

1. Please amend the statement concerning the everyday use of the drug to state that this should only be done where directed by the research team.
2. Please remove the tick-box for the option of informing a General Practitioner (GP) as this is mandatory.

**Decision**

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

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

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| **2** | **Ethics ref:** | **2022 FULL 12101** |
|  | Title: | Using A Digital Drawing Application (iTui) To Facilitate Communication With Patients In Paediatric Gateway Clinic: A Prospective Interventional Study |
|  | Principal Investigator: | Dr Jonathan Lee |
|  | Sponsor: |  |
|  | Clock Start Date: | 06 October 2022 |

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

Potential conflicts of interest

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

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

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 age ranges of child participants be stated as the protocol only refers to children aged over 4 and there is no upper limit.
2. The Committee noted that there were no assent forms and that these would need to be simplified for the age groups that would be assenting and need to be provided for review. More than one assent form will be required to ensure that there are age-appropriate versions for the different age groups. (*National Ethical Standards for Health and Disability Research and Quality Improvement* para *6.25-6.27).*
3. The Committee requested that the questionnaires that are to be used with children, caregivers, and clinicians be provided for review.
4. The Committee noted that there were recommendations made by the peer reviewer that had not been incorporated into the study, specifically the Committee would like to see addressed the peer review comments on the following:
   1. The possibility of purposeful sampling. This may be important given the potential age range and the desire to ensure the app is culturally appropriate/responsive.
   2. The assent forms for tamariki/rangitahi.
   3. Māori consultation (*National Ethical Standards* para *3.3).*
5. The Committee noted that the recruitment process allowed for little time for the Participant Information Sheet (PIS) to be read and processed and request that this be provided to the eligible families along with the clinic appointment letter for their consideration. (*National Ethical Standards* para 7.16)
6. The Committee noted the lack of detail surrounding recruitment in the Protocol. The Committee requested the following be included in more detail:
   1. A timeframe for the conduct of research.
   2. A description of the specific medical and demographic data that is being collected.
   3. Inclusion of the questionnaires as an appendix to the protocol *(National Ethical Standards* para *9.8).*
7. The Committee requested that the Data Management Plan (DMP) be revised to ensure that it is study specific, as there are many remnants of the template present that are not relevant to the study (*National Ethical Standards* para *12.15).*
8. The Committee requested that the DMP detail how long data is to be stored as well has who will have access to this data and if there are any potential future uses for this data (*National Ethical Standards* para *12.15).*
9. The Committee requested clarification on the expected dropout rate and incompletion rate throughout the study and how this may impact the data.
10. The Committee requested clarification as to whether there would be any possibility of inclusion of other outcomes, such as improving the assessment tool (the iTui app) and whether this tool improves the overall quality of Gateway Assessment.

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 & 7.16*:

1. Please provide a header with the institution listed.
2. Please provide details for the study investigators (including their names).
3. Please provide more information about the iTui app as this would be useful so if participants are not familiar with it, they have a good idea of what it does. A description of how the app is used by the clinician and the participant, and also its purpose to add to the information able to be gathered during the assessment would be useful.
4. Please include reference to the data that is collected in addition to the questionnaires giving feedback about the app. Participants should be advised what demographic and medical data is required to be collected.
5. Please specify how long the appointments are and how much time is added by completing the questionnaires.
6. Please clarify the length of time data will be kept and what potential uses are.
7. Please include the statement of HDEC ethical approval as can be found in the HDEC [PIS Template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).

**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:** | **2022 FULL 13195** |
|  | Title: | Equitable Hearing Health for Tamariki & Fanau |
|  | Principal Investigator: | Dr Angelique Nairn |
|  | Sponsor: |  |
|  | Clock Start Date: | 06 October 2022 |

Dr Angelique Nairn and Dr Rebecca Garland 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 the study would be overseen and sponsored by Point and Associates. Auckland University of Technology (AUT) is not the sponsor but will provide some funding.
2. The Committee clarified that the talanoa/interviews would be driven by specific themes with objectives that would be reached by exploring these themes. The primary theme is inequity. During talanoa the researchers will seek to uncover the participants’ personal experiences in a more free-flowing sense than an interview. The Committee requested inclusion of this explanation in the protocol.
3. The Committee clarified that a support person would be encouraged to accompany the participants.
4. The Committee clarified that the peer review notes had been noted and were being worked into the protocol.
5. The Committee clarified the interviews would be conducted by individuals of Māori and Pacific Island background and it was intended to meet with participants where this is wanted prior to the data-gathering talanoa phase to ensure these are conducted in a culturally appropriate way.
6. The Committee clarified that coercion was being minimised by ensuring consent was done by the clinic nurse rather than the surgeon. Contact further to this would be done separate from the treating surgeon or researcher. Please include this in the protocol.
7. The Committee clarified that some of the participants may be hard of hearing but that this was planned for with voice to text. The Researcher clarified that there would be no need for sign language interpreters.

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 protocol have numbered pages and include a version number.
2. The Committee noted that there were no inclusion criteria and the Researchers responded that this was in order to ensure that there was a more direct link created in the recruitment phase by people being forwarded directly from the participants clinicians. The Committee requested this be documented in the protocol and that there be a basic inclusion criteria.
3. The Committee noted that there was no clear consent process outlined, please provide this in the protocol.
4. The Committee requested that the option of having a support person be included in the protocol.
5. The Committee requested that the option of having a karakia be included in the protocol.
6. The Committee requested that further information be provided to the Data Management Plan (DMP) in particular: storage of data for ten (not 5) years, and the potential dissemination and/or future use of data for related or other research purposes.
7. The Committee requested that independent scientific peer review be conducted as per the [HDEC Peer Review Template](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2021.docx).

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

1. Please include a statement that identifies who is funding the study.
2. Please include the statement concerning HDEC approval as noted in the [HDEC PIS Template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
3. Please include the HDEC approval statement.
4. Please include the section on data usage as per the [HDEC PIS Template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/), including, storage, access and correction of data. Please note that health data must be stored a minimum of 10 years from when the youngest participant turns 16.
5. Please include contact numbers for Health and Disability support as well as Māori and Pasifika Cultural support.
6. Please include a statement concerning the return of results and a timeframe around this.
7. Please include a clear withdrawal pathway for participants (they do not need to withdraw in writing).
8. Please make it clear that audio recordings of the interviews will be taken. Please also make it clear that this will only be used for transcribing and where this will be stored as well as the ability for participants to alter these records.
9. Please provide detail of any information on reimbursement or payment that may occur for participation.
10. Please include the ACC compensation statement as per the [HDEC PIS Template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
11. Please include a place for the person consenting participants to sign.
12. Please include page and version numbers.
13. As a separate document, please provide a confidentiality statement for the person transcribing the audio recordings if they are not a member of the study team.

**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 Jade Scott and Ms Catherine Garvey

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| **4** | **Ethics ref:** | **2022 FULL 13450** |
|  | Title: | A randomized, cross-over, non-inferiority study comparing the Fisher and Paykel Airvo 3 non-invasive ventilator device to a  commercially available device in patients with resolved acute hypercapnic respiratory failure. |
|  | Principal Investigator: | Dr Louis Kirton |
|  | Sponsor: | Fisher and Paykel Healthcare |
|  | Clock Start Date: | 06 October 2022 |

Dr Louis Kirton, Professor Richard Beasley and Dr James Revie 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 timing of consent and how this would be managed to ensure the clinical and emotional safety of the participants. The Researcher noted that the participants may be incredibly unwell, and that consent would be gathered during a narrow window. The researcher noted that following discussion with clinicians the most acute cases will not be included, participants will have time to consider their involvement and there will be careful processes in place to obtain consent. The primary clinician would not be making the initial approach for recruitment. No critically unwell patients will be recruited.
2. The Committee clarified that if successful it is intended that the study device will be made available for use in public hospitals in the near future.

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 seniority of the peer reviewer and requested a second, expert independent review.
2. The Committee noted that the insurance will need to be updated during the course of the study.
3. The Committee noted that the Māori population is at greater risk of serious disease but that the application does not address whether the study device may address inequity. Please revisit this response in the application and amend.
4. The Committee requested submission of evidence of current indemnity as the certificate provided is expired.

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

1. Please clarify the flow chart to better demonstrate the pairing of the study procedures.
2. Please specify the number of minutes of rest after the removal of the first NIV and if the participants will have oxygen therapy during this time.

**Decision**

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

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

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| **5** | **Ethics ref:** | **2022 FULL 13229** |
|  | Title: | A Single-Group Treatment, Phase 2a, Open-label, Single-Arm Study to Assess the Safety, Tolerability, and Pharmacodynamic Effect of Oral BRN-002 in Adult Participants with Coronary Artery Disease |
|  | Principal Investigator: | Dr Richard Stubbs |
|  | Sponsor: | Beren Therapeutics, P.B.C and PPD part of Thermo Fisher |
|  | Clock Start Date: | 06 October 2022 |

Dr Richard Stubbs, Katelyn Diffin and Kathryn Stothers were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee advised that in order to access health information of the baby of a pregnant participant / partner there would need to be an additional consent after the birth. The Committee advised that a baby is not a legal person with human rights until after birth and during the pregnancy the parent can only consent to their own health information. The Committee recommended the addition of another signature box on the pregnancy participant information sheet (PIS) to consent to the baby’s information after the birth. The Committee also noted that a pregnant participant/partner PIS/consent form should only be submitted as an amendment in the event that a pregnancy occurs so it can be fit-for-purpose.
2. The Committee queried if it would be possible for incidental findings on the optional genetic biomarkers to be returned to participants, and how identifiable these samples are. After discussion, the Committee noted that deidentified and anonymised are different levels of identifiability and requested clarification around the identifiability of the samples. Participants will need to know if the samples can be re-identified and what follow up, if any, they should expect. Further, the Committee asked for more information around what tests were considered for these samples.

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

1. Please include more information for participants around the frequency of sample collection and how long they will be at the site at each visit.
2. The Committee recommended including a statement that while this is not first in human, this is the first time it is being used in people with cardiovascular disease and in multiple doses.
3. Advise participants that the study payment is taxed and at what rate.
4. Please ensure time limit for storing samples for future use is clearly stated and remove reference to “any time in the future”.

**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 Catherine Garvey and Dr Sotera Catapang.

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| **6** | **Ethics ref:** | **2022 FULL 11919** |
|  | Title: | New tests for invasive aspergillosis in immune compromised patients: Proof of principle studies. The ASPAG study |
|  | Principal Investigator: | Professor Stephen Chambers |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 06 October 2022 |

Professor Stephen Chambers 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 queried how the participant approach will work given the small window for recruitment. After discussion, the Committee was satisfied the potential participants have adequate time to decide their participation and are not time pressured.

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 long-term data collection is not entirely clear on length of collection and purpose of the collection. In some parts of the documentation, 20 years is stated which the Committee believed to be quite long. Please clarify in all documentation the nature of data collected and for what period (i.e., in Data and Tissue Management Plan (DTMP) and participant information sheet (PIS)).
2. The Committee stated that separate consent for Biobanking is typical and should be used here. Biobanking should not be a mandatory component of the study integrated into the main PIS.
3. The Committee requested that the DTMP is study specific. They noted that more information needs to be added around future use and Biobanking.

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

1. Please name the Biobank being used by the study and more information about the intended use of the samples being sent there.
2. Please replace reference to teaspoons of blood with millilitres (ml).
3. Please clarify that this is being done as part of a PhD.
4. Please include risk(s) involved in collecting tissue samples and other study procedures
5. Please amend the HDEC to state it Northern A as the approving Committee.

**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 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).
3. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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

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| **7** | **Ethics ref:** | **2022 FULL 13331** |
|  | Title: | A randomised controlled trial of budesoNide-FORMoterol vs terbutaline for symptom relief in adults with mild-moderate ASTHMA on inhaled corticosteroid maintenance therapy |
|  | Principal Investigator: | Professor Richard Beasley |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 06 October 2022 |

Professor Richard Beasley, Dr Jonathan Noble, Melissa Black and Bianca Black 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 recruitment process, particularly through potential participant’s general practitioners (GPs). After discussion, the Committee was assured the reimbursement was only for the administration involved. however the
2. The Committee reminded the Researchers to be aware of the Medical Council’s guidance for practitioners working with commercial organisations including for research, and to ensure that their arrangements were not in contravention of these.
3. The Researchers noted exploring local pharmacies to widen recruitment potential for the study to capture those who may not respond to the GP letter. The Committee noted that if there are future plans for this, this recruitment material can be submitted via amendment.
4. The Committee queried if the home FeNO testing is already approved for use in New Zealand and is not an investigational component. The Researcher confirmed that while this is novel for use in New Zealand, it is approved for this use. They additionally clarified there will be no cost to participants using the FeNO device in their home, including if the device is damaged.
5. The Committee noted the change in number of participants and no amendment would be required for that change.

Summary of outstanding ethical issues

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

1. On page 1, please replace Central Health and Disability Ethics Committee with Northern A.
2. Please highlight that participants will not cover the cost of needing to replace any of the devices used and what will need to be returned at the end of the study.
3. Please include the option of karakia for disposal.
4. Please clarify what data the study will be retained for those who fail the screening or cannot use the inhaler, etc.

**Decision**

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

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

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| **8** | **Ethics ref:** | **2022 FULL 13504** |
|  | Title: | A Phase 1a/1b Study to Evaluate the Safety and Tolerability of Repeated Doses of Nonreplicating Arenavirus Vector Therapeutic  Vaccines GS-2829 and GS-6779 in Healthy Participants and Participants With Chronic Hepatitis B (CHB) |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Gilead Sciences |
|  | Clock Start Date: | 06 October 2022 |

Professor Edward Gane, Courtney Rowse, Holly Thirlwall, Julia O’Sullivan, and Emily Griffiths 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 declared a potential conflict of interest. The Committee and Professor Edward Gane after discussion decided to allow Dr Forde 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 was assured that proper follow-up is in place for monitoring potential muscle-damage from the vaccine.
2. After discussion, the Committee was assured that New Zealanders will have opportunity for further phases of this vaccine trial.
3. The Committee queried the significant restriction of activities on participants and whether this was realistic. The Researchers stated this pertains to their time at the clinic and they are provided activities that work within that restriction.
4. The Committee noted this is not an adenovirus nor mRNA vaccine so queried the concern around interactions with other vaccines. The Researcher responded that this is due to lack of safety data but long-term the interaction with other vaccines would be explored.
5. Committee commended the Researchers on their comprehensive ACC statement in the participant information sheet.
6. The Committee was assured the participants will not be removed from their usual treatment.
7. The Committee noted that the application has also been submitted to SCOTT and separately to the EPA for consideration by the HSNO Committee. The Researchers confirmed that any amendments required to be made as a consequence of these parallel regulatory approvals will be advised the HDEC and any substantial amendments submitted.

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 policy period of the insurance certificate is contradicted by the footnote.
2. The Committee raised the following about the advertisements:
   1. The statement “10 [or 13]13 short morning visits, that's it!” minimises what is involved in the study, please remove.
   2. Please refer to the drug as an “Investigational therapeutic vaccine”.

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

All PIS/CFs

1. Absolute statements of 'you will not' should be replaced with 'may' or suitable wording to clearly convey that because this is investigational whether or not there will be any benefit to CHB participants is not able to be known
2. Please replace ‘treatment’ with 'vaccine for treatment'.
3. Herbal medicines are not allowed but vitamins are, please clarify any difference of interaction.
4. The Committee clarified with the Researchers that the compensation is consistent across the cohorts enrolled and different reimbursement amounts reflect differing requirements on participants, and requested this is made clear in the PIS.
5. Make sure any support and cultural contact details are up to date as they currently refer to DHBs.

Part 1 B PIS/CF

1. In addition to the comments above, please amend CHB “patients” to “participants”.
2. Please clarify whether in fact pregnancy tests at days 141, 197 and 225 are able to be performed at home and if so, whether this impacts on the reimbursement provided.

**Decision**

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

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

## General business

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

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| **Meeting date:** | 15 November 2022 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

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

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

The meeting closed with a karakia at 5.00pm.