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| **Committee:** | Ad hoc Health and Disability Ethics Committee |
| **Meeting date:** | 15 May 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 10.00-10.30am |  | Committee Welcome |  |  |
| 10.30-11.00am | 2025 FULL 22458 | J1I-MC-GZBO The Effect of Retatrutide Once Weekly on Cardiovascular Outcomes and Kidney Outcomes in Adults Living with Obesity | Dr Kalpa Jayanatha | Mrs Sandy Gill / Mrs Patricia Mitchell |
| 11.00-11.30am | 2025 FULL 22624 | CHASM CS-RCT | Dr Nicola Edwards | Dr Joy Panoho / Mrs Leesa Russell |
| 11.30am-12.00pm | 2025 FULL 22202 | Transplant and Cellular Therapies (TCT) Registries 2 | Dr Andrew Butler | Ms Kate O’Connor / Associate Prof Nicola Swain |
| 12.00-12.30pm |  | *Break (30 mins)* |  |  |
| 12.30-1.00pm | 2025 FULL 22562 | D7960C00013: A Phase III study to assess the effect of AZD0780 on LDL-C in participants with HeFH. | Professor Russell Scott | Dr Catriona McBean / Dr Andrea Furuya |
| 1.00-1.20pm | 2025 FULL 20397 | Community-Based Co-Modification of a Mental Health Support Model for Autistic Adolescents | Mrs. Victoria "Tori" Evans | Ms Kate O’Connor / Mrs Patricia Mitchell |
| 1.20-1.40pm | 2025 EXP 19904 | Oral irrigators and interdental brushes for the management of gum inflammation in adults with gum disease | Professor Donnabella Lacap-Bugler | Ms Maakere Marr / Mrs Leesa Russell |
| 1.40-2.00pm | 2025 EXP 22457 | MEtabolic Signatures in Rheumatoid Arthritis (MESRA Study) | Dr Katharina Robichon | Dr Joy Panoho / Associate Prof Nicola Swain |
| 2.00-2.10pm |  | *Break (10 mins)* |  |  |
| 2.10-2.30pm | 2025 EXP 22708 | Use of biologic agents in patients with inflammatory bowel disease in New Zealand: an analysis of patient characteristics. | Dr Joshua Quon | Mrs Sandy Gill / Dr Andrea Furuya |
| 2.30-2.50pm | 2025 EXP 22565 | Feasibility study to assess aetiology of heart failure in young to middle aged adults | Dr Kyra Innes-Jones | Dr Catriona McBean / Mrs Patricia Mitchell |
| 2.50-3.10pm | 2025 EXP 22676 | Bile Acid Malabsorption Study | Dr Simone Bayer | Ms Maakere Marr / Mrs Leesa Russell |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Ms Kate O’Connor  | Lay (Ethical/Moral reasoning) (Chair) | 13/08/2021 | 16/08/2024 | Present |
| Mrs Leesa Russell | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Absent |
| Mrs Sandy Gill  | Lay (Consumer/Community perspectives)  | 22/05/2020  | 22/05/2023  | Present |
| Mrs Patricia Mitchell  | Non-lay (Health/Disability service provision)  | 08/07/2022 | 08/07/2025 | Present |
| Dr Catriona McBean | Lay | 03/03/2025 | 02/03/2030 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Dr Joy Panoho | Lay | 03/03/2025 | 02/02/2030 | Present |
| Dr Andrea Furuya | Non-Lay | 03/03/2025 | 02/03/2029 | Present |
| Associate Prof Nicola Swain | Non-lay Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 10.00am and welcomed Committee members, noting that this is an ad hoc committee made up of members from across all the HDEC Committees.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## New applications

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| **1**   | **Ethics ref:**   | **2025 FULL 22458** |
|   | Title:  | A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Event-Driven Study to Investigate the Effect of Retatrutide on the Incidence of Major Adverse Cardiovascular Events and Major Adverse Kidney Events in Participants with Body Mass Index (BMI) ≥27 kg/m2 and Atherosclerotic Cardiovascular Disease and/or Chronic Kidney Disease (TRIUMPH OUTCOMES) |
|   | Principal Investigator:  | Dr Kalpa Jayanatha |
|   | Sponsor:  | Eli Lilly and Company |
|   | Clock Start Date:  | 02 May 2025 |

Dr Kalpa Jayanatha, Rebecca Sisterson, Tanya Poppe, Angeline Ferido, and Anjali Suman 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 this is a resubmission of a previous decline. Most of the concerns raised have been addressed, such as the monitoring of suicidality of participants being a researcher responsibility rather than a family responsibility.
2. The Committee noted that five years on placebo is a long time and queried how unwell participants are and what benefit there is for these participants to be in the study. The Researchers advised that how unwell the participants are depending on which group they are in. The Researchers noted that GLP-1 agonists may provide some improvement to proteinuria and slow kidney disease, however these are not approved for this use in New Zealand. Placebo participants have access to extensive lifestyle counselling as part of this study.
3. The Committee queried what is the difference between pre-screening and screening. The Researcher noted that the pre-screening was added as an option to check Urine Albumin Creatinine Ratio (UACR) for those participants who have not had this recently measured, to prevent them needing to go through all the screening process only to find out they are not eligible due to their UACR.
4. The Committee noted that the Investigators Brochure indicates Retatrutide is being developed to improve glycaemic control in adults with type 2 diabetes, however in this study individuals with type 2 diabetes are excluded unless their HbA1c is controlled and requested an explanation for the rationale behind this. The Researcher noted that glycaemic control was what this medication was originally developed for but subsequently it was discovered that it is effective for weight loss and is being investigated for controlling proteinuria in kidney disease.

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 if social media is used for advertising, that comments are either turned off or actively monitored.
2. The Committee noted that at the previous application the issue was raised of a need for a safety plan in response to potential mental health crisis that could be triggered by the questionnaires and felt this has not been thoroughly addressed. The Researchers were able to verbally describe a safety plan and the Committee were happy with this and would like to see it added to the participant information sheet.
3. The Committee queried whether ten million dollars is sufficient insurance for ten thousand participants should something go wrong given the very large number of participants expected globally.
4. The Committee requested that the advertising material has numbered pages. Please also check for typos, for example on page 6 it should say “an injection” not “and injection”.
5. The Committee requested the advertisement is rephrased to clearly present the two eligible population groups, as currently the sentence is unclear.

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

1. Please describe the safety plan should a participant require mental health support.
2. Rather than paying a stipend which is taxed and can impact on participants income who are on a benefit, please offer gift cards with an option for groceries or petrol.
3. Please make mileage reimbursement linked to CPI and inflation, due to the study running for five years.

**Decision**

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

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

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

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| **2**   | **Ethics ref:**   | **2025 FULL 22624** |
|   | Title:  | Cardiac Sarcoidosis multi-center randomized controlled trial (CHASM CS- RCT) |
|   | Principal Investigator:  | Dr Nicola Edwards |
|   | Sponsor:  | University of Ottawa Heart Institute |
|   | Clock Start Date:  | 02 May 2025 |

Evelyn Lesiawan was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that this is a study comparing two different standard of care options, and queried how it is decided currently, which option patients are prescribed. The Researcher advised that currently it is clinician preference but there is currently no evidence as to which is more effective.
2. The Committee queried the exclusion of pregnant and breast-feeding people. The Researcher advised this is due to Methotrexate being unsafe. This population group would not be included in the study and instead treated using prednisone.
3. The Committee noted that the study started in 2019 in Canada and queried why New Zealand is only starting now, and whether the Canadian arm of the study is close to completion. The Researcher advised that as their PhD is about Sarcoidosis, their supervisor pointed out the Canadian study and suggested they join. There is still about eighteen months left in the Canadian arm, which is due to Sarcoidosis being a rare disease.
4. The Committee noted that Māori consultation had not taken place. The Researcher stated that this will take place as part of locality authorisation.

Summary of outstanding ethical issues

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

1. The Committee queried how many participants there will be in New Zealand. The Researcher advised that the scale of Sarcoidosis is unknown in New Zealand, so they are unsure how many participants will be recruited. The Committee recommended stating that it is rare in New Zealand, but that x number of participants will be targeted.

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

1. Please rewrite the PIS/CF using the HDEC template and customise to a New Zealand audience. The submitted version is based off the Canadian version, which contains information that is not relevant for New Zealand. Please use the consent statements from the template. [Participant Information Sheet templates | Health and Disability Ethics Committees](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
2. Please correct the spelling of whānau to include the macron.
3. Please include advice that pregnancy should be avoided whilst on this study.
4. Please remove reference to race, collect ethnicity data only.
5. On page 13 please change the wording around participants having the option to be advised of other clinical results, participants should be advised as part of duty of care.
6. Please update the section on costs to be specific for New Zealand.
7. Please include contact information for HDEC and Māori cultural support.
8. Please include information about the process for addressing any issues arising from the quality-of-life questionnaires, noting that it is part of duty of care to act promptly.
9. Please make the “my data” section relevant for New Zealand and clarify which samples will remain in New Zealand and which will go overseas.
10. In the main PIS/CF please be clear about which specific genetic test will be carried out and highlight that this is not optional.
11. Please include information in the future unspecified research (FUR) PIS/CF about genetic testing and associated risks, not just for the individual but also their whakapapa.
12. Please provide information about how a person can withdraw from FUR if they change their mind.

**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 Joy Panoho and Ms Kate O’Connor.

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| **3**   | **Ethics ref:**   | **2025 FULL 22202** |
|   | Title:  | Transplant and Cellular Therapies (TCT) Data Collection and Management Registries |
|   | Principal Investigator:  | Dr Andrew Butler |
|   | Sponsor:  | Te Whatu Ora Waitaha Canterbury |
|   | Clock Start Date:  | 02 May 2025 |

Helen McDermott and Elizabeth Collin 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 this is a resubmission of a previous decline, and that patient registries are not a great fit for HDEC review which focuses on research and is set up to review research protocols which may be for studies that intend to use the data from registries.
2. The Committee queried why HDEC approval is being sought now, given that the registry has been in place for some time. The Researcher advised that it was raised in a review meeting, as to why this registry did not have HDEC approval when multiple other registries around the country have obtained HDEC approval.
3. The Committee queried why each site requires a different information sheet (and HDEC submission) and whether they could be treated as different localities. The Researcher noted that each site has its own principal investigator and does things separately and slightly differently, rather than operating at a national level.
4. The Committee queried at what point in the transplant process consent for the registry would be sought. The Researcher advised that this would occur in the work up for the transplant around four weeks before the transplant.

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 registries already exist offshore and there is mandatory collection of a minimum data set for transplant recipients. HDEC Committees cannot give retrospective approval. The only part of the application that the HDEC could consider for approval would be a participant information sheet and consent form for future unspecified research. A section of the protocol that addresses New Zealand date would be useful, particularly identifying how this data may be linked to other datasets (if at all).
2. The Committee noted that there needs to be a PIS/CF for parents, to go alongside the children’s assent forms.
3. The Committee queried how linkage would be done, and whether this would be via NHI number or date of birth.

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

1. Please adapt the future unspecified research template, ensuring that it is explained that data will go overseas, and under what conditions researchers may access identifiable information (for example, date of birth) for unspecified research and how it may be linked with other data (give examples). [Participant Information Sheet templates | Health and Disability Ethics Committees](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
2. Please make clear that participants will not be advised when their data is used in research.
3. Please clarify what is mandatory data collected for quality and safety purposes, and what is additional data collected for research purposes.
4. Please provide detail about data governance, including Māori data sovereignty and how this is affected by data going overseas.
5. Please highlight the differences for donors versus recipients.
6. Please state that HDEC have approved the information sheets only and not the ethical aspects of the registry.

**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 Kate O’Connor and Associate Professor Nicola Swain.

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| **4**  | **Ethics ref:**   | **2025 FULL 22562** |
|   | Title:  | A Phase III, randomised, double-blind, placebo-controlled, parallel-group study to assess the effect of AZD0780 on low-density lipoprotein cholesterol (LDL-C) in participants with heterozygous familial hypercholesterolaemia (HeFH). |
|   | Principal Investigator:  | Professor Russell Scott |
|   | Sponsor:  | AstraZeneca Ltd. |
|   | Clock Start Date:  | 02 May 2025 |

Professor Russell Scott, Kayla Malate, 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 queried why there is a separate consent form for genetic testing when the inclusion criteria is that participants are diagnosed with heterozygous familial hypercholesterolaemia. The Researchers advised that diagnosis can be made without genetic testing, and whilst most participants at the Christchurch site will already have had genetic testing done, this may not be the case at other sites, and therefore this will be offered as an option for those participants.
2. The Committee queried without genetic testing, how it would be determined that a participant was heterozygous for familial hypercholesterolaemia (FH), rather than homozygous. The Researcher advised that homozygous FH is incredibly rare and has traits that would allow diagnosis, noting that most participants will have had genetic screening anyway.
3. The Committee queried whether recruitment would be done via clinic or advertising. The Researchers advised that the Christchurch site would recruit entirely through clinical referral, however other sites may use advertising, although it is still anticipated that most participants will come from clinical referral.
4. The Committee queried the rationale for excluding pregnant and breastfeeding people. The Researcher advised this is based on current standard of care for people taking statin medications.

Summary of outstanding ethical issues

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

1. The Committee queried whether there will be an open-label stage of the study, given that this is a lifelong treatment. The Researcher advised that there isn’t at this stage, but they will raise it with the sponsor.
2. The Committee requested that the reimbursement amount is stated in the advertisement.

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

1. Refer to Te Tiriti o Waitangi in full.
2. Please rephrase, “If you could become pregnant, or your partner could become pregnant to you, and you are sexually active, you and your partner must use effective contraception during the study.”
3. Please clarify whether the total ml’s for blood samples, refers to per visit or the entire study.
4. On page 10 please include some examples of common drugs which could be a contraindication and state the importance of disclosing all medications.
5. Please check the master PIS for typos and grammar.

**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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| **5**  | **Ethics ref:**   | **2025 FULL 20397** |
|   | Title:  | Community participation in Autism mental health research: collaborative modification of Acceptance and Commitment Therapy-based model to meet mental health needs of Autistic adolescents in Aotearoa New Zealand |
|   | Principal Investigator:  | Mrs Victoria Evans |
|   | Sponsor:  | University of Canterbury |
|   | Clock Start Date:  | 02 May 2025 |

This is an expedited application and was reviewed online by Committee members only.

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 this would have been suitable for institutional ethics committee review, but this was not possible due to the University of Canterbury Ethics Committee not having Health Research Council accreditation.
2. The Committee commented that this is a well thought out and written PhD project.

Summary of outstanding ethical issues

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

1. The Committee queried whether the study has the correct institutional sign off as sponsor.
2. The Committee recommended reviewing the Data Management plan for relevance to this study and removing items from the template such as CROs and Monitors.
3. The Committee noted that the honorarium will attract tax. Either explain this in the information sheet or preferably use vouchers instead.
4. The Committee queried why the study is not using a not validated tool. If it is a customised tool, please state this, clarifying which validated tool it has been modified from and the purpose of the customisation.
5. The Committee queried where the Wellbeing plan will be stored and who will have access.
6. The Committee request to please provide an Information sheet for the focus group.
7. In the advertisement, please rephrase “Lending your thoughts”. Please state what the QR code links to. State what AAC stands for. When it states “are you autistic” please be clear whether this needs to be clinically diagnosed.
8. The Committee queried whether Māori consultation has been undertaken.

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

1. Please note that the V4.P1 PIS is the subject of this review, and the V3.P1 should not be used.
2. Please state when questionnaires will be assessed, currently this information is generic, but needs to be a specific safety plan. Please clearly state what will happen if there is an issue. Noting that there is a duty of care to act in a timely manner.
3. Please provide more information about the inclusion and exclusion criteria, and the basis for selecting participants if more than are needed apply to join the group.
4. It would be helpful to illustrate study procedures and visits in a table or flow chart. Explain what will happen at each meeting.
5. The Consent Form should contain an undertaking to respect the privacy of other focus group members by not disclosing any content discussed during the study.

**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 Kate O’Connor and Mrs Patricia Mitchell.

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| **6**   | **Ethics ref:**   | **2025 EXP 19904** |
|   | Title:  | Oral irrigators and interdental brushes for controlling periodontal inflammation in adults with periodontitis: A pilot randomised clinical trial |
|   | Principal Investigator:  | Professor Donnabella Lacap-Bugler |
|   | Sponsor:  | Auckland University of Technology |
|   | Clock Start Date:  | 02 May 2025 |

This is an expedited application and was reviewed online by Committee members only.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee discussed whether Panasonic is a sponsor, ultimately determining the study is investigator lead, not commercial.

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 a justification of the exclusion of pregnant people.
2. The Committee noted that the protocol exclusion of smoking and chewing tobacco has been extended to vaping in the Consent Form. Please make these consistent.
3. The Committee noted the consent form statement regarding "problems with drugs or alcohol" is nowhere else described, e.g. as an exclusion criterion. It is unclear what "problems" refers to.
4. The Committee noted that there should be an Ethics approval statement on the flyer.
5. The Committee noted that data obtained from screening for ineligible individuals will be kept in a "coded" format. As this is unconsented data this should be completely anonymised, or immediately deleted per the screening Data Plan.
6. The Committee noted that if distress is noted in questionnaires or screening, participants will be referred to student health. Please include support services for non-students.
7. The Committee queried why future use in studies outside of oral care and gum disease are included.

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

1. Please clarify if $120 is for every appointment or the entire study.
2. Please state that participants are required to keep a daily record of their oral care.
3. Future use of coded data is different to future use of samples, so future use of coded data should be included in the consent form.
4. Please check spelling on Māori words, particularly the use of macron.
5. Please remove the statement about ingesting a wireless device from the consent form.
6. Please clarify if data is data going overseas.
7. Please check for spelling and grammar.
8. Please remove the ACC statement from the future unspecified research PIS/CF.
9. Please state if the support person can be there for the entire visit, not just for the karakia.
10. “Mental or physical condition” please reword.
11. Main PIS/CF vs optional PIS/CF “have had this read to me in my own language”. Unclear if interpreters are available or not. Either put this statement on both forms or remove from the optional form if not.
12. Please clarify in the future unspecified research PIS/CF whether this could include genetic testing.
13. Please state the location of any known overseas laboratories where samples may be sent.
14. There are two sections on tooth plaque samples, please combine them.
15. Please add phone numbers for the Ministry of Health, and Advocacy services.
16. Please move the photos from page 3 to page 1 under “What is the purpose of this research” where it first refers to oral irrigators and interdental brushes.
17. Please use the wording from the HDEC template for the ACC statement. [Participant Information Sheet templates | Health and Disability Ethics Committees](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
18. Please state the process for advising participants of study results.
19. Rather than referring to costs involved in participating, refer to commitment involved. Please move the section earlier in the information sheet.

**Decision**

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

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

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| **7** | **Ethics ref:**   | **2025 EXP 22457** |
|   | Title:  | Cellular metabolic signatures as prognostic markers for treatment in rheumatoid arthritis. |
|   | Principal Investigator:  | Dr Katharina Robichon |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 02 May 2025 |

This is an expedited application and was reviewed online by Committee members only.

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 requested more detail in the Protocol (Section 5.3) with respect to the follow-up data collection. Please state which records will be kept over what period.
2. The Committee noted that the poster for healthy controls does not explain why they would be doing the study and what they are being compared with, i.e. Give a blood draw as a comparator for patients with rheumatoid arthritis. It should also contain the study title and relevant logos.
3. The Committee queried why the exclusion criteria on the poster is different from the protocol. These should be the same.
4. The Committee queried the justification for excluding pregnant and breastfeeding people.
5. The Committee noted that the optional genetic analysis should be separated out as an optional sub study.
6. The Committee noted that the data management plan needs to be specific for the study, not just the template wording, for example refer to the University as the sponsor and include their policies, also remove reference to things that are not relevant such as CROs. Clearly highlight the differences in data linking for healthy controls compared to the other cohorts.
7. The Committee noted some inconsistency around if a participant withdraws whether their data would continue to be used or not, and under what circumstances.
8. The Committee noted that there appears to be an error in the submission form stating that this study uses kaupapa methodology.
9. The Committee noted that the baseline data collection form has different inclusion criteria again, please make consistent.
10. The Committee queried whether the researcher had responded to the queries in the peer review regarding exclusion criteria.
11. The Committee noted that the first approach to patients needs to be made by their clinician. The researcher cannot screen the list and talk to patients before their specialist appointment, this would need to be done after.
12. The Committee noted that the brochure needs to include a little more information, such as medical records will be searched.
13. The Committee noted that it states consent forms will be destroyed after five years, these should be kept for ten years.
14. The Committee queried whether the thirty participants was total of newly diagnosed and on existing treatment or thirty of each.

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

1. Figure 1 is not relevant for healthy controls, please consider a table that clearly illustrates the three cohorts and what is involved for each.
2. Please address the reader, rather than referring to ‘the participant’, state ‘you/your’.
3. Please remove reference to biohazard waste.
4. Please be specific about what health information is collected as follow-up, from where and for how long.
5. Please remove tick boxes from the consent form unless they are truly optional.
6. Please remove “you have been chosen”.
7. Use lay terms throughout or provide definitions.

**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 Joy Panoho and Associate Professor Nicola Swain.

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| **8**  | **Ethics ref:**   | **2025 EXP 22708** |
|   | Title:  | Use of biologic agents in patients with inflammatory bowel disease in New Zealand: a multi-center retrospective study of patient characteristics. |
|   | Principal Investigator:  | Dr Joshua Quon |
|   | Sponsor:  | Te Whatu Ora Te Toka Tumai Auckland |
|   | Clock Start Date:  | 02 May 2025 |

This is an expedited application and was reviewed online by Committee members only.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee noted that the relevant points from the National Ethical Standards about a waiver of consent should be covered in the data management plan.
2. The Committee requested a suitably independent and appropriately qualified Peer review on the research protocol.
3. The Committee noted that other statistical methods such as Regression might be more meaningful.
4. The Committee noted that consultation with Māori needs to be undertaken, as part of the conditions for a waiver of consent under the National Ethical Standards. This will probably form part of the locality approval process.
5. The Committee requested that the questions about risks and benefits for Māori in the submission form are answered thoroughly. One example of a risk would be whakamā.
6. The Committee recommend consulting with an interest group and seeking a letter of support.
7. The Committee noted that there appears to be an error in the submission form, as the Researchers have advised that participants will be able to request a summary of results, however if there are no active participants this is incorrect.
8. The Committee noted that the study structure needs to be outlined in the Data Management plan.

**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.

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Sandy Gill, Ms Kate O’Connor, and Dr Andrea Furuya.

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| **9**   | **Ethics ref:**   | **2025 EXP 22565** |
|   | Title:  | Feasibility study to assess aetiology of heart failure in young to middle aged adults |
|   | Principal Investigator:  | Dr Kyra Innes-Jones |
|   | Sponsor:  | Te Whatu Ora Te Toka Tumai Auckland |
|   | Clock Start Date:  | 02 May 2025 |

This is an expedited application and was reviewed online by Committee members only.

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 request the protocol is more specific about what additional data from what is already in the clinical records, is being obtained from the interview.
2. The Committee noted that the Data Management Plan needs to be customized to this research. For example, S.8.5 discusses future unspecified use of data by the Sponsor, but a "Sponsor" is nowhere identified, and such future uses should be separated consented as an optional component of participation. Parties such as CROs and imaging vendors should be removed if they are not part of this study.
3. The Committee note that the recruitment period seems short, for the number of participants.

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

1. Please be clear that participation only involves an interview, and the rest of the information will be obtained in the clinical records.
2. Please remove from the benefits that the interview could be of benefit, as this implies that clinical records could be incomplete.
3. Please change the period data will be stored for to ten years.
4. Please update the phone number for ethics to the ministry of health general enquiry number.
5. Please clarify whether results will be individual or a summary.

**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 Catriona McBean and Mrs Patricia Mitchell.

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| **10**   | **Ethics ref:**   | **2025 EXP 22676** |
|   | Title:  | Bile acid sequestrant tolerability and symptom improvement in adults with chronic diarrhoea |
|   | Principal Investigator:  | Dr Simone Bayer |
|   | Sponsor:  | University of Otago, Research & Enterprise |
|   | Clock Start Date:  | 02 May 2025 |

This is an expedited application and was reviewed online by Committee members only.

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 this study should go to full review when it is resubmitted, as it is an intervention using a medication off label. When completing the submission form under S15 the option “An approved medicine being used for a new indication” should be selected.
2. The Committee requested a clinical peer review focusing on the use of this medication off label. (*9.26, 9.28 of the National Ethical Standards Research and Quality Improvement)*.
3. The Committee noted that the protocol needs significant rewriting. Please refer to section (*9.7 and 9.8 of the National Ethical Standards Research and Quality Improvement)*, for what a protocol must include.
4. The Committee noted that it is highly unusual to not state the number of participants that will be recruited for a study, noting that this should be sufficient to answer the research question while not exposing more people than necessary to potential risk. (*9.1 of the National Ethical Standards Research and Quality Improvement)*
5. The Committee requested that the recruitment poster and any other intended advertising is provided for review prior to use. (*11.12 of the National Ethical Standards Research and Quality Improvement)*
6. The Committee requested clarification about the study duration, currently it states that it is seventeen days for the participant and that the study will run for nineteen months. State whether there will be any further follow up with the participants over those nineteen months, or if that is the recruitment period over which multiple cohorts will run.
7. The Committee noted that the purpose of the study is unclear, if it is to validate a blood test, then more information about the blood test needs to be provided in the protocol.
8. The Committee noted that the study methods do not correspond to the study aims. These should be clearly aligned so that it is obvious how each of the aims will be tested and measured. (*9.1 of the National Ethical Standards Research and Quality Improvement)*

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

1. Please use the HDEC template for wording, particularly for the data section and consent form. [Participant Information Sheet templates | Health and Disability Ethics Committees](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) *(National Ethical Standards for Health and Disability* *Research and Quality Improvement, para 7.15 – 7.17).*
2. Please clarify whether there will be optional future unspecified research (FUR), if there will then a separate FUR PIS/CF will need to be provided.
3. Please state the risks and frequency of side effects, along with any contra-indications, since the intervention is given as part of research, and not Standard of Care.
4. The consent form refers to a procedure, but this is not mentioned anywhere else, presumably this is an error and should be removed.
5. Please refrain from using the term ‘treatment’, as this is research it is more appropriate to use ‘investigational product’.
6. On page 2 under cultural considerations a karakia is offered if preferred and participants are directed to the CF, but there is nothing there about karakia.
7. Please state that the participants will receive a koha, including how much this will be and when it will be provided. Please refrain from using the word ‘time’ when referencing the koha, as time is taxable. Consider offering a choice of a supermarket voucher as well as an MTA voucher, as not everyone has a car.
8. On page 2 the word whānau needs a tohu toa (macron).
9. Please clarify whether data is being sent overseas.
10. Please include the Ministry of Health general enquires phone number in the contact’s section.
11. In the ‘my participation’ section it states, “If you choose to take part in this study, ... in the morning, before breakfast and work to provide blood samples.”. This infers every participant works. Given the age range is up to 85 years, this is highly unlikely. Please reword.
12. Also, in the ‘my participation’ section, it states “you will need to collect information on your bowel movements for 17 days”. Please state if this is this via a questionnaire and whether online or hardcopy.
13. In the blood test section it states, “It is common that a test result falls just outside the normal range and is usually not concerning.” The Committee recommend removing this sentence as the next sentence provides better guidance.
14. The table is not clear, and no context is given. It could be interpreted that 10mls will be withdrawn for each test listed. Please amend.
15. Please explain the purpose of the prescribed medication.
16. Please clarify if the questionnaires are designed for a mobile phone or computer. If a patient does not have access to a digital device, will a paper version option be available. Clarify if the GSRS is completed at the clinic.

**Decision**

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

## General business

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

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| **Meeting date:** | 20 May 2025 |
| **Zoom details:** | 965 0758 9841 |

1. **Any other business**

The Committee noted that there are some updates needed to the HDEC templates, for example, removing reference to biohazard waste.

The meeting closed at 1.50pm.