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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 11 February 2025 |
| **Zoom details:** | 965 0758 9841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 10:30 – 11:00am | 2024 FULL 21473 | A Study to Learn About PF06821497 in Men with Metastatic Castration-Resistant Prostate Cancer Who Have Not Tried Novel Hormonal Therapy or Chemotherapy for Metastatic Prostate Cancer | Dr. Alvin Tan | Dominic / Amy |
| 11:00-11:30am | 2024 FULL 20445 | RHD echo screening study in school vs school and community settings in year 7 and 8 students. | Dr Karen Bartholomew | Maree / Joan |
| 11:30-12:00pm | 2024 FULL 21781 | Tandem Freedom Feasibility Trial #2 | A/Prof Martin de Bock | Dianne / Patries |
| 12:00-12:30pm | 2024 FULL 21884 | A study evaluating multiple doses of ANB033 in people with coeliac disease | Dr Nah Yeon (Tina) Baik | Joan / Neta |
| 12:30-1:00pm |  | **BREAK (30 mins)** |  |  |
| 1:00 – 1:30pm | 2024 EXP 12014 | Fiji Heart Study | Dr Pritika Narayan | Maree / Patries |
| 1:30-2:00pm | 2024 EXP 21832 | Exploring the ocular therapeutic potential of UVC | Prof Jennifer Craig | Amy / Neta |
| 2:00-2:30pm | 2024 FULL 21211 | ID Magic | Associate Professor Emma Best | Dianne / Amy |
| 2:30 -3:30pm |  | **BREAK (60 mins)** |  |  |
| 3:30-4:00pm | 2024 FULL 21402 | Point-of-Care Testing: Improving access to timely and safe care for rural whānau | Professor Beverley Lawton | Dominic /Patries |
| 4:00-4:30pm | 2025 FULL 22171 | YO45758: A Study to Evaluate RO7673396 in Patients with Advanced Solid Tumours (with RAS Mutation/s) | Dr Anthony Rahman | Maree / Amy |
| 4:30 – 4:45pm | 2024 AM 11606 | UNIFAI | Associate Professor Richard Roxburgh | Full committee |
| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Devonie Waaka | Non-lay (Intervention studies) | 18/07/2016 | 18/07/2019 | Apologies |
| Dr Maree Kirk | Lay (Consumer/Community Perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Mr Dominic Fitchett | Lay (the Law) | 05/07/2019 | 05/07/2022 | Present |
| Ms Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Ascc. Prof Nicola Swain | Non-lay Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Apologies |
| Ms Dianne Glenn | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Neta Tomokino | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Present |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Present |

## Welcome

The Chair opened the meeting at 10am and welcomed Committee members, noting that apologies had been received from Dr Nicola Swain and Dr Devonie Waaka.   
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Patries Herst, and Ms Joan Pettit 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 10 December 2024 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2024 FULL 21473** |
|  | Title: | A Study to Learn About PF06821497 in Men with Metastatic Castration-Resistant Prostate Cancer Who Have Not Tried Novel Hormonal Therapy or Chemotherapy for Metastatic Prostate Cancer |
|  | Principal Investigator: | Dr Alvin Tan |
|  | Sponsor: | Pfizer Inc. |
|  | Clock Start Date: | 30 January 2025 |

Dr Alvin Tan, Chris Scholz, and Kathleen Durbin 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 that screenshots of e-diaries are not easy to review and requested the core questionnaires are submitted separately to screenshots of other information in future submissions.
2. The Committee noted the pregnant partner information sheet had not been reviewed. Please submit this via the amendment pathway if a participant’s partner becomes pregnant and the sheet is 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. In the Data Management Plan there are some inconsistencies with reference to samples. Section 10.2.2 states no tissue samples for optional research yet 12.2.2 and the protocol state retained research samples will be collected. Please update 10.2.2. Please specify in section 12.2.2. that the appendix is located in the protocol.
2. The Committee noted family members would be contacted as part of follow up but there was no process for this in the protocol or information sheet. Please update the protocol and information sheet.
3. Please confirm whether the participants will need to use data or Wi-Fi for the e-dairy. If so, will they be reimbursed for this cost? This information should also be in the PIS/CF.

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

1. Please amend the short title to be shorter eg remove the repetition of metastatic prostate cancer.
2. Please proofread for typos.
3. Please remove repetitious information to make this document shorter and more concise.
4. Page 7 please specify the city and country that tissue will be sent to.
5. Please state that karakia will not be available at disposal of tissue.
6. Please remove reference to teaspoons of blood, please use millilitres.
7. Please review the use of square brackets and if anything is missing.
8. Pages 25 and 26, with regards to contraception, please ensure it is clear what is required of the participant (eg use a condom and a highly effective method of contraception).
9. Remove the yes/no tick box for informing a GP, as this should be mandatory.
10. Please stick with a consistent name for the investigational product.
11. Please ensure it is made clear that participants can withdraw at any time, including from follow up.
12. On page 34 state that the ethics committee only reviews the ethical aspects of the study. It can be stated that Medsafe and/or SCOTT have reviewed the safety aspects of the interventional product.
13. Please add a table outlining when the investigational product needs to be taken with food.
14. Please provide an option to request a lay person summary of results on the consent form.

**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 (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a*)
4. Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7*).

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Dr Amy Henry.

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| **2** | **Ethics ref:** | **2024 FULL 20445** |
|  | Title: | A cluster randomised control trial comparing the effectiveness and cost effectiveness of school vs school and community-based settings in echo screening for undetected RHD for year 7 and 8 students. |
|  | Principal Investigator: | Dr Karen Bartholomew |
|  | Sponsor: | Health New Zealand, Te Whatu Ora |
|  | Clock Start Date: | 30 January 2025 |

Dr Karen Bartholomew, Prof Nigel Wilson, and Tracey Hale 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 questioned whether there would be an opportunity to meet face-to-face with parents to discuss the study. The Researcher advised they are planning to have some information sessions. This needs to be evident in the process requested.
2. The Committee raised concerns about privacy during the echo procedure. The Researcher explained that around ninety percent of children will have a splash echo which can be done without removing clothing. The rest will change into a gown to maintain privacy.
3. The Researcher clarified that all screeners are women.
4. The Researcher confirmed that parents will provide consent and participants will provide assent.
5. The Researcher confirmed the term cluster school won’t be used in any material outside of the research team.
6. The Committee suggested a video would be valuable. The Researcher advised they are developing one which they will submit as an amendment.
7. The Researcher confirmed the study has been registered with a WHO-approved clinical trials registry.

Summary of outstanding ethical issues

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

1. The Committee requested that documentation clearly outlining the engagement process is provided. The Committee noted that it is very important that both Māori and Pasifika voices are captured.
2. The Committee requested that youth voice and agency is outlined in codesign and promotion.
3. The Committee requested further justification under the NEAC standards for a waiver of consent to access contact details for parents.
4. The Committee noted that there is a lot of information about the heart in the school curriculum that could be linked with the study information.
5. The Committee requested the Researcher provide details about the process of obtaining informed consent from the young people and parent/guardians; which comes first? What will happen if a child wants to participate but the parent does not consent? Who will be approached first?

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

1. Please outline what is involved in the echo procedure, in terms of touching their chest and that they may need to change into a gown.
2. Please amplify the Purpose section of the PIS to highlight that Rheumatic Heart Disease develops from Strep throat, which is prevalent in the community. It can be asymptomatic for years while it damages the heart, potentially leading to serious heart disease, disability, and death.
3. There should be an option to consent for where the echo procedure is carried out.
4. It should be made clear that without joining this study, this type of screening is not available as standard practice.
5. Remove the option for notifying the GP, as this is a requirement.
6. Please clarify that it is health research staff that will have access to their medical records.
7. Please clarify what information the school will have access to and the rationale
8. Please outline who will provide follow up care and for how long and who covers this cost.
9. Please add page numbers, header, and footer, including version number.
10. Please clarify what happens to the audio recording after transcription.
11. The parental consent form needs a title, also ensure font size and margins are consistent and easy to read.
12. Please clarify parental contact in engagement process for those with no internet access.

**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 provide further justification to support a waiver of consent to access contact details (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.47*)
4. Please supply documentation outlining the engagement process.

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

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| **3** | **Ethics ref:** | **2024 FULL 21781** |
|  | Title: | Tandem Freedom Feasibility Trial #2 |
|  | Principal Investigator: | A/Prof Martin de Bock |
|  | Sponsor: | Tandem Diabetes Care, Inc. |
|  | Clock Start Date: | 30 January 2025 |

A/Prof Martin de Bock, Dr Jordan Pinsker and Dr Ravid Katchalski 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 the study will need to be registered with a WHO-approved clinical trials registry.
2. Please consider covering costs, such as for meals, for a support person to attend with a disabled participant.
3. The Committee requested confirmation that the insurance certificate is valid for New Zealand and requested a certificate that states the amount in New Zealand dollars with New Zealand as a specified territory.

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

1. Please undertake a revision of technical terms and ensure participants understand the technical terms, either in the sheet or verbally during the consenting process.
2. Please ensure that translation services are offered if required and include a statement for this at the beginning of the sheet.
3. Please check for and correct any typos.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please supply an insurance certificate confirming ACC-equivalent compensation is available for participants in New Zealand (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Dianne Glenn and Dr Patries Herst.

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| **4** | **Ethics ref:** | **2024 FULL 21884** |
|  | Title: | A Phase 1, Randomized, Double-blind, Placebo-controlled Study of the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single and Multiple Doses of ANB033 in Adult Participants |
|  | Principal Investigator: | Dr Nah Yeon (Tina) Baik |
|  | Sponsor: | Anaptys Bio |
|  | Clock Start Date: | 30 January 2025 |

Dr Nah Yeon (Tina) Baik, Stefanie Unger, Heather McWhorter, Alicia Contreras, and Cheryl Glover, 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 that there was an advertisement mentioned but not attached. Advertisements require approval before use. The Researcher advised they will submit as an amendment.
2. The Committee appreciated the option to have karakia at the time of sample collection.
3. The researchers advised that this study (1b) won’t commence until 1a is completed and results have been submitted to the Committee via amendment.

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 protocol and PIS/CF were inconsistent about whether a full physical exam including genitals would be carried out, please make these consistent.
2. There are inconsistencies between the protocol (p. 52) and PIS (p.9) around whether alcohol consumption excludes participation or not. Please reconcile.

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

1. Please note that tests may identify something that the participant may not be expecting and that they would be notified of this.
2. In the benefits section please note any tests that the participant may have in the study that they would otherwise not have access to.
3. Page 22 please update details for who participants can contact for study questions.
4. Please remove the statement around the sponsor paying the research sites, as this is not relevant to participants.
5. Please update the reimbursement details on page 16 once the sponsor has confirmed arrangements.
6. Please note that karakia won’t be available at the time of sample disposal.
7. Please check for repetition and remove where possible for readability.
8. In side effects there is a typo, please change ingestion to indigestion.
9. Please revise the side effects to remove those that apply to intravenous injection, as this will be subcutaneous.
10. There needs to be a separate PIS for optional future research for blood biomarkers.

**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 Joan Pettit and Ms Neta Tomokino.

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| **5** | **Ethics ref:** | **2024 EXP 12014** |
|  | Title: | Genetics of premature coronary artery disease among Peoples of Fiji living in Aotearoa |
|  | Principal Investigator: | Dr Pritika Narayan |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 30 January 2025 |

Dr Pritika Narayan 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 whether non-Māori participants could opt out of whole genome sequencing. The researcher advised this is a critical component of the study, so would normally exclude someone from participating, but had made an exception for Māori, for cultural reasons.
2. The Researcher clarified that the participants have the option to have the advisory group present for the interview, to provide explanations in their own language.

Summary of outstanding ethical issues

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

1. The Committee asked for the support process for participants to be outlined in more detail in the protocol.
2. Please highlight that the advisory group are all Pasifika.
3. Please be mindful of the potential for stigmatising the participant population, when publishing results, particularly in relation to questions about familial relationships with partners and traditional practices involving the care or family placement of children.
4. Please provide a researcher safety protocol for in home visits.
5. Please outline duty of care procedures in place for participants’ who are all completing the presurvey questionnaire on premature coronary artery family history record of their family members.
6. The website for the study will need to be submitted as an amendment once the study is approved.

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

1. Please state that if any genetic testing picks up something that requires further investigation, that the participants GP will be notified, to refer for genetic counselling.
2. Please clarify that contacting next of kin would be in the situation where the participant had passed away.
3. Please provide some more information about what happens to the participants data, remembering that the participant doesn’t see the DMP.
4. Please remove reference to time when talking about Koha, as time is taxable.
5. Please provide a link to your website which outlines contact details for support post test results.
6. Please highlight the risk of genetic testing having unexpected results, such as genetic relationships may not be as anticipated.
7. Please specify that questions regarding the participants partner will only be asked if the partner is present.
8. Please note if the CRO may access identifiable information for audit purposes.
9. Please change reference of teaspoons of blood to millilitres.

**Decision**

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

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

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

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| **6** | **Ethics ref:** | **2024 EXP 21832** |
|  | Title: | An in-vivo Phase-I randomised controlled safety trial of ultraviolet C (UVC) light application to the healthy ocular surface |
|  | Principal Investigator: | Prof Jennifer Craig |
|  | Sponsor: | Photon Therapeutics Ltd |
|  | Clock Start Date: | 30 January 2025 |

Prof Jennifer Craig 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 what was involved in phone screening to ensure there wasn’t detailed health information being discussed prior to consenting.

**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 an insurance certificate specifying New Zealand as a covered territory will need to be provided to ensure ACC equivalent insurance is available to participants.
2. The Committee requested removal of the point in the protocol that states participants may be excluded if the Researcher feels it is in their best interests of the patients, as this could be perceived as cherry-picking participants given these are healthy volunteers.
3. The Committee reminded the Researcher that the trial will need to be registered in a WHO approved clinical trial registry.

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

1. Please remove reference to lab tests if these are not being carried out.
2. Please outline potential side effects and the process to address these should they occur.
3. Please clarify that the participant can withdraw at any time, but their data can only be withdrawn within the first two weeks, as analysis will have started after this point.
4. Please change reference to ‘patient’ to ‘participant’.
5. Please note that if participants are required to attend extra visits that they will be compensated for this.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
4. Please supply an insurance certificate confirming ACC-equivalent compensation is available for participants in New Zealand (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Amy Henry and Ms Neta Tomokino.

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| **7** | **Ethics ref:** | **2024 FULL 21211** |
|  | Title: | Individualised Dose optiMisAtion of Ganciclovir in Immunocompromised Children (ID-MAGIC) Trial |
|  | Principal Investigator: | Associate Professor Emma Best |
|  | Sponsor: | Murdoch Children's Research Institute |
|  | Clock Start Date: | 30 January 2025 |

Associate Professor Emma Best and Sharelle Joseland 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. It was clarified that New Zealand ethnicity data would be collected but not publicly reported due to the small group size.
2. The Committee clarified that the Researcher is not the participants primary care provider.

**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 that it should be noted when referring to conflicts of interests in the application form that the intention is to make the app freely available and isn’t for commercial gain.
2. The Committee requested modification to the recruitment outline in the protocol on page 22 to clarify that discussion will be had with clinicians rather than using the electronic medical record.
3. The parent/guardian CF would need to be used in conjunction with an assent form for children under 16 for paired consent-assent. After discussion, given these will be severely unwell children, the Committee acknowledged that assessing capacity for those of older ages may not yield anyone able to provide their own informed consent without paired-parental consent, but assent for all children participants should in some way be obtained and recorded.

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

1. Please correct the statement that no tissue is collected, as blood will be taken, and this is considered tissue.
2. Please make a statement as to whether Karakia is available at disposal or not.
3. Please make the wording specific for a New Zealand audience. Currently it is more relevant for an Australian audience. For example, the ACC statement, what will happen to my information, etc These examples can be found in the [HDEC template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates)
4. Please elaborate the acronym MRFF.
5. Please state that translators can be provided if required.
6. Please check for and correct typos.
7. Please make a statement about how this might alter the dose given, also reference that children are often under-treated.
8. Please rephrase the wording on page 2, currently it is biased towards the app, which could deter people from the control arm.
9. Please remove the statement about how long the form takes to read.
10. Please add to the risks the possibility of toxicity from an increased dose.
11. The New Zealand principal investigator name needs to be on page 1.

**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 Dianne Glenn and Dr Amy Henry.

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| **8** | **Ethics ref:** | **2024 FULL 21402** |
|  | Title: | Point-of-Care Testing: Improving access to timely and safe care for rural whānau |
|  | Principal Investigator: | Professor Beverley Lawton |
|  | Sponsor: | Victoria University of Wellington |
|  | Clock Start Date: | 30 January 2025 |

Professor Beverley Lawton, Dr E Jane MacDonald, Jo-Ann Stanton, Kendall, and Charles Lambert 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 sought clarity about how potential participants would be approached when presenting for care. The Researchers advised that they would have posters and flyers in the waiting room and there would be a short video to watch prior to consenting. The Committee advised these will need to be submitted for approval as an amendment when finalised later.
2. The Committee queried is it only people that consent to be on the study that get this point of care testing or does everyone regardless. The Researchers responded that they want to offer it to everyone regardless of who want to be in the study, but if everyone wanted the point of care but not be in the study, this would need to be reviewed. The current plan is that only those who consent to participation will receive it, and their standard of care will not be impacted.
3. The Committee questioned why identifiable data will be stored in Wellington and not at a site-level. The Researchers advised that it is for safety reasons so that they can follow up with participants to ensure they receive appropriate follow up.
4. The Committee raised the issue of under 16-year-olds having an STI test and whether they would want their parents to know about it. The Researchers indicated that this would be left to clinical discretion on a case-by-case basis and whether they will be tested for this in the context of the small clinics.
5. The Committee clarified with the Researcher that if an error occurs with a test, this can be re-tested with the extra sample and that the Researchers were confident the internal checks and balances can identify what the issue was.
6. The Committee commended the social-care approach woven into the design of the study.

**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 the noted that the trial needs to be registered with a WHO approved clinical trials registry.
2. The Data Management Plan needs to cover the storage of voice recordings as this is identifiable data.
3. The Committee noted there is no information about the interview part of the study; an interview outline, consent forms and any flyers/posters/community notices will need to be submitted before they can be used.
4. The Committee stated generally it could grant a waiver if the following conditions are met and detailed in the protocol and section 4 of the data management plan:
   1. It is not possible to get consent due to the age or quantity of the samples, seeking consent would impact on the scientific validity of the study (i.e. for epidemiological studies), or the act of seeking consent could cause undue anxiety or distress to those whose consent was being sought., and;
   2. No participant or their family would be disadvantaged by the inclusion of their sample, and;
   3. The public interest in the study outweighs the individual’s right to privacy.
5. The Committee noted that HDEC or CRO may need to access data for audit purposes and should be clarified in the data management plan.
6. Statements about participant withdrawal are inconsistent between documents. Please clarify these, and the Committee noted that participants should retain the right to withdraw already collected data from analysis, noting that the results will still remain as part of their clinical record.

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

1. Please provide two separate assent forms, one for younger children and another for older children which provides more detailed information. More mature children will be able to comprehend more information about the study.

PISCFs:

1. Will the patient have an opportunity to speak to friends, whānau etc prior to providing informed consent, given the time constraints of study enrolment? If not, then this should be deleted from the PIS/CF.
2. State how much time the study appointment is likely to take at the start of the PIS/CF, including the informed consent discussion and PCT (noting that a standard appointment is 10 minutes). State also whether the participant waits onsite for the result of the PCT, or whether they will be contacted about the result by telephone.
3. State that the point of care testing machines are commercially available, and that they have the same accuracy as the laboratory tests. Participants may not know what 'validated' means.
4. State the alternatives to participation, i.e. whether patients can request point of care testing but not be enrolled in the study. If this is not possible, a rationale should be provided.
5. When explaining who will have access to identifiable and de-identified information, please distinguish between researchers at the local site and those based off-site. Again, it is unclear why identifiable study data (other than the key linking NHI and participant ID codes) are being stored in Wellington rather than at the local sites.
6. Please amend the withdrawal of data section to permit the withdrawal of data up until the point it is analysed.
7. Please delete the following sentence, which should be included in the interview PISCF (as discussed at point 9 above): 'For interviewees, the transcript of the interviews will be made available to them before they are analysed so that the interviewee can amend anything that they are not happy with'.

Assent Form:

1. Please explain in simple terms what illnesses are being tested for.
2. The assent form includes throat and nose swabs only - if minors may receive point of care testing for sexually transmitted infections, please address these tests also.
3. Make it clear the young person can decline to take part even if the parent / guardian has given consent.
4. State what happens with the young person's data.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
4. Please update the data management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Dr Patries Herst.

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| **9** | **Ethics ref:** | **2025 FULL 22171** |
|  | Title: | A Phase I Dose Escalation and Expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Preliminary Clinical Activity of RO7673396 as a Single Agent and in Combination with Other Anticancer Therapies in Patients with Advanced Solid Tumors Harboring RAS Mutation(s) |
|  | Principal Investigator: | Dr Anthony Rahman |
|  | Sponsor: | Roche Products (New Zealand) Ltd |
|  | Clock Start Date: | 30 January 2025 |

Dr Anthony Rahman, Lucy Druzianic, Kayla Malate, Julia O’Sullivan, Meulasi Sandanayaka, Zarah Hossain, Erum Hafeez, and Hamish 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 consenting process as it is a complicated trial. The Researchers advised that this will be a two-step process with multiple conversations. It will also be made clear to potential participants that the genetic testing may discover unintended results, such as the BRCA gene, which could have implications for their wider family. The Committee confirmed with the Researcher that the approach to potential participants is more reasonable than what is documented and will involve significant care in the approach to potential participants and providing them support for this.
2. The Researcher clarified that the participants will only be given information for the part of the study that they will be participating in.

**Summary of outstanding ethical issues**

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

1. The Committee requested that the first time the sponsor is referred to, that the name of the sponsor is listed at the beginning of the protocol and other documentation if able.
2. The Committee requested page 118 of the protocol is updated to remove mention of the device as this is not applicable for this study or otherwise clarified through an appendix or cover letter what is relevant to New Zealand.
3. The Committee noted that the protocol details number of participants in stages, but this does not match the total of 345 worldwide plus 15 in New Zealand detailed in the application form, and just sought clarity on the intended total of participants.

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

1. Please change ‘institution address’ to ‘site address’.
2. Please state the NZ site.
3. On all the PISCF please specify the location that tissue will be sent to or stored in (pg 18).
4. Please state specifically what the reimbursement would be (travel and stay on site), it is currently vague and reads as if they need to negotiate for what is ‘fair’.
5. Please note that the investigational product has been reviewed by Medsafe and SCOTT.
6. Where it is not optional, please change ‘may’ to ‘will’.
7. Please note that if genetic testing identifies anything of concern, the participant will be referred for genetic counselling.
8. Please review and replace any American-specific jargon with New Zealand equivalent.

**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 Amy Henry.

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| **10** | **Ethics ref:** | **2024 AM 11606** |
|  | Title: | Friedreich Ataxia Global Clinical Consortium UNIFIED Natural History Study |
|  | Principal Investigator: | Associate Professor Richard Roxburgh |
|  | Sponsor: | Friedreich's Ataxia Research Alliance (FARA) |
|  | Clock Start Date: | 30 January 2025 |

Ms Juno Barnett Collins and Sarah were present via videoconference for discussion of this amendment.

**Potential conflicts of interest**

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

No potential conflicts of interest related to this amendment 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 sought clarity around the involvement of caregivers. The Researcher advised that they will not be going ahead with the caregiver survey.

**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 upload an assent form.
2. Due to the length of the study, the protocol should cover consenting of participants who turn 16 during the study.
3. Please remove mention of ‘healthy controls’ from the protocol as this is not applicable.

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

1. Please remove reference to genetic testing and blood samples.

**Decision**

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

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

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

**General business**

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

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| **Meeting date:** | 11 March 2025 |
| **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. **Other business**

The meeting closed at 4.45pm.