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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 22 November 2022 |
| **Zoom details:** | 965 0758 9841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 12.00-12.30pm | 2022 FULL 13824 | Home Blood Pressure Monitor for Optimising Cardiac Medications Study | Dr Tze Vun Liew | Mrs Helen Walker and Mrs Patricia Mitchell |
| 12.30-1.00pm | 2022 FULL 13309 | BURST -AF | Dr Matthew Daly | Ms Sandy Gill and Dr Patries Herst |
| 1.00-1.30pm | 2022 FULL 13799 | KEYVIBE-010 - Adjuvant MK-7684A vs Pembrolizumab for High-risk Melanoma | Dr Richard North | Ms Jessie Lenagh-Glue and Mx Albany Lucas |
| 1.30-2.00pm | 2022 FULL 13665 | VXA-NVV-202: A Study Investigating Bivalent GI.1/ GII.4 Oral Vaccine in Healthy Adults | Doctor Paul Hamilton | Dr Cordelia Thomas and Ms Julie Jones |
|  |  | Break (20) |  |  |
| 2.20-2.50pm | 2022 FULL 13700 | A Phase 3, 24-Week, Randomized, Efficacy and Safety Study with Open-label Extension of BLU-5937 in Adult Participants with Refractory or Unexplained Chronic Cough | Dr Michael Epton | Ms Sandy Gill and Mrs Patricia Mitchell |
| 2.50-3.20pm | 2022 FULL 12307 | PNOC022 | Dr Karen Tsui | Mrs Helen Walker and Ms Julie Jones |
| 3.20-3.50pm | 2022 FULL 13039 | Early Detection of KC using AI: Prospective Clinical Validation | Dr Rasha Altaie | Ms Jessie Lenagh-Glue and Mx Albany Lucas |
|  |  | Break (10) |  |  |
| 4.00-4.30pm | 2022 FULL 13676 | PB115-SAD-101: A study to evaluate PRX-115 in participants with elevated uric acid levels | Dr Alex Cole | Dr Cordelia Thomas and Dr Patries Herst |
| 4.30-5.00pm | 2022 FULL 13788 | VLS-01-201: A Study to Assess VLS-01 in Participants with Major Depressive Disorder | Dr. Cameron Lacey | Mrs Helen Walker and Mx Albany Lucas |
| 5.00-5.30pm | 2022 FULL 13791 | CM001001: A Study to Evaluate ABCI in Healthy Participants and Participants with Cystic Fibrosis | Dr Cory Sellwood | Ms Jessie Lenagh-Glue and Ms Julie Jones |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (Consumer/Community perspectives) (Chair) | 22/05/2018 | 22/05/2020 | 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 | Present |
| Dr Cordelia Thomas | Lay (the Law) | 20/05/2017 | 20/05/2020 | Present |
| Ms Patricia Mitchell | Non-lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Ms Julie Jones | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2022 | 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 |

## Welcome

The Chair opened the meeting at 11.30am and welcomed Committee members.

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 25 October 2022 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2022 FULL 13824** |
|  | Title: | Use of home blood pressure monitors for remote optimisation of cardiac medications (Home MED Study) |
|  | Principal Investigator: | Dr Tze Vun Liew |
|  | Sponsor: | Waikato Medical Research Foundation |
|  | Clock Start Date: | 10 November 2022 |

Dr Tze Vun Liew was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the data will be stored in the Cardiology Clinical Trails server which will be a password access only and with two factor authentication. The Researcher estimated that the data will be stored for a minimum of 10 years.
2. The Committee clarified that it is unlikely that the database from this study will be used for another trial.
3. The Committee queried whether the participants would be informed about what happens after the study and if there will be a follow up in 6 months’ time to check if the titration of their prescribed medication is still accurate. The Researcher replied that once they are discharged from the study, they are discharged back to their general practitioner (GP). The Researcher added that the public hospital is not funded to keep monitoring patients permanently and acknowledged the issues with lack of GP access but no ability for the study specialists to address this at this time.
4. The Committee clarified that Te Whatu Ora Waikato does not send digital blood test orders and that these would be provided physically to participants. This would be done according to standard of care.

**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 for the Waikato Medical Research Foundation to be identified as the sponsor in the data management plan (DMP).
2. The Committee noted there are sections of the DMP that need to be finalised, such as the site names.
3. The Committee queried whether there is a risk of participants not being able to use the monitors correctly. The Researcher replied that there will be a nurse that visits patients and helps them use the monitor if required. The Committee requested this be included in the participant information sheet.

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

1. Please ensure that there is clarity of the terms used to describe study nurses/heart nurses and other nursing staff and please clarify between these and regular clinical staff for the avoidance of confusion and improved consistency.
2. Please ensure that the Prezzy card Koha is specifically noted in the PIS.
3. Please move the section concerning signing the consent form and sending it back to the end of the form to improve the flow of the forms.
4. There is no reference to the aim of the study that was mentioned in the application form about reducing the expense and inconvenience of traveling to appointments and this intervention being home based. The Committee suggested clarifying the benefit of the study to include this and outlining the aim more for participants. These benefits should also be listed in the “benefits of the study” section.
5. Please outline where and for how long data will be stored and who will have access to it and in what form the data will be stored.
6. Please outline what is expected of the participants in usage of the monitor.
7. Please review for consistency when using terminology, i.e., just using ‘monitor’, instead of using both ‘monitor’ and ‘machine’.
8. Please utilize the cultural support statement as provided in the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v3.0july2022.doc).
9. Please move the statement “If you are happy to take part in the study, please sign and send back the closed consent form” and include it at the end of the form instead.
10. Please change the wording from “if you are happy to participate” to “if you want to/decide to participate”.
11. Please ensure that the language around “usual doctor” is consistent and where applicable change this to the GP for clarity.
12. Please amend the statement on page 4 … “your usual doctor will be informed if there are unexpected result” to include “with your consent” as participants need to consent to information being shared with their GP.
13. Please clarify how long participants will have the monitors for, and what would happen if they were damaged.
14. Please mention that at a particular stage after the trial, participants will need to see their GP for a blood pressure check-up.
15. Please underline all headings in all sections, specifically the data section.

**Decision**

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

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

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| **2** | **Ethics ref:** | **2022 FULL 13309** |
|  | Title: | Argá Medtech Coherent Sine Burst (CSE) Electroporation System Pilot Study in Patients with Atrial Fibrillation |
|  | Principal Investigator: | Dr Matthew Daly |
|  | Sponsor: | Arga Medtech SA |
|  | Clock Start Date: | 22nd November 2022 |

Dr Matthew Daly 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 about what the chances of the tissue behind the heart getting damaged. The Researcher voiced that the goal of the treatment is to deliver a lesion that is the full thickness of the atrium. The Researcher added that the limiting factor of ablation is that there is usually something directly behind the left atrium when doing treatment, like the oesophagus and nerves. This device respects tissue boundaries and does not cross the pericardium.

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 considering potential whakamā as participants can feel embarrassed when they get to a point of ablation that they are not able to do the things they were able to before, which can be debilitating.
2. The Committee suggested more thoroughly referencing and acknowledging the importance of Data Sovereignty for Māori and the importance of data as a taonga.
3. The Committee strongly suggested registering the device with Medsafe in the WAND registry. The Researcher noted that the registration was taking some time but could be investigated further.
4. The Committee requested an independent peer review be provided, utilizing the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2021.docx).

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

1. Please provide a lay title.
2. Please include a paragraph of past experimentation using this device as well as some inclusion of how it has been used as cancer treatment.
3. Please include the number out of 100 patients will experience adverse effects/complication rates beside the percentage rates.
4. Please include information about how ablation surgery is done and a diagram that shows how a normal heart works in comparison to how a heart with arrhythmias works.
5. Please amend ‘Māori health support’ to ‘Māori cultural support.’
6. Please ensure, that the statement about contacting general practitioner (GP) is amended to include the phrase “with your consent”.
7. Please amend duplication of paragraphs under the heading “what my participation involves.”
8. Please amend for grammar and spelling errors.
9. Please amend spelling of “ablation” in the first paragraph, under the heading ‘Discharge’.
10. Please clarify what would be the steps taken if something abnormal occurred during the trail specifically where there is reference to anything found whilst the participant is under sedation.
11. Please review and amend on page 5, clarify which doctor patients will be visiting on day seven.
12. Please also clarify on page 5 what the ‘phrenetic nerve’ is.
13. Please amend grammar under the heading “Medications”.
14. Please clarify who will be present during the procedure on behalf of the sponsor if required and what these people will be doing.
15. Please ensure the consent form includes consent for sponsor representative being there for the procedure.
16. Please clarify the exact process of the physical exam or if the participant will be required to remove clothing. Please also state whether the participant may have a support person present 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 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*).
3. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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

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| **3** | **Ethics ref:** | **2022 FULL 13799** |
|  | Title: | KEYVIBE-010 - Phase 3, Randomized, Double-blind, Active-Comparator-Controlled Clinical Study of Adjuvant MK-7684A  (Vibostolimab with Pembrolizumab) Versus Adjuvant Pembrolizumab in Participants with High-risk Stage II-IV Melanoma |
|  | Principal Investigator: | Dr Richard North |
|  | Sponsor: | Merck Sharp & Dohme (New Zealand) Limited |
|  | Clock Start Date: | 10 November 2022 |

Dr Richard North and Charlie Stratman were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried the recruitment process and how coercion is avoided. The   
   Researchers explained that potential participants will have the opportunity to discuss the study with the research nurse following a cool-down period after the initial study recommendation from their oncologist.
2. The Committee queried the circumstances under which samples can be returned to participants. The Researchers responded that while in most cases the Sponsor can arrange the return of tissues there may be circumstances where this is not possible. These limitations are made clear to participants.
3. The Committee confirmed that the participants withdrawing from the study are prompted to withdraw their consent for future unspecified research as the consent for these is separate.

Summary of outstanding ethical issues

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

1. The Committee requested the following changes to the study protocol:
   1. Please update the eResearch Technology Inc. privacy statement to reflect the level of information that is being shared with the Sponsor. Current level of detail cannot be approved by the Committee.
   2. Please update to include an end date for the study as currently the participant follow-up is indefinite.

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

1. Please use only the third option for the Māori cultural statement, amending appropriately for those sites where a karakia can or cannot take place.
2. Please ensure that the study documentation provided, including the potential side-effects, is complete.
3. Please update language to be gender neutral where possible (e.g., “if you are able to become pregnant”).
4. Please update interpreter statement from “will be provided” to “we will do our best to provide one”.
5. Please elaborate what the physical examination involves and if items of clothing are removed.
6. Please remove “you will not lose any benefits if you leave the trial” as the benefit from the trial is the access to the treatment which will no longer be available once a participant has left the trial.
7. Please remove the in the case if injury section as this is not applicable to this study.
8. Please remove “most” from “most new treatments require clinical trial” as all new treatments require trial.
9. Please remove “it takes many people all around the world to advance medical science” as it could be considered coercive.
10. Please outline what photographs will be taken as well as how they will be treated and stored to ensure they are unidentifiable.
11. Please add that any device provided for the duration of the study will need to be returned.

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Jessie Lenagh-Glue and Mx Albany Lucas.

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| **4** | **Ethics ref:** | **2022 FULL 13665** |
|  | Title: | A phase 2, multicenter, randomized, double-blind, placebo-controlled, single dose, dose-ranging study to determine the safety and immunogenicity of bivalent GI.1 and GII.4 vaccine administered orally to healthy volunteers aged ≥ 18 years and ≤ 80 years old. |
|  | Principal Investigator: | Dr Paul Hamilton |
|  | Sponsor: | Novotech (New Zealand) Limited |
|  | Clock Start Date: | 10 November 2022 |

Courtney Rowse, Dr Paul Hamilton, Julia O’Sullivan, and Dr Jane Kerr were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that there is sufficient evidence to support not having a sentinel dose in the second phase of research that this study is a part of.
2. The Committee confirmed with the Researchers that the insurance limit is appropriate for the risk of the study.
3. The Committee clarified that participants will be made aware of the capsule sizes and how many tablets they will be taking. The Researchers further explained that participants will have a swallowing assessment prior to study commencement.
4. The Committee queried how the pills are administered. The Researchers explained that these are administered by the medical team.

Summary of outstanding ethical issues

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

1. Please further define norovirus and its effects as soon as introduced (i.e., “a virus that causes nauseas and diarrhoea”).
2. Please standardise use of eliciting / causing for increased clarity.
3. Please standardise and clarify the units of time, where possible using years and months.
4. Please update the study termination section to be in line with legal limitations as the Sponsor is not able to terminate the study any time for any reason; specifically not for commercial reasons.
5. Please amend page 4 to state that it is a type of anti-body that “fights off infection” in place of “of”.
6. Please update the wording for medication restriction regarding the maximal duration of the abstention from anti-biotics and the resulting process if this cannot be maintained.
7. Please standardise the usage of “usual doctor” and “general practitioner” for clarity.
8. Please update the wording regarding future use of participant data to reflect that only the information collected as part of the sub study will be accessible for further research.
9. Please add that participants have a right to access and correct information about themselves.
10. Please clarify that the study samples will be destroyed following the study if the participant does not consent to future research.
11. Please add that information collected will be sent overseas.
12. Please clarify and standardise the total number of participants across the documents.
13. Please use wording in addition to percentages (i.e., 1 in 100 people).
14. Please update wording to be gender natural where possible (i.e., “people who can become pregnant”).

**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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| **5** | **Ethics ref:** | **2022 FULL 13700** |
|  | Title: | A Phase 3, 24-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Arm Efficacy and Safety Study with Open-label  Extension of BLU-5937 in Adult Participants with Refractory Chronic Cough Including Unexplained Chronic Cough (CALM-2). |
|  | Principal Investigator: | Dr Michael Epton |
|  | Sponsor: | IQVIA RDS Pty Limited |
|  | Clock Start Date: | 10 November 2022 |

Dr Michael Epton and Malina Storer were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified with the Researchers that their insurance expires before the study is due to complete. Researchers identified that renewal is annual.
2. The Committee clarified that participant mental health support referral would be managed on a case-by-case basis with the sponsor’s financial support and that mental health support for participants will be provided immediately if needed based on answers from the quality-of-life questionnaire.
3. The Committee clarified that both size pills will be provided for both the study drug and the placebo pill. This randomisation is to ensure double blinded protocol is followed.
4. The Committee clarified how many sites would be included in the trial and where these sites would be located.

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 reasoning for exclusion of people living with Hepatitis B, Hepatitis C and HIV.
2. The Committee suggested adding whakamā (embarrassment, shame) as a cultural issue for future applications.
3. The Committee requested reasoning for exclusion of information relating to changes in the eye as potential issues were outlined in animal studies. Please cite relevant studies and gain clarity from the sponsor about the risks related to this. The Committee requested clarification as well as to how any issues that developed with the eyes may be supported and responded to.

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

Main PIS/CF

1. Please provide the investigators contact details.
2. Please provide a safety plan in relation to mental health support for participants if emotional distress is identified and how this will be followed up and the timeline for this, especially given the high burden currently placed on the mental healthcare system in Aotearoa.
3. Please provide cultural support contacts to participants and note that mention of “Māori health support” should be amended to “Māori cultural support”.
4. Please remove the paragraph about the importance of individuals contributing in clinical research as it could read as coercive to participants.
5. Please amend the comments relating to patient payment of further medication as a result of side effects or symptoms from the research as this is incorrect.
6. Please remove tick-boxes where it is relating to general practitioner notification as this is not an optional part of the study.
7. Please clarify what RCC refers to.
8. Please amend statement following “Can I stop receiving the study drug” to match title question as currently the response appears to be related to leaving the study.
9. Please amend contradicting answers relating to data usage if participants withdraw from the study.
10. Please amend the sentence stating “ownership rights” as it appears to be an incorrectly placed title.
11. Please add a statement addressing that participant will need to sign a new consent form for participation in future unspecified research.
12. Please review for typos and repeated information throughout.

Future Unspecified Research (FUR) PIS/CF:

1. Please include a Māori cultural statement.
2. Please amend mention of the purpose of “this research project” where referring to FUR as this is unspecified and this should be noted instead as “any future unspecified research” instead.
3. Please review for formatting issues to improve readability.
4. Please remove the statement concerning personal data where the “data protection law” is mentioned as this is not true for Aotearoa. This should be amended with reference to the Privacy Act

**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 Sandy Gill and Mrs Patricia Mitchell.

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| **6** | **Ethics ref:** | **2022 FULL 12307** |
|  | Title: | PNOC022: A Combination Therapy Trial using an Adaptive Platform Design for Children and Young Adults with Diffuse Midline  Gliomas (DMGs) including Diffuse Intrinsic Pontine Gliomas (DIPGs) at Initial Diagnosis, Post-Radiation Therapy and at Time of Progression |
|  | Principal Investigator: | Dr Karen Tsui |
|  | Sponsor: | Australia and New Zealand Children's Haematology/Oncology Group (ANZCHOG) |
|  | Clock Start Date: | 10 November 2022 |

Dr Karen Tsui and Sonia Alix were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that participants would primarily be under 16 as diagnosis often occurs in paediatrics, however, if there are older individuals who may benefit from the study, they can be accepted up to the age of 39.
2. The Committee clarified that a separate pre-screening form was used due to extensive pre-screening testing. The Researcher confirmed that this is carried out to allow a quick induction into the study as time constraints are valid for participants.
3. The Committee clarified that future sites and study drugs would be identified to the Committee through amendments as they became apparent.
4. The Committee clarified that in the unlikely event of the need for reconsent for those aged 16 and over the regular consent form would be used.

Summary of outstanding ethical issues

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

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

1. Please provide lay title.
2. Please clarify use of different numbered groups in relation to individual participation. The Committee suggested the following statement, “Groups 1,3 and 5 may be added later if new drugs become available.”
3. Please clarify the differences between ‘groups’ and ‘cohorts’. The Committee recommended a diagram to indicate their different positions within the study.
4. Please contextualise “reidentification” comment. The Committee suggested the following state: “If you have concerns about your privacy during or after the study, please contact us.”
5. Please change the comment “All research done in New Zealand is reviewed by the ethics Committee…’ as not all health research is reviewed by an ethics committee. The Committee suggested utilizing the phrasing as in the [PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v3.0july2022.doc).
6. Please insert the consenting statements and other key information needed with the signatures on consenting information. The Committee recommended using the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v3.0july2022.doc) to identify key information needed.
7. Please delete crossed out text in relation to genetic testing.
8. Please review to make the text more lay-friendly.

**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 Ms Julie Jones

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| **7** | **Ethics ref:** | **2022 FULL 13039** |
|  | Title: | Early Detection of Keratoconus (KC) using Artificial Intelligence (AI): Prospective Clinical Validation of the AI Model |
|  | Principal Investigator: | Dr Rasha Altaie |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 November 2022 |

Dr Rasha Altaie and Nicola Jackson were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that should students be found to have Keratoconus (KC) that they would be forwarded through the public system to receive further care. The Committee queried the waitlists for this condition and how priorities would be managed due to the severity of disease.
2. The Committee noted that there would be a large inclusion of Māori and Pasifika peoples in the study and noted that currently there were no Māori or Pasifika research team members but that there was intent to find someone to fit this role, resource dependent.
3. The Committee clarified that there would be no funding available for interpreters.
4. The Committee noted that the study would initially be carried out in high schools but that the hope was that in the future this could be expanded to primary and intermediate schools. The study was beginning in high schools as the highest rate of incidence of KC is in the high school age group.
5. The Committee noted that the submission was incorrectly filled out for the section pertaining to one or more of the participants requiring decision-making support as children under the age of 16 cannot consent.

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 there was currently no opportunity for the participants to meet with the Researcher unless the Whānau requested it. The Committee suggested having the schools send out a notice in the school newsletter about the study team attending for the purpose of giving and encouraging opportunities for participating families to meet and discuss the research with the research team.
2. The Committee suggested that when presenting findings back to participating families that it would be a good idea to hold a fono or hui with food and in culturally appropriate spaces for communities to hold onto this information.
3. The Committee requested the removal of topics of education and other subjects that may result in feelings of stigmatisation where speaking on the importance of the study in preventing this disease. The Committee suggested review by Pasifika or Māori staff to aid in this.
4. The Committee noted that the younger age group participant information sheet (PIS) that will no longer be used will need to be removed.
5. The Committee requested an information sheet suitable for 12–15-year-olds be provided with more detail than what is currently in the document provided.
6. The Committee requested that the adult consent form be utilised for the 16+ year olds as well.

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

1. Please review language to ensure that it is clear that the child is participating, not the parent or guardian. Please ensure that it is clear that 16-to 18-year-olds will need to consent for themselves.
2. Please specify that parents can come along to the testing and how the parents would know when to attend the assessment.
3. Please explain how the Artificial Intelligence will be incorporated into the study.
4. Please explain in detail what will happen after the initial assessment has occurred.
5. Please note that people will need to be reconsented once the young person turns 16. This will need to be provided as another form as their data will continue to be used after the point, they can give their own consent.
6. Please remove mention of REDCAP and replace with “a database”.
7. Please remove ISO, HIPAA auditing and cybersecurity compliance information to avoid confusion.
8. Please amend the contact for Māori health support to be “Māori cultural support”.

**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 Jessie Lenagh-Glue, Mx Albany Lucas, and Dr Patries Herst.

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| **8** | **Ethics ref:** | **2022 FULL 13676** |
|  | Title: | A DOUBLE-BLIND, PLACEBO-CONTROLLED, SINGLE ASCENDING DOSE STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS AND PHARMACODYNAMICS PROPERTIES OF PRX 115 IN ADULT VOLUNTEERS WITH ELEVATED URIC ACID LEVELS |
|  | Principal Investigator: | Dr Alexandra Cole |
|  | Sponsor: | Novotech (New Zealand) Limited |
|  | Clock Start Date: | 10 November 2022 |

Dr Alexandra Cole, Holly Thirwall and Courtney Rowse were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified with the Researcher that the reimbursement values appeared different between sites due to processes for recruitment and were equal across sites but factored slightly differently due to process.

Summary of outstanding ethical issues

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

1. Please include in brackets the number of people who may be affected by a side effect out of 100 people or 1000 people rather than just the percentage.
2. Please remove reference to hypouricemia.
3. Please amend mention of “chaperone” on page 8 to “support person”.
4. Please clarify the use of “administrative reasons” under reason for termination of the study.

**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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| **9** | **Ethics ref:** | **2022 FULL 13788** |
|  | Title: | A Phase 2a Proof-of-Principle Study of the Acute Antidepressant Effects of Two Intravenous Doses of VLS-01-IV in Participants with  Major Depressive Disorder |
|  | Principal Investigator: | Dr Cameron Lacey |
|  | Sponsor: | Novotech (New Zealand) Limited |
|  | Clock Start Date: | 10 November 2022 |

Dr Cameron Lacey and Courtney Rowse 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.

Ms Jessie Lenagh-Glue member declared a potential conflict of interest and the Committee decided to excuse them from the discussion.

Summary of resolved ethical issues

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

1. The Committee clarified that the future use of information was only for data from this 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 noted that there was no safety plan or response timeline to the answering, analyses and follow up from the mental health questionnaires. Please include this in the protocol as well as in the participant information sheets (PISs).

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

1. Please clarify on page 7 the statement pertaining to participation should the participant be on medication.
2. Please add a bullet point in the consent form around consenting to future use of data.
3. Please note that in the section specifying which study samples will be sent overseas to specify that it will only be blood and urine samples sent in this manner.

**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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| **10** | **Ethics ref:** | **2022 FULL 13791** |
|  | Title: | A Randomized, Double-blind, Placebo-controlled, 3 part Study of ABCI: Single-ascending Dose Phase 1a Study in Healthy Volunteers (Part A), a 14- and 28-day Multiple-ascending Dose Phase 1b Study in Healthy Volunteers (Part B), and a 28 day Phase 2a Study in Subjects with Cystic Fibrosis (Part C) |
|  | Principal Investigator: | Dr Cory Sellwood |
|  | Sponsor: | Novotech (New Zealand) Limited |
|  | Clock Start Date: | 10 November 2022 |

Professor Chris Wynne, Julia O’Sullivan and Courtney Rowse were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified the insurance was coverage of $10 million for 72 patients and that the Researcher deemed this reasonable.
2. The Committee discussed with the Researcher the purpose of the sponsors and how these bodies were operating relative to each group.
3. The Committee noted that there would be no provision of the study drug after the study and the Researcher noted that as this is an early phase study in humans that this was largely for safety review reasons. The Committee clarified that there was no intention from the sponsor to include these participants in future studies at this time.
4. The Committee clarified that there was a final copy of the insurance document provided.
5. The Committee clarified that there would be no sentinel dosing as forms of the study drug has been given via inhalation before

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 clarity on what the local sponsor was for the participants, please consider changing the wording for the purpose of removing any potential confusion as to what sponsor is doing what regarding localities etc.
2. The Committee requested clarification on the qualifications noted in the questionnaire.

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

All:

1. Please clarify who the main sponsor is of the study and find consistent wording for the supervision or conduct of the study.
2. Please be clear that there will be no provision of the study drug after the study is finished.
3. Where mentioning smoking prior to the start of the study in inclusion/exclusion criteria, please amend the wording to say, “within 6 months prior to screening”.
4. Please include the word ‘relationship’ in the sentence currently reading “…this will not affect your with NZCR…”.
5. Please specify that mention of salivation in the possible side effects would refer to excessive salivation. Utilization of a term such as ‘drooling’ may be useful.

Part B PIS/CF

1. Please remove wording in cohorts G, H, and I to the effect of “this will not affect the care you receive” as these are healthy participants and are not receiving care.

Part C PIS/CF:

1. Please remove mention of MRI in New Zealand where necessary.
2. Please ensure that the section stating the right to access and correct information is included.
3. Please include a detailed safety plan and response timeline to the answering, analyses and follow up from the mental health questionnaires.

**Decision**

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

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

## General business

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

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| **Meeting date:** | 24 January 2023 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

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

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

The meeting closed at 5.30pm