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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 24 October 2023 |
| **Zoom details:** | https://mohnz.zoom.us/j/9738756003 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:00 - 12:30pm | 2023 FULL 18969 | Biomarkers and risk of future diabetic kidney disease | Associate Professor John Baker | Jessie / Nicola |
| 12:30 - 1:00pm | 2023 FULL 17990 | MA in Children with HAs | Miss Caelyn Eades | Cordelia / Albany |
| 1:00 - 1:30pm | 2023 FULL 18862 | BO42353: Crovalimab in aHUS adult and adolescent patients | Professor Robert Walker | Helen / Pat |
| 1:30 - 2:00pm | 2023 FULL 17794 | Rectal and blood concentrations of thioguanine given by suppository in inflammatory bowel disease | Professor Murray Barclay | Sandy / Amy |
| 2:00 - 2:20pm |  | BREAK (20 mins) |  |  |
| 2:20 - 2:50pm | 2023 FULL 18338 | After the Spots Fade | Dr Emma Best | Helen / Pat |
| 2:50 - 3:20pm | 2023 FULL 17818 | COG: AOST2032 | Dr Tristan Pettit | Cordelia / Amy |
| 3:20 - 3:50pm | 2023 FULL 18793 | A study to test whether BI 765845 helps people who have had an acute heart attack | Dr Philip Adamson | Jessie / Nicola |
| 3:50 - 4:20pm | 2023 FULL 18971 | Paeārahi supported health and wellbeing assessment for koeke | Dr Joanna Hikaka | Sandy / Albany |
| 4:20 - 4:40pm |  | BREAK (20 mins) |  |  |
| 4:40 - 5:10pm | 2023 FULL 18897 | GS-US-611-6472: Study in Participants with Normal Kidney Function and Reduced Kidney Function to Test How Kidney Function Can Change What Happens to Obeldesivir in the Body | Dr Nick Cross | Sandy / Amy |
| 5:10 - 5:40pm | 2023 FULL 18730 | A study exploring the use of continuous vital sign monitoring in acutely unwell general medical inpatients | Dr Julie Cook | Cordelia / Pat |
| 5:40 - 6:10pm | 2023 FULL 18795 | RIN-PF-305, TETON-PPF | Dr Catherina Chang | Jessie / Nicola |
| 6:10 - 6:40pm | 2023 FULL 18782 | Pliant PLN-74809-IPF-206 | Dr Catherina Chang | Helen / Albany |

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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  |
| Mrs Sandy Gill  | Lay (Consumer/Community perspectives)  | 22/05/2020  | 22/05/2023  | Present  |
| Dr Patries Herst  | Non-lay (Intervention studies)  | 22/05/2020  | 22/05/2023  | Apologies  |
| Dr Cordelia Thomas  | Lay (the Law)  | 22/12/2020  | 22/12/2024 | Present  |
| Mrs Patricia Mitchell  | Non-lay (Health/Disability service provision)  | 08/07/2022 | 08/07/2025 | Present  |
| Mx Albany Lucas | Non-lay (Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Present |
| Ascc. Prof Nicola Swain | Non-lay (Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members, noting that apologies had been received from Dr Patries Herst.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Associate Professor Nicola Swain and Ms Amy Henry confirmed their eligibility and were co-opted by the Chair as members 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 26 September 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 18969** |
|   | Title:  | New Techniques to Understand the Development of Diabetic Kidney Disease Amongst Māori and Pasifika |
|   | Principal Investigator:  | Associate Professor John Baker |
|   | Sponsor:  | Middlemore Hospital |
|   | Clock Start Date:  | 12 October 2023 |

Associate Professor John Baker, Distinguished Professor David Simmons and Ms Kanchana Perera 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 approved the waiver of consent subject to appropriate Pacific consultation on the proposed use of the samples.

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 Researcher undertake appropriate Pacific consultation on the proposed use of the samples and upload the subsequent report via the amendment pathway when available. The Committee recommended contacting the [Pacific Data Sovereignty network.](https://pacificdatasovereignty.com/)
2. Please update the data management plan to specify that data will be stored for a minimum of 10 years.

**Decision**

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

* Please undertake appropriate Pacific consultation and upload via the amendment pathway when available. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 4.11*).
* Please update the data management plan. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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| **2**  | **Ethics ref:**   | **2023 FULL 17990** |
|   | Title:  | Morphological awareness in children with hearing aids |
|   | Principal Investigator:  | Miss Caelyn Eades |
|   | Sponsor:  | The University of Canterbury |
|   | Clock Start Date:  | 12 October 2023 |

Miss Caelyn Eades and Dr Jayne Newbury were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried the exclusion of Māori who speak Te Reo Māori more than 20% of the time and raised concern the study may not comply with Te Tiriti obligations and would not have a representative sample of Māori participants. The Researcher stated population of deaf and hard of hearing children is limited and there are other difficulties such as measuring other languages using the same tools to measure English and bilingual and monolingual children follow different learning trajectories. The Researcher stated the inclusion of bilingual children would make it difficult to achieve the study’s objective. The Committee recommended making this exclusion and the rationale for it clear in the resubmission.

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 Researcher develop assent forms for recruiting children. The Committee recommended adapting the [HDEC assent form template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) The Committee suggested developing one form for older children with more information and one for younger children that is very simple. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.27*).
2. The Committee requested the Researcher adapt the [HDEC information sheet template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) and complete the prompts for sections missing from the current sheet (eg an ACC statement, Māori cultural statement, researcher contact details, footers). The Committee suggested one sheet for parents of children with hearing aids and one sheet for parents of children without hearing aids. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.20*).
3. The Committee requested the Researcher supply a form for schools to authorise the study.
4. The Committee requested the Researcher address the points raised by the peer review and incorporate the applicable feedback into the protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
5. The Committee requested the Researcher supply the questionnaire for parents.
6. The Committee noted the family would receive a koha and suggested the Researcher offer koha to the child as well.

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 a descriptive title instead of an acronym,
2. Please correct HDEC to Health and Disability Ethics Committee and clarify that only the ethical aspects of the study have been approved by HDEC.
3. Please amend the statement on withdrawal to specify that participants may withdraw at any time for any reason. The Committee noted a statement advising that information collected up until the point of withdrawal will continue to be used is permissible.
4. Please state whether parents will be able to review and correct the transcript.
5. Please explain why some sessions are at school and others are at university.
6. Please include a statement advising whether participation will involve two sessions.
7. Please include information that the study will collect information from and send results to an audiologist.
8. Please remove the statement in the assent form stating children won’t get into trouble by refusing to participate as this cannot be guaranteed.
9. Please remove the word caregiver and state parent / guardian.
10. Please include the ages of children eligible for participation in all sheets.
11. Please include a statement advising that the research may identify issues that will require support but these services have limited funding and accessibility.
12. Please include a yes/no tickbox on the assent forms instead of a signature box.
13. Please amend the statement on complete confidentiality to be less definitive as this cannot be guaranteed.

**Decision**

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

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| **3** | **Ethics ref:**   | **2023 FULL 18862** |
|   | Title:  | A Phase II, Multicenter Single-arm Study Evaluating the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of Crovalimab in Adult and Adolescent Participants With Atypical Hemolytic Uremic Syndrome (aHUS) |
|   | Principal Investigator:  | Professor Robert Walker |
|   | Sponsor:  | Roche Products (New Zealand) Limited |
|   | Clock Start Date:  | 12 October 2023 |

Professor Robert 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 queried the rationale for excluding 12–15-year-olds. The Researcher stated the only centre in New Zealand that would see a patient with this condition in this age group would be Starship Hospital. The Researcher stated discussions with Starship concluded it would be unlikely for them to see anyone with this condition during the period of the trial. The Researcher stated the effort to establish a clinical trial at Starship where no participants would be expected would not be feasible and Starship chose not to participate.
2. The Committee queried the response if a participant completing the quality-of-life questionnaire indicated they have moderate to severe anxiety or depression. The Researcher stated support services would be available and the study team would contact the participant’s primary carer with permission. The Committee noted about 200,000 New Zealanders were not registered with a primary care provider and the study team would be expected to ensure any participants who were not registered received appropriate support.
3. The Committee noted a study cannot be terminated solely for commercial reasons in New Zealand.

Summary of outstanding ethical issues

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

1. The Committee requested participants be offered a koha for participation. The Researcher agreed to consult the Sponsor.
2. The Researcher confirmed any vaccinations required for participation would be paid for by the Sponsor and participants would not incur any charges. The Committee requested information explaining this is added to the information sheet.

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

1. Please state whether the drug has been approved for any use in any overseas jurisdictions and that it is currently under Medsafe review.
2. Please state that the risk of infection is moderate to high due to the effect on the immune system.
3. Please include a statement in the optional research biosample repository (RBR) sheet advising participants that if they decide not to take part it will not affect their treatment for aHUS.
4. Please insert a comma after “during the main study” in the first sentence of the second paragraph on page 1 of the RBR sheet.
5. Please include a new ‘Access to Information’ heading for the second paragraph under ‘Ownership Rights’ on page 4 of the RBR sheet.
6. Please include a statement advising participants that their linking code will be retained for their sample so they may withdraw consent at any time in the RBR 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:**   | **2023 FULL 17794** |
|   | Title:  | Concentrations of Thioguanine and its metabolite 6TGN in Blood and Rectal Tissue Samples in Patients Administered Thioguanine by Suppository |
|   | Principal Investigator:  | Professor Murray Barclay |
|   | Sponsor:  | Barclay Gastroenterology Ltd |
|   | Clock Start Date:  | 12 October 2023 |

Professor Murray Barclay 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 the application indicated it involved Kaupapa Māori methodology in the application form but this did not appear to be accurate.
2. The Researcher confirmed any extra costs from the study would be covered by Douglas Pharmaceuticals and participants would not need to pay extra.
3. The Researcher confirmed the study has applied to the Australian New Zealand Clinical Trials Registry (ANZCTR).
4. The Researcher confirmed both sites are covered by the study’s insurance certificate and any insurance deductibles would be covered by the Sponsor.
5. The Committee advised cultural issues pertinent to Māori and Pasifika participants may include whakamā and sensitivity or discomfort around being undressed and the study involving access to the genital / anal area by someone of the opposite sex.
6. The Committee queried whether participants who receive benefit from the study drug would receive ongoing access. The Researcher stated they were unsure as a batch of the drug was produced by the Sponsor for the study but there is no ongoing manufacture at this stage. The Researcher confirmed if participants did benefit then they would be able to receive thioguanine through a suppository offered as part of the standard of care.
7. The Researcher confirmed sedation for the sigmoidoscopy would be offered to participants if required.

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 information sheet describes questionnaires on page 3 and requested these be uploaded.
2. The Committee noted the data management plan lacked detail on some of the required aspects (e.g. data breach) and requested the Researcher adapt the prompts from the [HDEC Data Management Plan template.](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/)
3. The Committee queried whether the procedure could be gender matched. The Researcher stated it may be possible in Auckland but not at the Christchurch site. The Researcher confirmed the study staff would be mixed gender. The Researcher confirmed a support person could be present but once the sedation is given the support person usually leaves the room during the actual procedure. The Committee requested information explaining the option of a support person is included in the information sheet and whether it is possible for someone of the same gender to be present during the procedure and when they would need to leave the room.
4. The Committee requested the Researcher investigate whether it is feasible for another member of the study team (eg a nurse) to make the initial approach to potential participants.

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

1. Please state whether pregnancy is an exclusion.
2. Please include contraception information from the [HDEC template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
3. Please include any known side effects of the study drug.
4. Please state the dosage of the drug to be given.
5. Please revise the sheet to remove leading language (eg ‘significant improvement’ on page 6) as benefit cannot be guaranteed. The Committee suggested revising the sentence to state it could produce improvement.
6. Please move the first paragraph under the ‘Who can take part in the study?’ heading to the beginning of the information sheet and revise the heading title as the other two paragraphs do not describe who can take part in the study.
7. Please re-order the paragraphs under “How is the study designed” and “What will my participation involve” so participants are informed of the routine blood test before treatment commences and then informed of the blood test after the first dose.
8. Please include a statement advising participants to hold the enema for as long as possible but if they need to pass it they are able to.
9. Please undertake a general revision to remove repetition (eg the right to withdraw information is on page 8 and 9).

**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).*
4. Please supply any questionnaires that will be used in the study.

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Ms Amy Henry.

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| **5**  | **Ethics ref:**   | **2023 FULL 18338** |
|   | Title:  | Understanding Measles: Severity and Sequelae - Substudy |
|   | Principal Investigator:  | Dr Emma Best |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 12 October 2023 |

Dr Emma Best and Dr Cath Gilchrist 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 Researcher confirmed any participants who turn 16 during the study can be reconsented on the adult PIS.

Summary of outstanding ethical issues

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

1. The Committee suggested offering a koha specific to the child.
2. The Committee requested the Researcher amend the questionnaire to change male and female to include additional gender options (eg nonbinary, intersex) as there may be others children would pick.
3. The Committee requested the Researcher rename the assent brochure as an assent form and include a ‘yes / no’ tick box for obtaining assent. The Committee advised while a written record of assent must be kept the child may give verbal assent and is not required to physically sign the sheet.
4. The Committee requested the revised sheets are uploaded separately.

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

1. Please remove any reference to caregiver and replace with parent / guardian.
2. Please clarify who will receive the koha.
3. Please amend the statement “I understand everything I say is private” as disclosure of intending harm would need to reported. The Committee suggested adding “unless we have concerns” on the end.
4. Please be specific when referencing questionnaires.
5. Please review all sheets and brochures for consistency on ages listed.
6. Please use the healthy images for all sheets and remove the cartoon of the sick child.
7. Please amend the statement “Why we are asking you to help” to “Why you are being asked to participate” or something similarly neutral.
8. Please remove the dollar value of the koha in the assent form as this could be perceived as inducive. The Committee suggested stating a small token of appreciation.
9. Please simplify the statement “we will keep the data until they are 10 years beyond 15 years old”. The Committee suggested rewording it to state the data will be kept until 10 years after the youngest participant turns 16.
10. Please remove the clause on the consent form stating the parent / guardian believes the child would have given consent if they had been able to understand the information.
11. Please amend the statement on the assent form from being happy to participate to agree to participate.
12. Please clarify the opening statement in the parental PIS as it currently states ‘you’ as if the parent would be a participant. The Committee suggested “We invite you to agree for your child to take part in this study.”
13. Please clarify ‘germs’ to mean infections.
14. Please clarify the 50 participants booked for minor surgery do not have measles.
15. Please amend the instructions on withdrawal to specify ‘one of’ the study team.
16. Please state that test results will not be returned.
17. Please amend the statement on using the results to inform the best way to care for measles to be less definitive.
18. Please clarify or remove the statement on the consent form on understanding who to contact (third to last bulletpoint).
19. Please amend the second to last bulletpoint to specify the child may withdraw at any time they wish.
20. Please revise the sheet to specify that taking part is the child’s choice as well as the parents.
21. Please remove the statement on reimbursement for clinical visits from the control PIS.
22. Please insert with to the clause “I have had the opportunity to discuss the study team” in the control consent form.
23. Please remove the clause on contacting the doctor or blood samples from the control group.
24. Please add an ‘S’ to the end of Cook Islands Māori.

**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 any questionnaires that will be used in the study.

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Ms Patricia Mitchell.

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| **6** | **Ethics ref:**   | **2023 FULL 17818** |
|   | Title:  | COG AOST2032: A Feasibility and Randomised Phase 2/3 Study of the VEFGR2/MET Inhibitor Cabozantinib in Combination with Cytotoxic Chemotherapy for Newly Diagnosed Osteosarcoma |
|   | Principal Investigator:  | Dr Tristan Pettit |
|   | Sponsor:  | Children’s Oncology Group |
|   | Clock Start Date:  | 12 October 2023 |

Dr Tristan Petit and Mrs Meredith Woodhouse 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 whether ongoing access would be offered if the drug showed benefit. The Researcher stated they usually have ongoing access programmes but it is currently not known how long to use cabozantinib after the chemotherapy component of osteosarcoma treatment. The Researcher stated if a survival benefit associated with cabozantinib use is discovered this may be incorporated into the next trial. The Researcher confirmed if participants in this study had a survival benefit they would investigate compassionate access.

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 crossed-out text in the information sheet. The Researcher explained this was only applicable to the United States and had been crossed-out for the New Zealand version of the sheet. The Committee requested removal of the crossed-out text and to remove any non-applicable text so it is not confusing to participants.
2. The Committee expressed concern at participants potentially having to pay for their own supply of cabozantinib as indicated in the information sheet. The Committee stated if benefit is shown to a participant who has consented to an experimental treatment then the drug should continue to be supplied free of charge to be consistent with [Standard 10.9 of the National Ethical Standards](https://neac.health.govt.nz/national-ethical-standards/part-two/10-ethical-features-of-studies/). The Committee suggested including a line in the information sheet to advise that compassionate supply can be organised at times but if the researchers are unsuccessful then participants may need to pay.

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

1. Please insert the reproductive risks information available in the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) and use gender-inclusive language.
2. Please simplify the assent sheet by removing acronyms participants would not be familiar with and explaining what biobanking is, as this may be too complex for younger participants.
3. Please move the definition of participants to the beginning of the sheet in the main PIS.
4. Please move the side effects / risks heading above as it is currently underneath the side effect information. The Committee suggested organising the side effects as a bulleted list.
5. Please include age-appropriate information in the older children’s assent form on reproductive risk and examples of appropriate contraception.
6. Please remove or rephrase the sentence “sometimes bad things can happen to people in a research study”.
7. Please remove the list of named doctors from the older children’s sheet and simplify it by stating they can ask any of the doctors.
8. Please remove the name of the study drug and replace it with ‘medicine’ in the younger children’s sheet.
9. Please remove or significantly simplify the biobanking section from the younger children’s sheet.
10. Please remove the not able to have children in the future line from the side effects in the younger children’s 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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| **7**  | **Ethics ref:**   | **2023 FULL 18793** |
|   | Title:  | Randomised, double blind, placebo-controlled study to investigate a single administration of BI 765845 on top of standard of care in patients with acute myocardial infarction |
|   | Principal Investigator:  | Dr Philip Adamson |
|   | Sponsor:  | Boehringer Ingelheim Pty Ltd |
|   | Clock Start Date:  | 12 October 2023 |

Dr Ian Crozier and Mr Michael Hume 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 noted the response to E8 in the application form and advised that a commercial trial cannot be halted solely for commercial reasons in New Zealand.
2. The Committee advised the pregnant partner form had not been reviewed. If this sheet is required during the study, it can be submitted via the amendment pathway for approval.

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 Researcher ensure New Zealand ethnicity data is collected at a site-level for final reporting to HDEC.
2. The Committee requested confirmation the data linking code would be kept for 30 years. Please amend the information sheet accordingly if required.
3. The Committee requested confirmation that participants who withdraw can withdraw the use of their data up to that point. If it is not optional then please remove the yes / no box in the consent form.

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

1. Please include a statement in the introduction of the long PIS advising participants that the sheet is in addition to the emergency consent form they have already signed and this sheet is to determine their interest in continuing participation in the study even though they have already received the drug or placebo.
2. Please remove any references to legally authorised representatives as this is not applicable in New Zealand.
3. Please change the long PIS to the past-tense (eg “You have undergone”) as it will be presented to participants after they have undergone the intervention. The Committee recommended shortening this information for simplicity.
4. Please remove ‘choice’ from ‘random choice’ for simplicity.
5. Please include all the side effects from the appendix in the risks section of the long PIS.
6. Please include the Māori tissue statement available on the [HDEC template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
7. Please rewrite the privacy section to meet New Zealand privacy standards (see the HDEC template for prompts).
8. Please include a figure for compensation for travel and parking expenses (eg “$20 travel allowance unless you come from further away”).
9. Please include information on reporting incidental findings to the participant’s GP as there is currently an option for this in the consent form.
10. Please change ‘may’ to ‘will’ in the statement on informing the participant’s doctor whether they received the drug or placebo.
11. Please amend the information on page 5 to make it clear participants may withdraw from all participation and any further visits will be done with their consent.
12. Please amend the information on pregnancy to be gender neutral and address the contradiction as it currently states women of child-bearing potential are excluded and then the next paragraph begins with “If you become pregnant”.
13. Please amend the statement on page 8 “If you decide to stop being given the study drug” as the drug has already been administered and review the following paragraphs for consistency.

**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 Jessie Lenagh-Glue and Associate Professor Nicola Swain.

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| **8**   | **Ethics ref:**   | **2023 FULL 18971** |
|   | Title:  | Paeārahi supported interRAI Check Up Self Report (CU-SR) Assessment Delivery Project |
|   | Principal Investigator:  | Dr Joanna Hikaka |
|   | Sponsor:  | Te Whatu Ora |
|   | Clock Start Date:  | 12 October 2023 |

Dr Joanna Hikaka, Ms Gabrielle Stent and Ms Kirsty Walker 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 how the study would respond to whakamā and literacy issues. The Researcher stated it was a feasibility study and they intended to test the appropriateness of this assessment tool in a culturally safe way. The Researcher stated they would not be recruiting people without support mechanisms in place and would only be recruiting participants enrolled in a Kaupapa Māori health and social service provider. The Committee suggested including information on this in future applications.
2. The Committee queried what safety measures were in place for the quality of life questionnaires and how the researchers would manage participants who indicated distress. The Researcher stated as soon as an assessment has been completed assessors at Te Whatu Ora would be notified and are experienced in responding to anyone in need. The Researcher confirmed no questionnaires would be sent via mail.
3. The Committee suggested the Researcher record an agreement of support people at the focus groups to maintain confidentiality. The Committee advised if support people at the focus group wish to participate they would need to sign an information sheet and consent form.
4. The Researcher confirmed extra resourcing was in place to support any participants who have an unmet need discovered during the study.
5. The Committee advised it would be best to offer the voucher as a thank you koha for participation and to avoid any suggestions it is reimbursement for participants’ time as this may have tax implications.

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 if paeārahi are providing data for the study they are participants and would require an information sheet and consent form. The Researcher agreed to extend the stakeholder form to include paeārahi.
2. The Committee requested the Researcher update the data management plan to include information on how the photos of participants would be used and stored.
3. The Committee requested the Researcher update the data management plan to reflect that interview recordings/transcripts are identifiable data unless all identifying information is removed from them.
4. The Committee requested the Researcher update the data management plan to specify that health information will be stored for 10 years.

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

**Main PIS for Koeke**

1. Please clarify the questionnaire can be completed at home and will be picked up by a paeārahi.
2. Please elaborate more on what involvement will entail for participants (eg questionnaires involving mental and physical health).
3. Please amend the statement on page 2 that states follow up / referrals ‘may’ be useful to state they will happen if required.
4. Please explain what any future research using the study data is or remove it from the sheet.
5. Please include information on how participants will be selected for the focus group.
6. Please make it clear the koha is for the focus group only.
7. Please include information on participant photographs, what these will be used for and where/how they are stored.
8. Please include the Māori data statement from the [HDEC template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
9. Please amend ‘Māori health support’ to ‘Māori cultural support’.
10. Please include information on the risks of publishing identifying photographs on the internet.

**Whānau and stakeholder PIS**

1. Please undertake a general revision to remove information that is only applicable to the koeke (eg statements advising participants will still be able to access normal health support services).
2. Please include information on the photos.
3. Please include the Māori data statement from the HDEC template.
4. Please amend ‘Māori health support’ to ‘Māori cultural support’.
5. Please remove the clause on the consent form about no identifying information being available in reports as the study will use photos of participants.
6. Please include a statement in the beginning to advise participants what their role is (eg “You are being given this sheet because you may be filling in an assessment with..”).
7. Please include information on the risks of publishing identifying photographs on the internet.
8. Please remove the statement on page 3 on results of screening tests.
9. Please adapt the sheet to include paeārahi as participants (or alternatively develop a standalone paeārahi information sheet).

**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 Mx Albany Lucas.

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| **9**   | **Ethics ref:**   | 2023 FULL 18897 |
|   | Title:  | A Phase 1 Open-label, Parallel-Group, Single-Dose Study to Evaluate the Pharmacokinetics and Safety of Obeldesivir in Participants With Normal Renal Function and Renal Impairment |
|   | Principal Investigator:  | Dr Nick Cross |
|   | Sponsor:  | Gilead Sciences, Inc |
|   | Clock Start Date:  | 12 October 2023 |

Dr Nick Cross, Ms Holly Thirlwall, Ms Julia O’Sullivan, Ms Kayla Malate and Ms Susanna Abigail 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 how the study would manage a participant not enrolled with a primary care provider. The Researcher stated to be eligible for the trial patient participants would need to be enrolled somewhere in order to be treated their chronic renal failure so did not anticipate it being an issue with this population. The Researcher stated it may be the case with healthy volunteer participants who will be encouraged to enrol with a GP as the study team cannot provide GP services.
2. The Committee queried if the Hepatitis / HIV testing would be done to exclude participants who test positive from the research. The Researcher stated a positive result would exclude participants in order to isolate the effect of renal failure on the excretion of the study drug.

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

1. Please correct the typo on page 7 (‘stem baths’).
2. Please make it clear that participants will need to avoid strenuous exercise or prolonged UV exposure for the duration of the study.
3. Please clarify the duration participants must avoid donating blood or plasma (it currently states ‘3 0’).

**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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| **10**   | **Ethics ref:**   | **2023 FULL 18730** |
|   | Title:  | Automated vital sign monitoring devices in acutely unwell general medical inpatients: an exploratory study |
|   | Principal Investigator:  | Dr Julie Cook |
|   | Sponsor:  | Fisher and Paykel Healthcare |
|   | Clock Start Date:  | 12 October 2023 |

Dr Louis Kirton 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 the exclusion of pregnant people. The Researcher stated the main part of the study is to compare how the recordings measure the early warning score differently between automated and manual recordings done by nurses. The Researcher stated the early warning score system has only been validated in people who are not pregnant and is not validated for the physiology of a pregnant person. The Researcher stated the findings from a general medical cohort could not be applied to a pregnant cohort and vice versa. The Researcher stated the study team chose to exclude pregnant people in the early stages of learning the technology and subsequent studies would include pregnant people.

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 an independent peer review for this protocol as the one supplied is for a different device.
2. The Committee noted the photo of the device has an image that appears like a bleeding heart and suggested this be revised to something more suitable.
3. The Committee requested evidence of Sponsor insurance.
4. The Committee suggested the study provide a koha to participants for their participation. The Researcher agreed to investigate whether this is feasible. The Committee suggested a thank you letter would be appropriate.

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

1. Please amend the statement that discusses the head being tapu to state the study team ‘will’ be respectful and remove the ‘aim to’.
2. Please include a statement advising that data collected up to the point of withdrawal will continue to be used. The Committee noted it is mentioned in the consent form but not the PIS.
3. Please include a clause in the consent form for participants to agree to coded data being sent overseas.
4. Please revise the clause in the consent form on taking photographs to remove reference to another person as one person cannot agree on behalf of another. Please include information regarding this clause in the PIS.
5. Please revise ‘Māori health support’ to ‘Māori cultural support’.
6. Please revise the statement on same-sex to state participants can choose who will apply the patch if they wish.
7. Please include a statement advising participants that if they find the device uncomfortable and remove it this will remove them from the trial.
8. Please include an option in the consent form for receiving a lay summary results.

**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 ACC-equivalent compensation available to all participants in the event of injury during the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
4. Please supply an independent peer review for the current version of the study protocol. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* *9.26*).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Cordelia Thomas and Ms Patricia Mitchell.

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| **11**  | **Ethics ref:**   | **2023 FULL 18795** |
|   | Title:  | A Randomized, Double-blind, Placebo-controlled, Multinational, Phase 3 Study of the Efficacy and Safety of Inhaled Treprostinil in Subjects with Progressive Pulmonary Fibrosis (TETON-PPF) |
|   | Principal Investigator:  | Dr Catherina Chang |
|   | Sponsor:  | United Therapeutics Corp. |
|   | Clock Start Date:  | 12 October 2023 |

This application was *withdrawn* by the Sponsor prior to the meeting discussion.

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| **12**   | **Ethics ref:**   | **2023 FULL 18782** |
|   | Title:  | A randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of PLN-74809 (bexotegrast) for the treatment of idiopathic pulmonary fibrosis (BEACON-IPF) |
|   | Principal Investigator:  | Dr Catherina Chang |
|   | Sponsor:  | Pliant Therapeutics Inc |
|   | Clock Start Date:  | 12 October 2023 |

Dr Rebekah Antsey and Ms Christine Tuffery 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 Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please revise the sentence on page 2 “There will be no penalty and you will not lose any benefits you will otherwise have” as the study will not have benefits for individual participants.
2. Please include a diagram on page 3 when discussing the different groups for clarity.
3. Please define EOS on page 4.
4. Please include some of the inclusion and exclusion criteria on page 4.
5. Please remove the question mark from the bulletpoint on contraception on page 5.
6. Please define ICF when it is first used or replace with ‘this form’.
7. Please clarify whether participants are required to remove clothing as part of the physical exam and whether they may have a support person present on page 6.
8. Please revise the information on pregnancy to be gender neutral (eg “If you can get pregnant”) on page 7. The Committee recommended adapting the neutral wording from the HDEC template.
9. Please specify whether counselling would be available in the result of a positive Hepatitis / HIV test and that they are notifiable diseases.
10. Please include the completion of mental health questionnaires in the risks section as these may be triggering.
11. Please revise the statements on page 10 and 18 on participant withdrawal to advise it may be done verbally and remove the requirement to withdraw in writing. Please revise the similar statement in the optional PIS.
12. Please include a statement advising whether a karakia will be available at the time of tissue destruction.
13. Please remove the sentence on page 11 “Almost all medications both old and new can cause severe reactions”.
14. Please remove the partner of a healthy participant having a miscarriage from the adverse effects as participants on this trial are required to be on birth control or abstinent.
15. Please remove all references to Scout Clinical services if these will not be used. If it will be used please include an explanation.
16. Please revise the statement that participants right to see their personal data may be suspended until the study is completed to state if they request access to which arm they are in it will withdraw them from the study.
17. Please include the Māori tissue statement from the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) in the main PIS and biobanking PIS.
18. Please remove the ‘yes / no’ tickboxes from the consent form unless they are truly optional (ie the participant can answer ‘no’ and still participate).
19. Please amend the statement on page 10 regarding leftover biological samples being used to include ‘with your permission’.
20. Please make it clear the end of treatment study visit is with participant consent.

**Decision**

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

1. 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 Mx Albany Lucas.

## General business

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

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| **Meeting date:** | 28 November 2023 |
| **Zoom details:** | To be determined |

 The following members tendered apologies for this meeting.

* Dr Patries Herst
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 6:10pm.