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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 28 February 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 12.00-12.30pm | 2023 EXP 14019 | Te Ngākau Aronui Pilot | Associate Professor Miriam Scadeng | Ms Sandy Gill and Mx Albany Lucas |
| 12.30-1.00pm | 2023 FULL 15177 | DEPOSITION | Dr Shay McGuinness | Mrs Helen Walker and Ms Julie Jones |
| 1.00-1.30pm | 2023 FULL 15129 | The POWDER-CIED RCT study | Dr Martin Stiles | Ms Jessie Lenagh-Glue and Mr Barry Taylor |
| *1.30-2.00pm* | *Break* |  |  |  |
| 2.00-2.30pm | 2023 FULL 15200 | ADVANCE-DCB | Prof Mark Webster | Dr Cordelia Thomas and Ms Amy Henry |
| 2.30-3.00pm | 2023 FULL 15130 | A Study of Safety, Tolerability, Pharmacodynamics, and Pharmacokinetics of KAN-101 in People With Celiac Disease | Dr Dean Quinn | Mrs Helen Walker and Mx Albany Lucas |
| 3.00-3.30pm | 2023 FULL 13920 | EURELIA 2: A study to assess the efficacy and safety of Tigulixostat in gout patients. | Dr Alan Doube | Ms Sandy Gill 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 | Apologies |
| Dr Cordelia Thomas | Lay (the Law) | 20/05/2017 | 20/05/2020 | Present |
| Mrs Patricia Mitchell | Non-lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Apologies |
| 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 |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Ms Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |

## Welcome

The Chair opened the meeting at 11.30am and welcomed Committee members, noting that apologies had been received from Dr Patries Herst and Mrs Patricia Mitchell.  
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mr Barry Taylor and Ms Amy Henry confirmed their eligibility and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 24 January 2023 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2023 EXP 14019** |
|  | Title: | Te Ngākau Aronui Observational Pilot: MRI study of victims of family harm and sexual violence |
|  | Principal Investigator: | Associate Professor Miriam Scadeng |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 16 February 2023 |

Professor Tim Dare and Associate Professor Miriam Scadeng 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 requested an overview and the Researcher clarified that it was a pilot project aiming to reduce instance of family violence in Māori utilizing Kaupapa Māori methodology.
2. The Committee suggested that it was unnecessary to utilize medical resonance imaging scanning (MRI) for comparative analysis when there would be subjective data showing the progress made by participants from the questionnaires and the responses from participants. The Researcher responded that MRI would not be used to the same effect as in the bigger planned future study but that the MRI usage in this study would be around sensitivity and statistical power.
3. The Committee clarified with the Researcher that reporting of exclusion criteria would be self-reported to decrease invasiveness.

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 more information about the timeline around the person being affected by family violence to when they will be recruited. The Researcher noted that it would be before they had been through any other type of treatment. The Committee queried if it was necessary to include the 16-18 age group given this is a pilot. The Researcher agreed to amend this for the pilot study.
2. The Committee queried how the MRI process would be part of the Kaupapa Māori methodology-based programme. The Researcher, after prompting, noted that the methodology would be used in recruitment and that there would be no intervention in this study. This needs to be clarified in all study documentation.
3. The Committee noted that the questionnaires ask questions that are very likely to cause distress and have potential for harm for the participants and that there is no safety plan to deal with this. The Committee noted that what is currently planned insofar as the provision of cultural input from staff at Mātai is not adequate and needs to be built on and included in the protocol and Participant Information Sheets (PIS) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.1-8.3)*.
4. The Committee noted that there seems to be no plans to mitigate the possibility of this research creating stigmatisation of the Māori people. This needs to be addressed and may require rephrasing to be focused more on whether Kaupapa Māori methods work best for Māori in these cases rather than the current focus on the higher incidence of violence in Māori *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.8, 10.55, 11.51)*.
5. The Committee requested that included in the safety plan, there be a section discussing the possible identification of differences in the brain anatomy and how this will be handled. There should also be planning around possible disclosure of intent to harm either themselves in the case of the participants, or their family members.
6. The Committee queried the exclusion criteria and how exactly exclusion of psychiatric disorders would be managed where comorbidities exist. The Researcher noted that the inclusion/exclusion disorder was to attempt to reduce the number of confounding factors that may affect the MRI results. The Committee noted that as PTSD can often be linked to different psychiatric disorders this may not be possible and that at least the major disorders that will be excluded needs to be listed at the start of the section in the PIS.
7. The Committee noted that the questionnaire for exclusion was not accessible and needs to be either simplified significantly or changed to request access to medical records.
8. The Committee noted that there may be legal issues with this study due to the potential for victim name suppression and evidence quality that may affect the processes of the Courts. It may be necessary to gain legal advice. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.1).*
9. The Committee noted that the PIS was misleading as it appears to primarily address the bigger study.
10. The Committee requested that the recruitment information and image included in the protocol be included in the PIS as this is really the primary focus of the study.
11. The Committee requested that the consent capacity inferenced in the study be either explained or rephrased to avoid further confusion.
12. The Committee requested that the information in the data management plan and the PIS are consistent.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please rewrite the PIS to focus entirely on this pilot.
2. Please ensure that the writing is clear and specifies timelines as the “2 weeks” mentioned on page one as an example is too cryptic and does not indicate when the 2-week period commences.
3. Please clearly explain the processes of data destruction.
4. Please define the timeline, the details of and other pertinent information as to why the participants “may be invited back”. Please remove if irrelevant.
5. Please include information with regards to the potential removal of clothes etc. when having an MRI.
6. Please clarify how the participants may be informed or know to ask about findings.
7. Please clarify what tasks may occur during the MRI should there in fact be tasks required of them. Please amend the mention of falling asleep during this process if it is not correct.
8. Please clarify that MRIs in this pilot are purely to prove that MRIs can be used to view brain changes as a result of abuse.

**Decision**

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

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| **2** | **Ethics ref:** | **2023 FULL 12707** |
|  | Title: | Improving health services for people with musculoskeletal chest pain - a randomised controlled feasibility trial |
|  | Principal Investigator: | Dr Ewan Kennedy |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 February 2023 |

No one from the research team was present via videoconference for discussion of this application, which had been a response to provisional approval that the Committee requested be reviewed via full meeting discussion.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee noted that as investigators the researchers have a duty of care to ensure that psychological distress or other issues be addressed promptly and thoroughly. Please supply an adequately detailed safety plan addressing these concerns.
2. The Committee noted that as per Right 7(1) of the Code of Rights, consent cannot be given until the participant has been fully informed. The period of 5 minutes after consent before informing individuals does not comply with the requirements of the Code of Rights. The Committee suggested that there be 2 participant information sheets (PISs), one for those not receiving the physio and another for those who will. This should then be consented after provision of this and there be no information included as to the other group in each PIS. This is particularly relevant as saying no to people who are in a position of power makes most people uncomfortable. The Committee noted that this was requested in the provisional approval as the Researchers coming up with a solution to this issue, but nothing has been offered to resolve this issue.
3. The Committee noted that many of the points had been addressed, but there were still outstanding items that would need to come back for Committee review. As there is no second Provisional Approval decision, the Committee’s only option was to Decline and encourage the Researcher to resubmit to the Central HDEC at their earliest convenience.

**Decision**

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards and had outstanding changes requested that could not be met under an Approved with Non-standard Conditions.

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| **3** | **Ethics ref:** | **2023 FULL 15129** |
|  | Title: | POlysaccharide haemostatfor WounD haEmatomas Reduction in Cardiac Implantable Electronic Devices procedures – a Randomised Controlled Trial (The POWDER-CIED RCT study) |
|  | Principal Investigator: | Dr Martin Stiles |
|  | Sponsor: | Centre for Heart Rhythm Disorders |
|  | Clock Start Date: | 16 February 2023 |

Dr Martin Stiles, Liz Low, Dr Charles Ho, and Josh McLoughney were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried how the team would be using Kaupapa Māori methodology.
2. The Committee clarified the 6 month follow up would be standard of care.
3. The Committee clarified that the clotting agent has been used in other cases and that this study was looking into using this in this specific fashion.

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 were errors in the submission that are inconsistent with the actual intent of the research.
2. The Committee queried how the team would be using Kaupapa Māori methodology. The research team described their intent, but the Committee noted that this was incorporation of tikanga rather than actual Kaupapa Māori methods. The Committee noted that this was unable to be changed in the submission but that there should be further consultation with a Māori advisor to ascertain cultural issues which were not addressed in the application. Currently the cultural consideration is incredibly limited.
3. The Committee requested that the initial approach to the participant should be done by someone who is not part of the research team. This should be done to reduce coercion.
4. The Committee noted that there would be human tissue used in this study but that this was not listed in the application.
5. The Committee requested that any hospitals that will be participating in the study in New Zealand should be listed in the protocol.
6. The Committee requested clarification that the images taken of wound sites would be used only for internal purposes. Please specify what these images may be used for and who may see them and how they will be non-identifying if the participant has identifying features such as tattoos.
7. The Committee requested a safety plan for the quality-of-life questionnaire given it deals with mental health issues. The Committee requested that this addresses the timeline for review of the questionnaires. This needs to be in the participant information sheet (PIS) as well as the protocol.
8. The Committee requested that the investigator brochure be provided and relevant information pertaining to this be included in the PIS.

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

1. Please remove the repetitive paragraph on pregnancy.
2. Please note that commercial interest of the sponsor is not a valid reason to discontinue the study. Please amend.
3. Please remove reference to privacy laws that are not relevant to New Zealand. This section should be solely concerning New Zealand law.
4. Please amend mention of “Māori health support” to “Māori cultural support”.
5. Please include any information relating to karakia as outlined in the data and tissue management plan.
6. The Committee suggested using the [HDEC Main PIS Template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) to avoid missing necessary sections.
7. Please include how many participants will be from Aotearoa New Zealand.
8. Please review for lay friendly explanations of the technical terms used. Many of these concepts would be better conferred through use of diagrams and flow charts and the Committee suggests incorporating this into the PIS for improved accessibility.
9. Please remove mention of the device being “safe and effective” on page 2, given that this is an experimental study, and this phrasing could be misleading to participants.
10. Please include a section on the future use of data. Please refer to the HDEC PIS Template.
11. Please include mention of data going overseas in the PIS and CF.
12. Please ensure that all data sections are corresponding to what is outlined in the data and tissue management plan.
13. Please make sure it is clear the study treatment is explained in the context of Aotearoa New Zealand, rather than only stating it is approved in Australia.
14. Please amend reference to different forms of doctor as mentioned on page 3 and 4. This should either be a general practitioner (GP), or a doctor who is part of the study team.
15. Please explain the process for the de-identification of images of wounds, particularly in cases where there may be tattoos.
16. Please note that the release of information noted in the CF should first be mentioned in PIS as no new information should be introduced in the CF.
17. Please include a statement noting that the GP of the participant will be notified of participation.
18. Please amend the wording around side effects. This should be straight-forward and not veiled by pseudo-legal wording. Please also include numerical data (i.e., incidence per 100 patients) and remove mention of lab values as this is not relevant information.

**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 and Mr Barry Taylor.

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| **4** | **Ethics ref:** | **2023 FULL 15200** |
|  | Title: | ADVANCEd NanoTherapies Dual Active Pharmacological Ingredient (Dual-API) Drug-Coated Balloon to treat De-Novo lesions in patients with symptomatic stable angina, unstable angina and NSTEMI (ADVANCE-DCB) |
|  | Principal Investigator: | Professor Mark Wesbter |
|  | Sponsor: | Advanced NanoTherapies, Inc |
|  | Clock Start Date: | 17 February 2023 |

Robin Clarke and Dr Jith Somaratne were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried whether potential participants would have enough time to provide fully informed consent without delaying any treatment. The Researcher responded that there is usually a delay for those in this clinical setting, between 24 and 48 hours. Those who do not have enough time to look through information will not be included in the study. The Researcher also confirmed initial approach will be made by a research nurse.
2. The Committee queried whether the peer review provided for this submission was from someone independent of the study team. The Researcher confirmed they did not belong to the study team and had no vested interest in the trial, belonging to a different research group.

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 some follow-up visits for the study are outside of usual frequency for visits (such as the 30 days and 6 months). Please provide travel reimbursement for these visits.
2. The Committee stated that therapeutic studies cannot be terminated for commercial reasons, so references to this in the protocol and participant information sheet (PIS) must be amended.
3. The Researcher noted the error of reference in the guardian PIS and protocol about them signing on behalf of the participant. The Committee requested this is removed.

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

1. Please include the bold First-In-Human box like the one in the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) at start of PIS.
2. HDEC only approve the ethical aspects of a study, not all aspects. Please amend this statement. The HDEC template has wording that may be helpful.
3. On page 1, the first bullet point says stent, please remove.
4. Page 3 states that participant will be enrolled into the study that will be determined by their doctor. Please adjust to state “with your consent.”
5. Early in PIS, lactating is referred to, but is later referred to as breast-feeding. Please amend to use breast-feeding all the way throughout.
6. Examples of contraception are not provided, please refer to the ones outlined in the [HDEC template for reproductive risks](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
7. The Committee noted that the PIS is quite dense and could be simplified.
8. Page 8 mentions Advanced NanoTherapies, Inc. retaining recordings. This is the first-time recordings are mentioned and makes it sound like there are video and audio recordings. This is likely just reference to the data being recorded, please clarify.
9. The data section is not clear on what is identifiable and de-identified. Consider referring to HDEC Main PIS template and using that section.
10. The risk section has different font sizing. The Committee noted that the .5 increase is easier on the eye.
11. In the risk section, also explain risks in words as well as percentages i.e., 1 in 1000, etc.
12. The Committee noted that if reimbursement is for expenses such as public transport, direct reimbursement over vouchers should be considered for those who do not have a car.
13. Unclear in PIS which components of the study are commonly used and which are the new things being introduced as part of the study, please outline clearly.
14. Please clarify the role of the representative from the Sponsor being present.
15. Māori cultural support contact is not listed on sheet. Please include.
16. In alternatives to taking part, change study doctor to usual medical team (even if they are the same person).

**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 Dr Cordelia Thomas and Ms Amy Henry.

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| **5** | **Ethics ref:** | **2023 FULL 15130** |
|  | Title: | A PHASE 1B OPEN-LABEL/ PHASE 2 DOUBLE-BLIND PLACEBO-CONTROLLED STUDY FOR PHARMACODYNAMIC ACTIVITY, PHARMACOKINETICS, SAFETY AND TOLERABILITY OF KAN-101 IN PATIENTS WITH CELIAC DISEASE |
|  | Principal Investigator: | Dr Dean Quinn |
|  | Sponsor: | Pfizer New Zealand Limited |
|  | Clock Start Date: | 16 February 2023 |

Dr Dean Quinn, Katie Kennett, and Dr Dahong Yu ere 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 quality-of-life questions asked through the e-diary are about symptoms more than mental health.

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 application form states that genetic testing not mandatory which is incorrect.

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

1. The Committee noted that the number of pages indicated is incorrect (23 not 24)
2. Page 1 has the phrase “losing any benefits” which is misleading as there aren’t any direct obvious benefits to taking part.
3. In study procedures, state explicitly when participants may be required to remove items of clothing.
4. State that the e-diary needs to be returned at end of study
5. Under study procedures, clarify that blood samples will be taken over 4 hours at different time points, not continuously.
6. State explicitly if karakia is available for samples at time of destruction.
7. Make it clear that the additional endoscopy that some may be required to have is not optional for participation.
8. Amend “sedation may be available” to “will be”.
9. On page 12, identify what standard of care treatment is under the gluten challenge.
10. On page 13, in the context of using e-diaries and websites, it says someone’s data could be shared with researchers such as texts, call logs, etc. The Committee noted that this shouldn’t be shared with researchers, please review and amend.
11. Contraception section is long and could be condensed. Please refer to current [HDEC reproductive risks template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
12. Remove phrase “additional cost” and just use “cost”
13. The CF itself doesn’t state that the research team will ask permission to access GP or hospital records.
14. Please quantify risk of endoscopy in the PIS.
15. Check for a few filler words missing from sentences.
16. Make it clear what the reimbursement is for i.e., expenses or payment for time. Note that reimbursement for time is taxable.
17. Ownership of rights of data is covered in 3 places, some can be deleted
18. Future Unspecified Research (FUR) CF has tick-box that shouldn’t be optional about using samples being used for other research.
19. Please ensure it is clear which samples are part of the main study and which are part of the FUR. Page 16 discusses the use of biological samples for product development which does not seem to be part of the main study. Page 6-7 talk about use of genes and other analysis, it should be clear if this is to be consented on a separate FUR and not part of the main study.

**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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| **6** | **Ethics ref:** | **2023 FULL 13920** |
|  | Title: | A Phase 3, Randomized, Multi-regional, Double-blind, Double-dummy Parallel-group, Placebo and Allopurinol-controlled Study to  Assess the Efficacy and Safety of Tigulixostat in Gout patients with Hyperuricemia. |
|  | Principal Investigator: | Dr Alan Doube |
|  | Sponsor: | LG Chem Ltd |
|  | Clock Start Date: | 16 February 2023 |

Denise Darlington 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 digital photos are anonymised as required.
2. The Committee confirmed that the deductible as part of the insurance for the study will be paid by the Sponsor not participant.

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 raised the following about the NZL Study Information Sheet (not the participant information sheet):
   1. The question ‘Are clinical research studies safe?’ is not really answered in text.
   2. Regarding the question ‘Will I go to my regular doctor for EURELIA 2 Study visits?’, the participant information sheet (PIS) says information from GP may be collected and this is not optional. This does not entirely align with this information text: "However, we do encourage you to inform your regular doctor that you are taking part in this study. "
   3. The question ‘What should I consider before taking part?’ has recommended reading information provided. It should state that a PIS will need to be read and signed, it’s not optional.
   4. The answer to ‘Who will have access to the information collected during the study?’ is confusing. It talks about identifiable information and publishing data and permissions but not in a clear way.
   5. The information under ‘How do I join?’ is currently not appropriate. If someone read and gave their details on this doc, they are now not eligible for a screening visit, they still need to read the PIS before any tests or information is collected.
   6. The Committee noted that these documents may be unnecessary if there is already a PIS. Please remove the signature line and re-title as an FAQ with the above issues raised above amended.
2. The Committee noted that B7 of the application form says standard treatment is not being withheld, which is incorrect.
3. Preferable if its someone other than the investigator approaching patients initially. Not comfortable with having research staff reviewing full list of patients attending the clinic as they haven’t given consent for this. Clinician should identify who is a potential participant, ask them if they are interested and refer them on.

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

1. The Committee requested an inclusion of a table for visits for ease of understanding.
2. Page 12 states that study medicines must be locked in a cabinet. Please soften language that this is a requirement, stating that it’s a recommendation that it is stored securely.
3. The Committee noted some typos such as double question marks used.
4. Page 19 should have “may be reimbursed” to “will be.”
5. CF asks for agreement on GP being contacted optional, but in PIS its not optional. Remove the optional yes/no in the CF.
6. Please state that because mental health related questions are being asked, researchers will check that they are okay, also outline what you will do if they are not okay.
7. For risks, please provide a likelihood such as common, uncommon or rare and ratios like 1 in 1000, etc.
8. At the end of the trial, for participants already on gout medication, please provide advice for how to resume their usual medication.
9. Please state if karakia will be available at time of tissue disposal.
10. Please state where samples are sent overseas.
11. When first stated that blood will be drawn, include sentence of reassurance that it is not much being taken. This is stated elsewhere but should be provided first.
12. Under procedures, please indicate if the physical exam has the expectation that participants will be required to remove clothing.
13. As there is HIV and Hepatitis testing, please state if the team can provide counselling and medical advice. The Committee encouraged this to be provided.

**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 Sandy Gill and Ms Julie Jones.

## General business

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

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| **Meeting date:** | 28 March 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 3.30pm