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| **Committee:** | NTA Health and Disability Ethics Committee |
| **Meeting date:** | 15 April 2025 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:00 - 12:30pm |  | Committee welcome |  |  |
| 12:30 - 1:00pm | 2025 FULL 22729 | SWiFT STUDY | Dr Richard Charlewood | Catherine / Andrea |
| 1:00 - 1:30pm | 2025 FULL 21477 | Prosthetic Joint Infection Trial (ROADMAP) | Dr Thomas Hills | Jonathan / Kate |
| 1:30 - 2:00pm | 2025 EXP 22533 | Kai ā Nuku | Dr Nicola Gillies | Catriona / Jade |
| 2:00 - 2:30pm |  | *BREAK (30 mins)* |  |  |
| 2:30 - 3:00pm | 2025 FULL 22492 | BGB-11417-303\_Study of Sonrotoclax Plus Anti-CD20 Antibody Therapies Versus Venetoclax Plus Rituximab in Patients With Relapsed/Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma | Dr. Sarah Tan | Jonathan / Kate |
| 3:00 - 3:30pm | 2025 FULL 21130 | Closure of emergency midline abdominal incisions | Dr Henry Witcomb Cahill | Catriona / Jade |
| 3:30 - 4:00pm | 2025 FULL 22600 | NEU-627-MS101: A Study to Evaluate NEU-627 in Healthy Volunteers | Dr Leanne Barnett | Catherine / Sotera |
|  |  | *BREAK (10 mins)* |  |  |
| 4:10 - 4:40pm | 2025 FULL 21774 | RELATIVITY 1093: Nivolumab + Relatlimab Fixed-dose Combination with Chemotherapy Versus Pembrolizumab with Chemotherapy in Participants with Non-squamous Stage IV or Recurrent NSCLC and PD-L1 ≥ 1% | Dr Aileen Ludlow | Jonathan / Sotera |
| 4:40 - 5:10pm | 2025 FULL 21847 | Australia and New Zealand Heart Transplant Registry | Dr Thomas Pasley | Catherine / Andrea |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Kate Parker | Non-lay (Observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Dr Andrea Forde | Non-lay (Intervention studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Catherine Garvey | Lay (the Law) (Chair) | 11/08/2021 | 11/08/2024 | Present |
| Dr Sotera Catapang | Non-lay (Observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Ms Jade Scott | Non-lay (Intervention/Observational studies) | 15/08/2021 | 15/08/2024 | Present |
| Dr Catriona McBean | Lay | 03/03/2025 | 02/03/2030 | Present |

## Welcome

The Chair opened the meeting at 12:00 and welcomed Committee members, noting that no apologies had been received.

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 18 March 2025 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2025 FULL 22729** |
|  | Title: | Study of Whole Blood in Frontline Trauma in Aotearoa New Zealand - A Randomized Controlled Double-Blinded Feasibility Trial Assessing Platelet-Rich Whole Blood versus Platelet-Poor Whole Blood In Pre-Hospital Traumatic Haemorrhage. |
|  | Principal Investigator: | Dr Richard Charlewood |
|  | Sponsor: | New Zealand Blood Service |
|  | Clock Start Date: | 3 April 2025 |

Dr Richard Charlewood, Dr Christopher Denny and Mrs Helen Knight 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 the Researchers had identified that both the USA and Canada used PRWB in emergencies when patients were retrieved in the field, and that a trial on PRWB was ongoing in the UK. The Committee queried the use of PRWB in Australia as a comparable counterpart with respect to rurality, remoteness and the nature of injuries. The Researchers clarified that blood was not given on air transportation in Australia.
2. The Committee requested information on the rural hospitals that patients were transferred from to more appropriate facilities, in situations other than emergency attendance at the site of injury. The Researchers identified many of those rural hospitals particularly in Northland and clarified their extensive relationships with clinicians in those hospitals.
3. The Researchers explained that the consenting process on the helicopter follows the same process as in hospital but often patients are in emergency situations where they are unable to provide consent. If they are not wearing a ‘do not transfuse’ medallion or bracelet and do not have family or friends present to consent to or to decline blood, then they are treated in their best interest based on clinical judgment. If patients do have capacity and decline a blood transfusion this is respected and the hospital is informed. The Committee queried the proportion of patients who have capacity to consent. The Researcher explained most injuries in New Zealand that require helicopter rescue and retrieval, and that will meet the eligibility criteria for inclusion in the study, are blunt force injuries, such as car crashes and falls, and patients often have concomitant head injuries. The Researcher estimated about two thirds may have capacity to consent but those in the remaining third with severe head injuries or traumatic cardiac arrest would be unable to provide consent.
4. The Committee queried if the trial would require additional product from the blood service and implications for additional use of resource and whether this may affect other users. The Researcher explained the use of resources in this trial would not impact the blood supply as it uses a small amount compared to what is collected nationally. The Researchers explained as the blood is used in the helicopter trial replacement units would be made. These units of PRWB have a shorter shelf life so the feasibility aspect is whether a trial can be run with manufacturing of platelet-rich units on demand. The Committee queried the risk of wastage. The Researchers confirmed wastage is low and the units of blood that are not used on the helicopter every day are then transferred into hospital for use. The Researchers acknowledged that as the platelet rich blood is not registered for use in non-trial patients there is a chance of wastage and they will attempt to minimise this.
5. The researchers clarified that they perceive no safety issues with the use of platelet rich whole blood (the investigational blood product) in any patients receiving a transfusion on board the rescue helicopter including upon arrival at hospital and determination of further transfusion requirements.
6. The researchers confirmed that they will report use of the platelet rich whole blood product to MedSafe in accordance with reporting requirements for prescribing under s29 of the Medicines Act 1981.

Summary of outstanding ethical issues

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

1. This study is related to SWiFT UK. Enrolment in that study was completed in October 2024. The researchers identified some distinguishing factors between the UK and NZ air ambulance services but the Committee requested clear justification for why it was not more appropriate to wait for publication of those UK findings, and the potential implications for the proposed NZ study.
2. The Committee acknowledged the relationships that the Researchers have with clinical services but requested the Researchers undertake specific consultation with iwi and hapū in areas North and North West of Auckland where it is likely that some participants will come from. The Committee noted the Researchers have undertaken some engagement with hospital localities and agreed that it is important to ensure adequate engagement with iwi and hapū in those areas from where people with acute injuries are likely, on past evidence, to be rescued in the field. Further consultation can be undertaken through the researchers’ existing relationships. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.3 – 3.5).*
3. The Committee discussed New Zealand legal restrictions regarding inclusion of nonconsenting participants in research. It requires consideration beyond the threshold for regular or emergency treatment without consent. The Committee noted the intention to randomise the blood product used prior to enrolment of participants and that the helicopter will carry either the standard of care blood product or the investigational platelet rich blood product. This means that all patients who receive a transfusion on board will receive the investigational product if that is what is being carried, including those with non-traumatic indications for transfusion (i.e those being transferred acutely to a bigger facility who become acutely unwell while in transit). In the first instance the Committee queried how these people would be informed of the trial. The Researchers agreed to develop an information pack or letter for patients who receive the intervention without being part of the study. The Researchers agreed to provide more information in support of meeting the best interests of each participant included in the trial without consent. The researchers subsequently noted that (contrary to the Protocol) it may be possible to carry both blood products on the helicopter. The researcher is to clarify this, and the implications for non-consenting patients.
4. The Committee encouraged the Researchers to revise the argument for best interests in the protocol with reference to Right 7(4) of the Code of Consumer Rights and Standard 7.70 of the National Ethical (NEAC) Standards. The Committee noted support from engagement with local iwi and hapū may be used in support of this argument. If there are direct benefits to participants such as the shortened transfusion timeframe, and/or following the intervention such as increased follow-up or other support they would not receive from standard care then this should be described. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.70).*
5. The Committee noted the protocol did not include a section describing the process for the event of a participant’s death and the discussion with their family about their participation. The Committee requested this is included. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
6. The Committee noted that some patients on the helicopter may require a transfusion and be capable of providing consent to this but be ineligible for study inclusion and would still receive whatever product was on board. The Committee noted there was no consent form or information for those patients and the implications for those people who receive an investigational product if they are on board a helicopter that is solely carrying this product. Please provide. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
7. The Committee queried how the Researchers will practically take into account whānau views in an emergency situation. Please ensure this is reflected in the documentation.

**Decision**

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

* *please revise the best interests argument to ensure every participant enrolled in the study without consent is participating in their individual best interest more than if they received the product but were not in the study*
* *please update the protocol to include a process for discussion with whānau of participants who do not survive*
* *please supply an information sheet and consent form for individuals who are able to provide consent at the time of the intervention on the helicopter*
* *please provide evidence of engagement with iwi and hapū from the remote rural whenua where, based on previous data, participants are most likely to be enrolled, with respect to advising them of the study and the issue of enrolling people without consent into a research study*

## New applications

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| **2** | **Ethics ref:** | **2025 FULL 21477** |
|  | Title: | RandOmised Arthroplasty infection worlDwide Multidomain Adaptive Platform trial (ROADMAP) |
|  | Principal Investigator: | Dr Thomas Hills |
|  | Sponsor: | Hunter Medical Research Institute |
|  | Clock Start Date: | 3 April 2025 |

Dr Thomas Hills and Alexandra Mowday 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 Researchers clarified that participants will be able to request their own results and will know if they have met the primary outcome.
2. The Committee noted the quality of the submitted documents and the support that will be provided to Māori participants.
3. The Researchers clarified that the samples taken from the infection of the joint are not themselves stored, rather the progeny of the cultured bacteria are grown and then stored for an extended period of time with the intention of further research being done on isolates of those bacteria.
4. The Researchers confirmed that they have experience with pathogens being sent offshore from a previous trial and intend to follow previously used protocols for isolation, storage and transport.
5. The Researchers confirmed that a waiver was being sought for the registry as it is for secondary use of deidentified data for patients who were not involved in the research 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 requested that this study include only participants who are able to give consent.
2. The Committee noted that if a participant wishes to withdraw from the study, they do not have to complete a form, participants can notify researchers verbally.
3. The Committee queried how participants will access video links if they only have access to paper copies of the PIS. Please clarify if technology will be provided to participants who do not have already existing access to technology that would allow participants to view the linked videos in the PIS.
4. The Committee requested that the landing page for the website with the available videos be formatted in a way that identifies clearly which videos are more specifically relevant to the study and which contain additional content that can provide further detail for those who wish to see it.
5. The Committee requested that the DTMP data linkage statement be revised to identify the three datasets mentioned by the researchers. The National Minimum Dataset, the joint registry and the medicines data repository.
6. The Committee noted that the DMP indicates that there will be indefinite storage of samples, this needs to be amended and a time limit for storage of samples included.
7. The Committee requested that the governance be strengthened in the DTMP for the New Zealand context as there is current emphasis on Australia.

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

1. Please include in the PIS more detailed explanation of what is planned for the bacteria taken from the infected joints and the intentions for the bacterial isolates. This should include how they may be used in research and how long they will be stored.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee*. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
4. Please supply a tissue management plan to ensure the safety and integrity of participant tissue *(National Ethical Standards for Health and Disability Research and Quality Improvement, para* *14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Kate Parker and Mr Jonathan Darby.

## New applications

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| **3** | **Ethics ref:** | **2025 EXP 22533** |
|  | Title: | Kai ā Nuku Research Project |
|  | Principal Investigator: | Dr Nicola Gillies |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 3 April 2025 |

Dr Nicola Gillies 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 Researcher clarified that recruitment will primarily take place through advertisements on social media and distribution of flyers, by members of the Centre for Health team who are not involved in the research.
2. The Researcher clarified that recordings of interviews will only be audio recordings.
3. The Researcher confirmed that the access to ingredients and recipes may differ by individual, and that personalised recommendations can be made by the student dietician around how participants can adopt the dietary requirements for this study based on the means available to the participant.
4. The researcher clarified that there is an existing, paid programme publicly available, and that participants in the study will receive resources without charge including ongoing access to resources used in the study.

Summary of outstanding ethical issues

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

1. The Committee requested that resources and documents that are referred to in the Protocol and PIS be uploaded for review including the Kai ā Nuku fundamentals and the weekly reflection journal.
2. The Committee requested that documentation reflect that data will be held for 10 years as opposed to 6 years.
3. The Committee requested that participants who wish to withdraw be able to do so via phone as well as verbally or via email.
4. The Committee requested that the DMP include the details of the Centre for Health.
5. The Committee requested that the mention of electronic consent forms on REDCap be removed, as the Researcher identified that they will not be needed.
6. The Committee noted that the interviews will be analysed in ‘Vivo’, which is a University of Auckland software. Please include this information in the DMP.
7. The Committee requested that it be made clear in both the DMP and the PIS that information will be transferred to the University of Auckland.
8. The Committee noted that participants may be attending up to 7 visits however, no koha, reimbursement for travel or parking is provided. Participants should not be out of pocket after being part of the study and should be reimbursed as appropriate. The researchers were asked to consider whether koha was appropriate.

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

1. Please clarify in the information sheet exactly what expectations are for participants. Outline that the preference is for participants to follow the programme as closely as possible.
2. Please include in the information sheet that participants in the study will continue to have full access to Kai ā Nuku resources after the study finishes.
3. Please include in the PIS that healthcare providers will be contacted directly and notified of any actionable incidental findings as a result of tests during the study. This should be consistent with the information provided in the consent form.
4. Please ensure email and contact details are correct.
5. Please add contact details to first page as per HDEC template including phone number
6. Please change wording ‘you have been asked.’ to ‘you have been invited.’
7. Please include how long visits and interviews are expected to take.
8. Please clarify in the PIS the location where visits will take place.
9. Please clarify if participants are able to bring a support person along to their interviews.
10. Please ensure that participants are aware that they will not be paid, but will receive reimbursement for travel and parking, to take part in this research.
11. Please correct the 0800 ethics number
12. Please remove reference to HDEC approving for 3 years as this is not the case.
13. Please add page numbers to the document
14. Please include ACC statement, this can be found on the HDEC template.
15. Please only include yes/no boxes in the consent form if the statement is truly optional.
16. Please explain to participants that a karakia is available at tissue disposal.
17. Please review PIS for typos.

**Decision**

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

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

## New applications

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| **4** | **Ethics ref:** | **2025 FULL 22492** |
|  | Title: | A Phase 3 Randomized, Open-Label, Multicenter Study of Sonrotoclax Plus Anti-CD20 Antibody Therapies Versus Venetoclax Plus Rituximab in Patients With Relapsed/Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. |
|  | Principal Investigator: | Dr Sarah Tan |
|  | Sponsor: | BeiGene NZ Unlimited |
|  | Clock Start Date: | 3 April 2025 |

Dr Sarah Tan 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 outstanding ethical issues

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

1. The Committee requested that the wording indicating that the study can be terminated at the decision of the sponsor be removed from the protocol, as a study cannot be terminated for commercial reasons in New Zealand.
2. The Committee requested clarification of the pre-screening process assessing age, disease and past history. This can be done prior to contact with potential participants. Please provide clarity on at what point people are approached to be in this study and when they are given the PIS.
3. The Committee requested clarification on why the whole genome was being tested, and if any results would be made available to participants. If this is not part of this study, it should be covered in a separate Future Unspecified Research information sheet and removed from the main study PIS.
4. The Committee queried whether the results of any testing of archival samples can be passed on to participants, especially in the case that their entire archival sample is used, and they may have the opportunity to enrol in another study.

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

1. Please revise the PIS for repetition and use of lay language to address length and accessibility for participants.
2. Please refer to HDEC PIS structure to assist in revising the PIS for this study.
3. Please clearly state at the beginning of the PIS that the study drug is not approved in New Zealand.
4. Please revise the table from page 6-13 for simplicity. Remove any repeated information and ensure that what is provided is easy to understand.
5. Please consider providing separate summary sheets for each arm of the study which can be provided to participants where relevant.
6. Please clarify whether the study drug will be available after the study has ended for as long as the participant is receiving benefit. Please ensure this is consistent throughout documentation.
7. Please remove wording indicating that participants need to provide receipts for reimbursement of travel, this is not required.
8. Please revise wording requesting that grapefruit or oranges are consumed ‘with caution’. If Researchers do not want participants to eat these fruits, please state clearly in unambiguous language.
9. Please remove ‘instructions for investigators’ box from the PIS.
10. Please revise the reproductive risks section.
11. Please revise the security and storage section where it indicates that identifiable information will be stored for at least 25 years to provide a maximum length of storage, the Committee do not approve of indefinite storage.
12. Please revise the FUR PIS to explain the privacy associated risks and clarify the sharing of genetic results with participants.
13. Please revise the word ‘treatment’ and replace with ‘study’ as there are therapeutic misconceptions about the use of ‘treatment’.
14. Please include the processes in place for following up quality of life questionnaires assessing risk of self-harm or suicidality outlined during the discussion. Including the availability of psychologist/psychiatrist referral pathways if needed, how this process works, including timeliness how this would be paid for and that it will not be at the expense of the participant or to publicly funded health services.
15. Please outline in the PIS that this study has been ongoing outside of New Zealand and that participants in New Zealand are joining the study.
16. Please revise precision of blood collection volumes in the PIS, these can be rounded for clarity.
17. Please revise ‘side effects’ to ‘adverse events’ as there is mention of COVID.COVID infection is not a side effect of the investigational products.
18. Please revise the reproductive risk statements, remove references to babies and unborn children instead, refer to pregnancy and the outcome of pregnancy as live birth cannot be assumed.
19. Please remove mandatory monthly pregnancy testing. If patients are not pregnant when enrolled in the study and agree to follow the contraception precautions this is sufficient. Mandatory testing is coercive.
20. Please remove ‘willingly’ consent from the optional consent form as it is unnecessary.
21. Please ensure that, when referring to contraceptive options, a male participant is not consenting to their female partner undertaking highly effective contraceptive methods that they may not be using. Clarify wording to make it clear that this is not what is being asked.

**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 Kate Parker and Mr Jonathan Darby.

## New applications

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| **5** | **Ethics ref:** | **2025 FULL 21130** |
|  | Title: | Impact of small-bite (5 mm) fascial closure following emergency midline laparotomy: a single-centre randomised clinical trial |
|  | Principal Investigator: | Dr Henry Witcomb Cahill |
|  | Sponsor: | Te Whatu Ora - Waitaha Canterbury |
|  | Clock Start Date: | 3 April 2025 |

Dr Henry Witcomb Cahill and Tim Eglinton 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 the submission states that funding will be provided by the locality, HRC, ACC and medical device company sponsorship, but this is not clear in the study documentation. The Researcher advised that this is to be determined, as they are pursuing multiple options but have yet to secure funding. This will be clearly stated in a revised protocol and in the PIS.
2. The Committee queried whether data would be sent overseas. The Researchers confirmed that it would not be sent overseas.
3. The Committee queried whether there is a commercial aspect to the study with regard to the company providing suturing materials and whether that company will have access to data. The Researcher advised that the study would not be for commercial benefit and no data is provided to the suture manufacturing company.
4. The Committee queried whether all the surgeons involved in this study will be adequately trained to avoid variability. The Researcher advised that this is a standard part of surgeon's skill set and that that small bite sutures are commonly used in elective settings. There is training material available including video. The Researcher noted that there is a surgeon in New Zealand who received training as part of the original research into the small bite procedure and that they hope to have them train the surgeons for this study.
5. The Committee queried how the size of the incision will impact on the study. The Researcher noted that there will be variability in the incision size and the pathology behind the surgery. The length of the incision and the suturing would be recorded as part of the study. The Researcher also noted that that large number of participants should account for variability. The power calculations were based on elective settings; however, it is anticipated that rates of post operative hernia will be higher in an emergency setting.

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 in the application it states that the study is single blinded, however this is not mentioned in the protocol or participant information sheet. Please update these documents to reflect that the participants will be blinded to which intervention arm they have been randomised to.
2. The Committee noted that the study must be registered with a World Health Organisation approved clinical trial registry prior to commencing.
3. Please update the protocol to reflect that the only study site will be Christchurch Hospital.
4. Please include information about the consenting process in the protocol, including who will be approached and at what point and how long they will have to consider the information. Noting that only participants who can consent may be included in the study.
5. Please ensure the number of participants and the recruitment period are consistent across all documents.
6. The Committee requested that a statement is added to the protocol and PIS to advise participants that they may receive a lay summary of the study results should they wish to.
7. Please provide some more information about who will be carrying out internal safety data monitoring in the protocol.
8. The Committee noted that the Data Management Plan currently references data gathered from questionnaires, interviews and apps. If none of these are being used in this study, then please remove reference to them.
9. The Committee noted that the Data Management Plan states that data will be stored for seven years. Please update this to the required ten years.
10. The Committee noted that the participant information sheet states that no cost will be incurred by the participant, however there are twelve and twenty-four months post operative follow up visits, if these are not standard of care then please explain who will cover these costs. Should a participant move away from Canterbury please have a plan for how this will be handled and any associated costs.
11. The Committee noted that there was mention of an easy-to-read version of the participant information sheet but that this had not been submitted. The Committee felt that this would be useful to have but would need to be submitted for review.
12. The Committee requested that the protocol includes an explanation of the intent to address the current gap in evidence about the effectiveness of small bite fascial closure in patients with a BMI above thirty.
13. The Committee requested that detail about how randomisation will be done and be added to the protocol.
14. The Committee noted that there may be benefit in adding a qualitative aspect to the study to survey surgeons on their reasons for reticence in using small-bite fascial closure in emergency settings.
15. The Committee noted that the participant information sheet refers to a twenty-four-month visit, however this is not in the protocol. Please amend these documents to reflect whether this visit is occurring or not.

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

1. Please include advice to the participants that it is possible that during surgery the surgeon may determine that the course of intervention required is opposite to the intervention arm they have been randomised to and what impact this will have on their ongoing participation.
2. Please include the information from the protocol about the thirty day post operative follow-up.
3. Please provide more information about what type of wound closure that will be provided to those individuals who choose not to participate in the study and how equipoise is maintained.
4. Please add a note that there is no additional risk associated with this procedure for participants who become pregnant post-surgery.
5. Please remove reference to data going overseas if this is not the case.
6. Please remove the statement from the consent form referring to the prevention of pregnancy, as this does not apply to this study.
7. Please change references to ‘DHB’ to ‘Health New Zealand’.
8. Please provide information about scans, including what type of scan and when these would occur.
9. Please include information to inform participants of the ionising radiation present in the procedure including its risk.
10. Please include a picture of the sutures (‘bites’) to provide clarity for participants.
11. Please explain what an incisional hernia is and that it is a risk.
12. Please remove reference to ‘we’ when referring to randomisation, rather explain how this will occur, so it is clear that it does not involve personal input.

**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 Ms Jade Scott.

## New applications

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| **6** | **Ethics ref:** | **2025 FULL 22600** |
|  | Title: | A Phase 1 Study of NEU-627 to Evaluate Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Food Effect in Healthy Volunteers |
|  | Principal Investigator: | Dr Leanne Barnett |
|  | Sponsor: | Neuron23, Inc. / Novotech (New Zealand) Limited |
|  | Clock Start Date: | 3 April 2025 |

Dr Leanne Barnett, Lucy Druzianic, Julia O'Sullivan, Kayla Malate, Mayoma Wijesun and Samantha Nie 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 asked for clarification about the consent process at the pre-screening stage and what the purpose of this was. The Researchers advised that on rare occasions when pre-screening healthy volunteers a past medical condition may be mentioned which the individual is unsure of the details, so a request for consent to access medical records is made in order to confirm whether it is something that could exclude them from participating in the study. This is documented and access limited for the stated purpose.
2. The Committee noted that it is stated that individuals who are pre-screened may have their data retained and queried whether this is clear to those individuals if this is a verbal conversation. The Researcher clarified that if the individual is being pre-screened then they will previously have been given hard copies of the participant information sheet and consent form, where this information is explained.
3. The Committee clarified the “optional cohorts”, as being optional whether the sponsor decided to run these cohorts.
4. The Committee clarified the use of sentinel dosing and determination of dose levels in the optional cohorts. The optional cohorts would only go ahead if the lower-level doses were determined to be safe by the safety monitoring committee.
5. The Committee confirmed that if the sentinel group in any cohort was dosed and it was found the dose was unsafe, the rest of the participants in the cohort would not be dosed and would be paid a prorated amount to reflect the contribution they had made to the study. Reserve participants are advised upfront that they may not be dosed and if this is the case they will be paid a fair amount.

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 requests that the sponsor consider licencing the drug in New Zealand should the trial be successful.
2. The Committee request confirmation in writing from the sponsor that there is no US Federal government funding for this study.

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

1. Please remove reference to a baby and instead refer to pregnancy and outcome of pregnancy, as a live birth cannot be assumed.
2. Please amend the statement about not consuming alcohol and cannabis to make it clear whether this is referring to both together or that neither should be consumed either separately or together.
3. Please rephrase the wording in appendix 3, regarding people who can get pregnant and people who can get other people pregnant. Currently it reads that people who can get pregnant can chose abstinence if it is part of their current lifestyle, however this should be a valid option just for the study if they so choose. People who can get other people pregnant currently are not given abstinence as an option but should be. Where a participant is a male the statement about their partner having to use contraception, needs to reflect the non-participating partners right to bodily autonomy.
4. Please state that the quality-of-life questionnaires will be completed in the presence of a clinician and if the participant become distressed the clinician will make appropriate and timely arrangements for support.

**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).*

## New applications

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| **7** | **Ethics ref:** | **2025 FULL 21774** |
|  | Title: | RELATIVITY-1093: A Phase 3, Randomized, open-label Study of Nivolumab + Relatlimab Fixed-dose Combination with Chemotherapy Versus Pembrolizumab with Chemotherapy as First-line Treatment for Participants with Non-squamous (NSQ), Stage IV or Recurrent Non-small Cell Lung Cancer (NSCLC) and with Tumor Cell programmed death-ligand 1 (PD-L1) expression ≥ 1% |
|  | Principal Investigator: | Dr Aileen Ludlow |
|  | Sponsor: | Bristol Myers Squibb |
|  | Clock Start Date: | 3 April 2025 |

Dr Aileen Ludlow 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 Researchers confirmed that there is a ‘blind’ independent review of radiology to assess outcomes as part of the study design to reduce bias caused by individual local interpretations.
2. The Researchers clarified that notification of GPs is mandatory for this study and that they will not be using sponsor provided brochures.

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 clarification around the use of the investigational assay as a mandatory part of the study and the process that will take place if locally available assays indicate a positive result, and the investigational Roche assay does not. Once clear this information should be included in the PIS and discussed with participants.
2. The Committee requested that the PIS or protocol documents outline any relevant commercial interest in the investigational assay.
3. The Committee requested assurance from the sponsor in writing that there is no US government funding for this project as BMS is based in the United States.
4. The Committee queried whether an open label design in comparing two groups will result in a possible bias effect especially in subjective endpoint assessment.

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

1. Please describe what participants can expect from a biopsy procedure, including related risks.
2. Please include that participants will not be confined to the clinic/ hospital for the duration of the study.
3. Please include in the PIS where tissue will be sent overseas.
4. Please include timepoints and any restrictions for PK determination.
5. Please remove the use of the word ‘treatment’ on its own and replace with ‘study drug’ or similar to avoid the potential misconception of therapeutic benefit.
6. Please change wording tissue ‘destruction’ to tissue ‘disposal’.
7. Please revise section ‘will it cost me anything’ for clarity.
8. Please revise wording ‘unborn babies’ and refer to pregnancy and the outcome of the pregnancy.
9. Please revise language in the contraception section of the PIS for the New Zealand context. The use of brand names can be provided to give clarity on what forms of contraception are available.
10. Please remove statement indicating that funding is not provided for any obstetrics or childcare.
11. Please use the wording ‘adverse events’ instead of ‘side effects’ where applicable and in line with the wording provided in the IB.
12. Please ensure continuity across different versions of the PIS for the different locations.
13. Please revise PIS for repetition of information and consider revision of the order on which information is presented for the lay perspective.
14. Please include effect/s of ionising radiation of imaging (scans).

**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 Mr Jonathan Darby and Dr Sotera Catapang.

## New applications

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| **8** | **Ethics ref:** | **2025 FULL 21847** |
|  | Title: | Australia and New Zealand Heart Transplant Registry |
|  | Principal Investigator: | Dr Thomas Pasley |
|  | Sponsor: | Te Whatu Ora Te Toka Tumai Auckland |
|  | Clock Start Date: | 3 April 2025 |

Dr Thomas Pasley and Kelly Marshall 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 what the time frame is from going onto the waitlist to receiving a transplant and whether this allows sufficient time for individuals to consider the participant information sheet prior to consenting. The Researcher advised that the time frame from going onto the waiting list to receiving a transplant can be anywhere from twelve hours to two years. However, there is a minimum of one week but often a few months between coming under the clinicians' care and being put on the waiting list, which allows adequate time to provide information and allow the individual to consider it properly prior to consenting.
2. The Committee noted there was a disconnect between information provided in the application submission and the participation information sheet regarding New Zealand representation in governance over decisions related to the data. The Researcher advised that this was an error and that according to their terms of reference all sites would have representation, which would include New Zealand.
3. The Committee asked for justification about including identifiable data such as names in the registry. The Research advised this is because there will be data linking regarding where the donor organ has come from and eventually data linking with death records.
4. The Committee queried what will happen in the instance of a privacy breach. The Researcher advised that there is a written policy outlining how this would be handled.

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 there will be paediatric participants, parental PIS/CF and assent forms will need to be provided. Please include assent forms for younger children and older children, and a consent form for children able to consent under Gillick competency.
2. The Committee noted that currently the Researchers do not intend to advise the participants’ GPs that they will be included in this registry. The Committee thought that it could be beneficial for the GP to be notified in case they hold information which could be relevant for the registry. The Researcher mentioned that there is a letter that goes to the individuals GP to notify them that the patient is going on the transplant waiting list and the registry could be included in this letter. The Committee agreed that this would be appropriate.
3. The Committee noted that in the protocol there are some errors where lung is referred to instead of heart, please amend.

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

1. Please remove reference to Medicare, as this is not relevant to New Zealand and replace with NHI.
2. Please be consistent when using gender or sex throughout.
3. Please ensure that appropriate ethnicity data is collected for New Zealand.
4. Please ensure that it is clear to participants that their information will be added to the registry when they go onto the waiting list, rather than when they receive a transplant.
5. Please update contact information to be specific for New Zealand rather than Australia.

**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 Catherine Garvey and Dr Andrea Forde.

## 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:** | 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 5:10pm.