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| **Committee:** | Extra Meeting Health and Disability Ethics Committee |
| **Meeting date:** | 20 February 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11.00-11.30am |  | Committee welcome |  |  |
| 11.30am-12.00pm | 2024 FULL 21475 | VIR-CHDV-V203: A Study to Evaluate Tobevibart+Elebsiran in Chronic HDV Infection (ECLIPSE 1). | Professor Edward Gane | Maree / Barry |
| 12.00-12.30pm | 2024 FULL 22032 | A Study of Safety and Efficacy of FB102 in Adults with Vitiligo | Dr Purnima Olu De Rozario | Maakere / Patries |
| 12.30-1.00pm | 2024 FULL 20242 | Brace vs Observation Randomised Control Trial for Developmental Hip Dysplasia | Dr Nikki Hooper | Helen / Nicola |
| 1.00-1.30pm | 2024 FULL 21812 | Topical Gout Buster Gel for Tophaceous Gout. | Professor Nicola Dalbeth | Maakere / Barry |
| 1.30-2.00pm |  | **Break (30 mins)** |  |  |
| 2.00-2.30pm | 2024 FULL 21507 | BO45287:A study to look at mosunetuzumab in combination with pirtobrutinib in people with chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) | Dr Sophie Leitch | Maree / Nicola |
| 2.30-3.00pm | 2024 FULL 22102 | GuiDIng energy provision using indiREct CalorimeTry - DIRECT trial\_Revised | Ms Varsha Asrani | Helen / Patries |
| 3.00-3.30pm | 2025 FULL 20474 | Exploring the neurophysiological effects of chiropractic care: a feasibility study | Dr Angus McMorland | Maakere / Nicola |
| 3.30-4.00pm | 2025 FULL 21831 | Behaviour analytic understandings of confabulation in adults with Major Neurocognitive Disorder | Dr Rebecca Sharp | Helen / Patries |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (Consumer/Community perspectives) (Chair) | 22/12/2020 | 22/12/2024 | Present |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Present |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Dr Nicola Swain | Non-lay (Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 11.00am and welcomed Committee members for this extra Committee.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

As this is an ad hoc meeting not part of the usual schedule, no previous minutes were reviewed.

## New applications

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| **1** | **Ethics ref:** | **2024 FULL 21475** |
|  | Title: | A Phase 3 Randomized, Open-Label Study to Evaluate the Efficacy and Safety of Tobevibart+Elebsiran Combination Therapy in Participants with Chronic HDV Infection (ECLIPSE 1) |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Vir Biotechnology, Inc. |
|  | Clock Start Date: | 07 February 2025 |

Professor Edward Gane, Kayla Malate, Julia O'Sullivan, Lucy Druzianic, Kaylynn Zhang, and Winnie Chen were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee commended the specific cultural support put in place for this kind of study.
2. The Researchers confirmed the rationale for the 12-week delay arm.

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 the indemnity expiry and requested provision of a new MPS certificate.
2. The Committee requested if it could be noted when labs used are referenced, to at least include city and country.

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

1. Please rephrase ‘fairly reimbursed’ and just definitively say they will be reimbursed so it doesn’t sound like they will need to negotiate.
2. Across all sheets, just ensure it is clearer the participants GP will be notified by the study team.
3. Please add number of participants who took part in studies related to this investigational product.
4. Small error on page 4 regarding allergic reaction.
5. Clarify the biopsy is a needle biopsy.

**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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| **2** | **Ethics ref:** | **2024 FULL 22032** |
|  | Title: | A Randomized, Double-Blind, Placebo Controlled, Multi-Center Study to Evaluate the Safety and Efficacy of FB102 in Patients with  Non-Segmental Vitiligo |
|  | Principal Investigator: | Dr Purnima Olu De Rozario |
|  | Sponsor: | Forte Biosciences Australia Pty Ltd |
|  | Clock Start Date: | 07 February 2025 |

Dr Purnima Olu De Rozario, Srikanth Pendyala, Chandra Bodda, Michelle Tang, Kshemina Mhaskar, Cheryl Glover, Claudette Lionnet 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 noted that the advertisement wording is emotive and can be potentially stigmatising and coercive. Inclusion of statements such as asking potential participants to “help”, that the team “hopes” this will lead to better treatment, and “making a difference together” paired with statements surrounding what it is like to have this condition can be potentially coercive and are unnecessary. Please amend these statements.

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

1. Provide an estimated turnaround time on page 11 for the blood and urine results just for participant’s knowledge as these are going to Australia.
2. The Committee noted that reimbursement of travel is not taxable. Refund of travel costs should not be optional.

**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 20242** |
|  | Title: | Comparison of brace to observation in stable, radiological developmental dysplasia of the hip: A randomised controlled non-inferiority trial |
|  | Principal Investigator: | Dr Nikki Hooper |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 07 February 2024 |

Dr Nikki Hooper 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 confirmed with the Researcher that any signs of distress will be caught in real-time interactions in clinic and not take a week to respond.
2. The Committee noted that E9 of application form said that treatment was not being given by registered health practitioners and is incorrect. The Researcher confirmed this answer may have been mixed up with the recruitment answer in which they are avoiding white coat bias with enrolment.
3. The Committee confirmed this will be WHO database registered.

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 relevancy of using the quality-of-life questionnaires in the parents which ask about daily activities around recovery and also depression and anxiety. If the information being gathered is to assess how much of a burden treatment is, the Committee recommended creating a custom survey to capture the specific points the study wants to evaluate as the current questionnaires are not fit for purpose and can create extra burden. There are currently caregiver burden questionnaires that are validated that can be used.
2. The Committee noted that an assent form isn’t required given the age of participants.
3. The Visual Analogue Scale mentioned is not provided with study documents. Further to the above point, please consider whether this captures what the study wishes to capture and whether it should be used.
4. 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. It states no data will be collected from participants, but the study is collecting from parents and infants.
   2. Participants are infants, so the ‘all will give consent’ statement needs amending.
   3. Breach of privacy needs to be amended to say parents of participants will be informed.
5. The Committee noted that this is not being very promotive of child health and appears to be focusing on parent’s burden. Please review how this is framed in the participant-facing documents.

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

1. The box at the top not relevant i.e. ‘if you are under 16’.
2. Given the only thing this study is imposing is that the choice for treatment between the options is made randomly. The essence of this study should be upfront and in lay language.
3. Take out the explainer of “when it says you” and just always refer to “you and your child” as the children are infants, but both are participants.
4. Please include relevant confidentiality statements from [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates).
5. Please clarify what is required of the parents (filling in forms) and the infants for participation.
6. Please include the ACC statement applicable from the HDEC template.
7. Please provide an image of the brace for parents to see.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Dr Nicola Swain.

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| **4** | **Ethics ref:** | **2024 FULL 21812** |
|  | Title: | Six-month, single-centre, triple-blind, cross-over, placebo-controlled clinical trial of topical Gout Buster Gel in people with tophaceous gout (GOUTBUST01) |
|  | Principal Investigator: | Professor Nicola Dalbeth |
|  | Sponsor: | MedCryst Therapeutics |
|  | Clock Start Date: | 07 February 2025 |

Anne Horne 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 Committee noted that the evidence of sponsor insurance provided is only a quote. Please provide a full certificate.
2. The CI indemnity provided is currently expired, please provide an updated version.
3. The Committee queried the mechanism of action for this gel, noting the FDA have the ingredients listed as inactive. After discussion, it was confirmed SCOTT are currently evaluating this in tandem, and whether it is appropriate for them to provide scientific review of. Please provide either confirmation SCOTT are reviewing this, or if not, an independent scientific peer review using the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance).

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

All:

1. Please review all sheets and correct Māori words missing macrons.

Main PIS/CF:

1. Include your inclusion/exclusion criteria for participants to check.
2. Specify in millilitres how much blood will be taken.
3. Specify that $150 koha is per visit.
4. Given that this is a first-in-human and the risks aren’t yet known, please put the First-In-Human black box warning at the top of the PIS.
5. Please take the list of ingredients out and state “Identical in appearance and smell”.

**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 evidence of appropriate 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).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Maakere Marr and Mr Barry Taylor.

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| **5** | **Ethics ref:** | **2024 FULL 21507** |
|  | Title: | BO45287: A Phase 1B Open-Label, Multicenter Study Evaluating the Safety, Efficacy & Pharmacokinetics of Mosunetuzumab in  combination with Pirtobrutinib in Patients with R/R Chronic Lymphocytic Leukemia |
|  | Principal Investigator: | Dr Sophie Leitch |
|  | Sponsor: | F Hoffmann-La Roche |
|  | Clock Start Date: | 07 February 2025 |

Dr Francisca Reed and Yvette Mainwaring 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 biomarker section of the protocol (section 8.7) is the related testing to mention of genomic testing in the participant information.
2. The Researcher clarified screening data retained are just summaries of the reason for screen-failure and are not keeping identifiable information about individuals.

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 no continued access in the app form to medications, but there is a PIS for ongoing access. The Researcher responded that patients will either go into continuation or sponsor puts together a compassionate supply but at the moment this is still an ongoing decision. The Committee requested this be clarified by the Sponsor.
2. In the data management plan, please list the names and country of labs being used located.

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

Main PIS/CF:

1. With the generic comments referring to ‘local laws’, please just insert the New Zealand laws.
2. The header of ‘Genome Testing’ should just be clarified as ‘Biomarker Testing’. Section surrounding the use of biomarkers should be defined in less broad terms.
3. Current wording of page 5 implies it is the obligation of the participant is to inform their GP and should be the study team’s. Please amend this.
4. Under compensation, please remove ‘reasonable’ when referring to costs as it implies negotiation. If this will also be a voucher, please specify.
5. The language around sharing de-identified data is unclear if this is broadly for anyone, for specific studies related to this condition, etc. Please refine this.
6. There is room to mention two optional sub-studies and that they have their own consent.
7. CF mentions testing of and mandatory reporting of HIV, etc. But PIS does not mention this when it will happen. Please amend.

Tissue Bank PIS:

1. Clarify whether identifiable data is attached to tissues sent to Singapore.
2. Section 1.7 is too much like the main study: no one from New Zealand can audit anything about these samples; the GP does not need to know, people will not have the right to see information about their tissue bank (TB) samples, Māori sovereignty may not have sway for overseas TB samples, etc. Please review for relevancy and amend to ensure this PIS is more specific for the tissue banking.

Biopsy PIS:

1. All items stated regarding the Tissue Bank PIS apply here, please review for relevancy to the optional component.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Maree Kirk and Dr Nicola Swain.

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| **6** | **Ethics ref:** | **2024 FULL 22102** |
|  | Title: | GuiDIng energy provision using indiREct CalorimeTry: a pilot feasibility randomised controlled trial in critically ill adults with obesity. |
|  | Principal Investigator: | Mrs Varsha Asrani |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 07 February 2025 |

Varsha Asrani 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 discussed the consenting process with the Researcher. It was detailed that all people in the study will be sedated and unable to provide consent. Whānau members under Right 7(4) of the Code of Rights will be consulted to help inform the clinician’s decision under best-interests. Further down the line when they are no longer sedated, the participant will be approached once they are determined to be competent to provide their own consent, and asked whether they wish to continue to have their information as part of the study. If a participant does not consent, then they are excluded, and all data collected about them so far is discarded.

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 request for withdrawal doesn’t have to be in writing from the participant and can be given verbally but documented down by study staff.
2. The Committee noted the survey for staff on the acceptability in the protocol. If the Researchers are folding in data from them, then they count as participants and their participant information sheet should be provided, even if it is brief and can be folded in at the start of the survey with a line of ‘completing this survey counts as providing consent to participate’.

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

1. Please ensure there is a direct consent paragraph for the participant to later consent to and sign.
2. Using all of Right 7(4) in the participant information is not needed in the PIS. It reads aggressively. The PIS can just say “you were enrolled because clinicians assessed it was in your best interests along with conversations with your whānau” or similar, and reference to Right 7(4) can be provided if anyone has further questions.
3. In the case of whānau, the wording surrounding ‘responsible’ should not be used with whānau as it is the clinician’s responsibility. The whānau are being sought for their opinion.
4. Māori cultural support, not health support.
5. Do not refer to randomisation as ‘flipping of a coin’

**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 Mrs Helen Walker and Dr Patries Herst.

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| **7** | **Ethics ref:** | **2025 FULL 20474** |
|  | Title: | Feasibility of recording resting state EEG and ECG in infants receiving chiropractic care |
|  | Principal Investigator: | Dr Angus McMorland |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 07 February 2025 |

Jenna Duehr was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified the recruitment of participants into this study. The Researcher explained that the families will not be known to the clinicians or researchers ahead of time, but that advertising will be present in clinics to capture those already attending the clinics for treatment. Those who participate will not be expecting treatment by participation, and the chiropractor at the clinic will refer the parents onto the researchers.

Summary of outstanding ethical issues

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

1. The Committee requested to amend the posters to say ‘up to 2 hours’, and to explain in lay language what an intervention and control is.
2. The Committee requested to give parents a choice of petrol or grocery voucher.
3. The Committee requested clarification surrounding the role of the parents – after discussion the Committee acknowledged that the parents are not participants as their role is just to help guide the infant or hold them if they are distressed, but this should be made clearer.

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

1. Please indicate that de-identified information will be stored in the open database at the University and whether its optional.
2. The current wording of the discussion of AI use should be amended to be more lay friendly that the modern way to analyse the EEG data is through use of an algorithm, etc.
3. The Committee noted that it would be helpful to have a picture of the EEG/ECG on an infant, so parents know what to expect.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Maakere Marr and Dr Nicola Swain.

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| **8** | **Ethics ref:** | **2025 FULL 21831** |
|  | Title: | Exploring behaviour analytic conceptualisations of confabulation: assessment and interventions for confabulatory behaviours in adults with Major Neurocognitive Disorder |
|  | Principal Investigator: | Dr Rebecca Sharp |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 07 February 2025 |

Dr Rebecca Sharp and Victoria Burney were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified with the Researcher how recruitment will be broached. The Researcher confirmed that they will be asking those who promote the care of individuals affected with confabulation to nominate them for participation. There is an assisted supported consent model in place.
2. The Committee queried if a Researcher would have to always be present to ensure observations are legitimate and nothing was missed. The Researchers responded that best practice would have it be as natural as possible, so the time or context provided by the support person on when these observations can be made will be arranged for a researcher to be present for. This will also be integrated well into the organisation’s usual routine to be as least obtrusive as possible.
3. The Committee confirmed that all Researchers are registered psychologists.

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 ‘confabulation’ is an emotive and stigmatising word when used in participant and whānau-facing documentation and speak. Please find another way of phrasing it, including the title to not suggested manipulative behaviour as the motivation behind these people’s false memories.
2. The Committee requested amendment to the data management plan to state ‘not applicable’ under 7.3 regarding anonymised data, and to also include that auditors from HDEC will have access to information.
3. The Researchers confirmed that a member of the team will confirm capacity to consent in the participant. There is a built-in assessment for this study. The Committee requested this approach and procedure be detailed in the protocol.
4. The Committee requested provision of examples of how supported consent participant information sheet will look and be tailored so Committee can be assured of these in use.

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

Organisation PIS:

1. On page 2, remove any references to PPPR; that is not used here and cannot be used for research purposes either.
2. On page 3, please clarify where will data be stored.
3. On page 4, ‘additional observers’ to the research sessions mentioned. Clarify who these will be.

Whānau PIS:

1. Please correct "your family member who is consented to take part in the study". who HAS consented.
2. Please provide more information about identifiable and deidentified data of participants. Statements for use can be garnered form the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates).

**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 Mrs Helen Walker and Dr Patries Herst.

## General business

1. As this was an ad hoc meeting, the next ad hoc meeting was confirmed to be for 20 March 2025 to assist with the backlog. All submissions submitted to this agenda that receive approval or subsequent approval will be assigned to Central HDEC for post-approval monitoring.

The meeting closed at 4.00pm