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| **Committee:** | NTB Health and Disability Ethics Committee |
| **Meeting date:** | 3 June |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11.00-11.30am |  | Committee Welcome |  |  |
| 11:30am-12:00pm | 2025 FULL 18061 | STeroids in preschool Asthma Reliever (STAR) Study | Prof Stuart Dalziel | Ms Alice McCarthy / Dr Andrea Forde |
| 12:00-12:30pm | 2025 FULL 22419 | NIV-Lite Feasibility Study | Dr Tony Williams | Ms. Kate O'Connor / Dr Kate Parker |
| 12:30-1:00pm | 2025 FULL 23110 | NIV with airway washout for dual limb ventilation: Improvement in minute ventilation. | Dr Christopher Hands | Dr Joy Panoho / Dr Amber Parry Strong |
| 1.00-1.30pm |  | *Break (30 mins)* |  |  |
| 1:30-2:00pm | 2025 FULL 22066 | Brain Change Following Swallowing Skill Training | Dist. Prof. Maggie-Lee Huckabee | Ms Dianne Glenn / Dr Andrea Forde |
| 2:00-2:30pm | 2025 FULL 21897 | Bloodstream Infection Trial (BALANCE+) | Dr Susan Morpeth | Dr Joy Panoho / Mrs Leesa Russell |
| 2:30-3:00pm | 2025 EXP 22902 | ROSA® Knee System v1.5 - Pilot Study | Dr. Marc Hirner | Ms. Kate O'Connor / Dr Amber Parry Strong |
| 3.00-3.10pm |  | *Break (10 mins)* |  |  |
| 3.10-3.40pm | 2025 FULL 22793 | D7960C00015: A Phase III study of AZD0780 on major adverse CV events in patients with a history of ASCVD events or at high risk for a first event. | Dr Jane Kerr | Ms Alice McCarthy / Dr Kate Parker |
| 3:40-4:10pm | 2025 FULL 18549 | GEn-1124-003:  A Study Assessing a Single Oral Dose of GEn-1124 in Healthy Male Participants | Dr Christopher Wynne | Ms Dianne Glenn / Mr Barry Taylor |

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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 | Present |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Ms Alice McCarthy | Lay (the Law) | 22/12/2021 | 22/12/2024 | Present |
| Dr Amber Parry-Strong | Non-Lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Apologies |
| Dr Joy Panoho | Lay | 03/03/2025 | 02/02/2030 | Present |
| 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 Dianne Glenn | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |

## Welcome

The Chair opened the meeting at 11:00am and welcomed Committee members, noting that apologies had been received from Ms Maakere Marr. As this was their final meeting, the Chair thanked outgoing members Dr Amber Parry-Strong, Ms Leesa Russell, and Mr Barry Taylor.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Dianne Glenn, Dr Kate Parker and Dr Andrea Forde confirmed their eligibility and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 6 May 2025 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2025 FULL 18061** |
|  | Title: | A double-blinded non-inferiority randomised controlled trial of 1- versus 3-days of oral prednisolone for preschool children with moderate to severe exacerbations of asthma/wheeze |
|  | Principal Investigator: | Prof Stuart Dalziel |
|  | Sponsor: | Te Whatu Ora |
|  | Clock Start Date: | 22 May 2025 |

Prof Stuart Dalziel and Julia Laing 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 the hospital is the appropriate Sponsor for this study.
2. The Researchers clarified that the first dose of steroid is given to the patient prior to consenting process, in this case the consent discussion is around whether the participants will receive two more days of steroids, or placebo with the goal of comparing one day of steroid treatment compared to three days of steroid treatment.
3. Researchers clarified that the upper age limit for children included in the study is 4 years and those admitted are likely to be short of breath and distressed and would most likely not have the capacity to look at an assent graphic or form due to their condition.
4. The Researchers clarified that the reasoning for including New Zealand and Australia in the documentation was that the HDEC approval would be sought first, and then they would register the study, followed by application to the relevant Australian authority for their ethics approval.
5. Researchers indicated that they are confident that the issue raised by peer reviewers around recruiting enough participants will not cause any problems for the study, highlighting that the barrier to recruitment will be the resource constraints of emergency departments as opposed to eligible candidates.
6. The Researchers indicated, when addressing a peer review comment about exclusion of people who had received steroids within three weeks, that the three-to-four-day half-life of steroids means they are confident with continuing with their initial exclusion period of having treatment within 7 days.
7. The Researchers clarified to the Committee that they do not find that the possibility of being in the placebo group deters many parents from having their children included in the study and those that do decide not to have their children in the study for this reason do not affect the generalisability of the results of the study.

Summary of outstanding ethical issues

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

1. Please review the PIS for length, ensure that the information provided is as concise as possible.
2. Please ensure that the methods available for participants to fill out questionnaires is clearly described in the PIS.
3. Please ensure that it is clear in the PIS what form the $30 gift card is in and describe any koha that child participants will receive as acknowledgement for their contribution to the study.
4. Please clarify in the PIS what steps can be taken after discharge in emergency situations. Describe clearly that if their asthma gets worse, they should go to the emergency department, and if they have concerns about the study then they should contact the study doctor.
5. Please explain that they will receive a letter explaining their enrolment in the study that they can produce at the hospital or emergency department if required.
6. Please use a variety of language and greetings as there will be Māori and Pacific tamariki in the study.

**Decision**

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

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

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| **2** | **Ethics ref:** | **2025 FULL 22419** |
|  | Title: | Feasibility of a novel NIV nasal mask in patients receiving NIV therapy in the acute setting: An exploratory study |
|  | Principal Investigator: | Dr Tony Williams |
|  | Sponsor: | Fisher & Paykel Healthcare Ltd |
|  | Clock Start Date: | 22 May 2025 |

Tony Williams, Reuben Ayeleke and James Revie 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 explained that ‘dead space’ in this context references expired gas from the lungs that when a person exhales stay in the airways.
2. The Researchers and the Committee discussed the feasibility of any benefits for particular populations and identified that there would be little benefit for people who primarily breath through their mouth or are very sick. The Committee noted that the target population for this study seem to be quite unwell and queried if the study population should be healthier. The Researchers explained that this device has been tried by health volunteers and the aim of the current study is to determine if the patient group for this study would benefit in some way from the device. The Researchers also clarified that these participants would be clinically quite stable and would be settled in their treatment, or at the tail end of their treatment, who are able to give consent and be able to provide useful feedback to the researchers.
3. The Researchers confirmed that clinicians will still have all necessary data available as a secondary pulse oximeter is used to collect study data.
4. The Researchers confirmed that participants will only be asked one question in the ‘questionnaire’, the visual analogue scale.
5. The Researchers confirmed that the Sponsor pays an annual fee for nursing research and medical input, so although public health resources are used, this is paid for by the sponsor.
6. The Researchers clarified that they would not be excluding people with acute respiratory infections if they were well enough to meet the inclusion criteria. All patients who are admitted to the ICU needing respiratory support who are well enough to meet the inclusion criteria can be included 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 the exclusion of pregnant and breastfeeding people be removed as, from a clinical standpoint, these people would not be at risk from being included in this study.
2. The Committee requested that the Data Tissue and Management Plan (DTMP) provide more detail on the governance of the feasibility study, and remove any references to participants under the age of 16. Governance documentation policies outlined by hospital or clinical trials unit can be named and linked in the DTMP

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

1. Please simplify and shorten PIS for clarity, as patients are getting better but still quite unwell, a shorter PIS or PIS summary could be considered. A one-page summary of the PIS could be used and the inclusion of diagrams, tables, and flow charts for clarity.
2. Please include in the PIS and consent form data being used for future research
3. Please include in the PIS and consent form that data is being sent overseas.
4. Please remove incorrect wording around pregnant partners and tissue being sent overseas.
5. Please outline in the PIS what Borg scale stands for when it is first used.
6. Please either remove or make mandatory notification of GP of any incidental findings in the consent form.
7. Please remove Medicines New Zealand guidelines from the compensation section of the PIS

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).
4. Please update the data and tissue management plan, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O’Conner and Dr Kate Parker.

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| **3** | **Ethics ref:** | **2025 FULL 23110** |
|  | Title: | NIV with airway washout for dual limb ventilation: Improvement in minute ventilation. |
|  | Principal Investigator: | Dr Christopher Hands |
|  | Sponsor: | Fisher and Paykel Healthcare |
|  | Clock Start Date: | 22 May 2025 |

Dr Christopher Hands and Lotte Van Den Heuij 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 recommendations to include only people who are well enough to give informed consent made during a previous application to meet Right 7.4 of the Code of Rights have been implemented into current application.
2. The Researchers explained that pregnant people are excluded from this pilot study because of the differences in minute ventilation for pregnant people versus non-pregnant people and how this could skew their results as it is a small pilot study. In future larger studies, pregnant people will not be excluded.

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 consent section in the Data and Tissue Management Plan (DTMP) be updated using the consent wording in the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-tissue-management-template-Nov2022.docx)
2. The Committee requested that the DTMP add detail around the blood samples that are being collected for biomedical monitoring, include how samples are being collected, where they are going, and how they are being stored. If all of the sample is used up in the analysis provide that information.
3. The Committee noted that sites will have research data policies for section 3 of the DTMP that will govern research data coming out of that site.

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

1. Please revise wording indicating that the hospital internal ethics board have approved the study. This should refer to the locality assessment process as hospitals do not have internal ethics boards.
2. Please ensure that the reference to Medicines New Zealand guidelines for compensation is removed.

**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).*
* 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).*

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| **4** | **Ethics ref:** | **2025 FULL 22066** |
|  | Title: | Evaluation of Neurological Change Following Swallowing Skill Training in Patients with Dysphagia Secondary to Parkinson’s Disease |
|  | Principal Investigator: | Professor Maggie-Lee Huckabee |
|  | Sponsor: | University of Canterbury |
|  | Clock Start Date: | 22 May 2025 |

Professor Maggie-Lee Huckabee, Ms Madeline Mills and Mr Tracy Melzer 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 this is a research driven project and is not a commercially driven study. Swallow Technologies will not have any access to identified data, nor have any access to data until the study is published. During analysis and interpretation of data the commercially linked academic supervisor of the researcher will not be involved.
2. The Researchers clarified that the app does not currently AI, it is unable to manage or analyse any data outside of indicating when, or how many times, a patient hits their target.
3. The Committee commended the recognition of equity from a disability perspective in relation to this study.
4. The Researchers confirmed that they will be collecting disability and ethnicity data, however, due to the small sample size in this study may not be able to draw any statistically significant findings in these areas
5. Researchers clarified that people with visual impairments would not be included in this study as the biofeedback data involves visual output that would not be able to be interpreted by someone else.

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 if participants are receiving benefit from the app, whether they are able to continue to access the study intervention after the study has finished in order to continue receiving benefit. This free, continued access could be provided in recognition of the participation in the study.
2. The Committee requested that an alternative person to the primary academic supervisor sign as Sponsor on behalf of the institution.
3. The Committee requested that the lay summary be revised as this study has not yet determined that the use of this app is a treatment approach, these changes should also be made in the PIS.
4. The Committee requested that it be made clear why people should avoid pregnancy during this study, highlighting exposure to ionising radiation.
5. The Committee requested that a researcher safety plan be provided as there may be home visits made by the researchers.
6. The Committee requested that the indication that anything that goes wrong would be reported to HDEC be revised, as the HDEC cannot respond to any emergencies or urgent matters in respect of individual participants.
7. The Committee requested that the governance section in the Data and Tissue Management Plan (DTMP) be updated and remove references to participants under 16 years of age
8. The Committee requested that the DTMP outline to whom and to where data is being sent overseas. Possible commercial use of data should also be outlined in the DTMP.
9. The Committee requested that the study be registered with WHO clinical trials.
10. The Committee noted that the instructions for the app will be in English, which means that there may be a literacy requirement in order for participants to be able to follow app instructions, this should be outlined to participants and included as a criterion for inclusion in the study.
11. The Committee noted that a test for cognitive capacity will occur very early on in the study to determine if participants can be included in the study, and that there is a very low threshold for exclusion based on this cognitive test. This information should be clearly stated in the PIS and appropriate safety measures must be in place for individuals who may experience distress or face clinical or other implications due to an unexpected, low cognitive score revealed by the assessment.

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

1. Please provide information around the processes and funding for referrals if any abnormal results are found or if any distress is indicated from the participant. A pathway that would result in more timely care than referral to primary healthcare should be included.
2. Please clarify in the PIS that the $10 amount given to the participants per visit is to cover parking or travel
3. Please ensure that it is clear that HDEC only approve ethics of study not scientific aspects
4. Please remove tick boxes on consent form unless truly optional
5. Please explain that the video recordings will not be taken in a way that would allow for identification of the participant
6. Please include images or diagrams of any equipment or instruments that may be used in the study in the PIS.
7. Please clarify that the Northern B HDEC is approving this study.
8. Please clearly state the commercial interests involved in this 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).*
3. Please update the study protocol, taking into account the feedback provided by the Committee (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
4. Please provide a researcher safety plan, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62).*
5. Please update the data and tissue management plan, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

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

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| **5** | **Ethics ref:** | **2025 FULL 21897** |
|  | Title: | BALANCE+: A Platform Trial for Gram Negative Bloodstream Infections |
|  | Principal Investigator: | Dr Susan Morpeth |
|  | Sponsor: | Sunnybrook Research institute |
|  | Clock Start Date: | 22 May 2025 |

Dr Susan Morpeth 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 indicated that they expect approximately 20% of their participants will be able to give supported consent, and another 20% are expected to not be able to consent in for themselves at all. The Researchers explained that they believe their study meets the threshold for best interest for including people who cannot consent for themselves in a study as inclusion means that participants will receive more input and oversight of their treatment from a specialist infection service group, more timely follow ups and referrals, and more time with research nurses for additional advice. The Committee indicated that they were satisfied that the study meets right 7.4 of *The Code of Health and Disability Services Consumers' Rights* threshold for including these participants.
2. The Researchers clarified that the reason for the starting age in the protocol being 18 is to keep in line with the Canadian protocol, the Researchers also indicated that it is unusual for gram negative sepsis to appear in teenage years.
3. The Researchers explained the amount of time that people will have with the participant information sheet to decide if they wish to participate can vary, however, would most likely be a few days and no less than 24 hours. This time variation can depend on a range of factors, including, how unwell people appear upon presentation, whether they are sent to general medicine or Intensive Care Unit (ICU) and then, whether they will need surgical or medical intervention. The Committee were satisfied that participants are given sufficient time with the study information to decide if they wish to take part in the study.
4. The Researchers confirmed that catheter retention outlined in the protocol is relevant only to the Canadian study and is not going to be used in New Zealand

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 a separate Participant Information Sheet is provided to allow participants to consent to continue in the study and to permit the use of previously collected data once they have regained the capacity to give fully informed consent. The main adult PIS cannot be used as continued consent is given in a different context to which the main adult PIS is given i.e after randomisation. The Committee recommended the researchers contact Colleagues known to have extensive experience in this to refer to documents around contingency for non-consenting studies that highlight what will happen to data in myriad of situations for example, where participants cannot be contacted before they give a consent-to-continue.
2. The Committee noted it was unclear in documents whether there will be Future Unspecified Research (FUR) with stool samples. The Data and Tissue Management Plan (DTMP) indicates that tissue will be included in biobanks and that there is FUR agreed to, however the PIS indicates broadly specified future research, however no indication of biobanking. For participants who cannot consent ‘specified future research’ is more generally acceptable. In the PIS the specificity of the future research still falls under specified future research and such information should be included in the DTMP. The information provided in the DTMP on biobanking should be clarified to indicates that the tissue samples are held for a maximum of 5 years and should also be included in PIS and in the protocol.
3. The Committee requested that the data linking information be provided clearly and more specifically in the protocol and DTMP, detailing exactly what data will be used and accessed, this information should also be provided in the PIS.
4. The Committee noted that peer review #40 describes a Kaupapa Māori principles protocol that is not consistent with the submitted protocol and requested clarification of the relevance of this peer review to this study.

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

1. Please revise wording on main PIS indicating that participants ‘could receive additional follow up care’ to say that participants ‘will receive additional follow up and care’.
2. Please identify the points of follow up that participants will receive due to participation in the study and provide information on what will happen if further follow up is needed.
3. Please consider a New Zealand specific addendum for the Protocol to address New Zealand specific legal and ethical requirements around consent for this population. This will need to include provisions for clinical sign-off of participation in best interests, follow up consent, ascertaining of family wishes, and the section on deferred consent needs to be revised for New Zealand context.
4. Please provide a supported consent PIS document.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
4. Please update the data and tissue management plan, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O’Connor and Dr Joy Panoho.

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| **6** | **Ethics ref:** | **2025 EXP 22902** |
|  | Title: | A single-arm, monocentric, cross-sectional, pilot study evaluating the new OptimiZe and Activ Track applications for The ROSA® Knee System, v1.5, in patients undergoing primary total knee arthroplasty. |
|  | Principal Investigator: | Dr Marc Hirner |
|  | Sponsor: | Zimmer Biomet Pty Ltd |
|  | Clock Start Date: | 22 May 2025 |

Massoud Shahi and another sponsor representative 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 Sponsor confirmed that the ROSA system is in clinical use and clarified that this study aims to evaluate a new version of the software to be introduced into the system. This version update is primarily for updating User Interface (UI) and additional information provided to surgeon on what knee alignment the surgeons could execute on specific patients. The introduction of this new version of software would not impact the standard of care.
2. The Sponsors clarified that the ROSA system is licensed for use by Medsafe and that the Sponsor is carrying out due diligence before rollout of the new version.
3. The Sponsor confirmed that if a patient does not consent to be in the study the surgeon can use the previous software version for their surgery.
4. The Sponsor clarified that, while the lead investigating surgeon is an advisor to the company, he is not a consultant with responsibilities for advising on this particular product. This is a bespoke product and does not have a large pool of potential surgeons who would be users. It was a safety provision for patients to have a surgeon who is familiar with the product without the need for training. This was a key consideration for having this lead investigator.
5. The Sponsor highlighted that if the ten cases were split between multiple surgeons, then the statistical significance of any findings becomes much smaller.
6. The Sponsor clarified that the exclusion of pregnant people is an exclusion for having the surgery itself, not to do with any study requirements.
7. The Committee clarified that Te Whatu Ora was not involved in the study which is conducted solely at Kensington Hospital which will be the sponsor.

Summary of outstanding ethical issues

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

1. The Committee raised concerns around the PI and his role in the study, in terms of potential conflict of interest with the commercial aspect of the study and in relation to the power dynamic between himself and the potential participants. The Committee requested that the researchers address these risks, and clearly provide for how these aspects will be minimised and managed.
2. The Committee noted that the provided self-insurance certificate is not an acceptable form of insurance to provide to ensure that the Committee is confident that, if a participant is injured as part of study will they be compensated. As such, the Committee requested that evidence of ACC equivalent insurance should be provided
3. The Committee noted that the participant list is being sourced from the lead investigator’s patient list, this raises concerns around the power dynamic when asking people to participate in the study and during the consent process. The Committee requested that someone in the hospital who is not clinically responsible for the patient be able talk through the consent process with patients in order to remove power imbalance when patients are deciding if they wish to participate.
4. The Committee requested reassurance that participants will not be moved up the waiting list if they are included in the study, this should also be outlined in the recruitment and consent section in the protocol.
5. The Committee requested that any references to ‘legally authorised representatives’ are removed as this is both not relevant in New Zealand and all participants will be consenting themselves.
6. The Committee requested that evidence of Māori consultation be provided. Kensington may have given locality approval and may have carried out consultation as part of their process, however, evidence of this consultation needs to be provided to the HDEC. This should include a letter from someone who has some form of mandative authority to indicate that consultation has taken place and outline if they are willing to be approached by participants who would like cultural advice.
7. The Committee requested more information about the peer reviewer’s affiliation and other appropriate details
8. The Committee noted that the Data Management Plan (DMP) references Future Unspecified Research (FUR) data, however this is not mentioned in the PIS. Please remove the FUR section from the DMP.
9. The Committee noted that the demographic questionnaire does not have New Zealand specific options. The Committee requested that a sperate questionnaire be used to capture New Zealand specific ethnicity data.

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

1. Please explain what the difference between participating and not participating is, outlining what will occur in this study that would otherwise not happen in standard of care. Describe the different features available for the new software version, including the new UI, how it is expected to be more easily understandable for the primary benefit of the surgeon. And that the additional layer of information that will be provided for the surgeon will display options for the surgeon to use for alignment of the knee that have been recorded preoperatively.
2. Please revise the wording in the PIS to address the reader of the as ‘you’ not ‘the participant’ or ‘patient.
3. Please clarify how ‘lifestyle choices’ data collected is relevant to the study.
4. Please remove ‘protected populations’ as that is not a category in New Zealand
5. Please clarify if participants are required to do anything as part of the study, if there is not then clarify this.
6. Please revise information indicating that data is anonymised, instead the PIS should indicate that the data in this study is coded which means participants can still be identified using unique identifiers.
7. Please ensure that information indicating that participants should check with their insurer whether taking part in the study would affect their cover is moved into the discussion about co-payments and gap payments
8. Please remove yes/no tick boxes if statement refers to mandatory part of participation
9. Please revise wording indicating that the scientific aspects have study has been approved by a peer reviewer, instead, there could be an explanation that there has been extensive internal review by Zimmer Biomet, if that is the case

**Decision**

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

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

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

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| **7** | **Ethics ref:** | **2025 FULL 22793** |
|  | Title: | A Phase III, Randomised, Double-blind, Placebo-controlled, Parallel-group Study to Assess the Effect of AZD0780 on Major Adverse Cardiovascular (CV) Events in Patients with Established Atherosclerotic Cardiovascular Disease (ASCVD) or at High Risk for a First ASCVD Event |
|  | Principal Investigator: | Dr Jane Kerr |
|  | Sponsor: | AstraZeneca Ltd. |
|  | Clock Start Date: | 22 May 2025 |

Jane Kerr, Lucy Druzianic, Kayla Malate, Julia O’Sullivan and Kody Shaw 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 indicated that for this study they do not believe there is much risk of double enrolment across different sites, as there is a relatively low monetary reimbursement for ‘reasonable travel’
2. The Researchers clarified that the reasoning for the difference in age inclusion criteria between men and women is because of the differences in risk for cardiovascular disease between these two groups. The Researchers also acknowledged that Māori would typically have a younger age of onset for cardiovascular disease, which is not reflected in the study as it is an international protocol. The Researchers also noted that anyone over the age of 18 who has had an event can be included in the study.
3. The Committee noted that placebo is justified as participants are on regular standard care and more frequent follow ups
4. The Researchers clarified that the PI is not the participant’s usual doctor.

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 a study specific safety protocol be put in place and provided to outline processes in the case that any psychological concerns are raised because of a participant’s responses to the EQ5D questionnaire. This should be in addition to any site-specific safety protocols. Although participant questionnaires are checked for completeness the day that they are filled out, further referral or funding for a specialist appointment should be provided in case any concerning results. Participants will need to be made aware that concerns will be followed up and given an outline of the safety process that are put in place.
2. The Committee requested that reproductive statements be reviewed to ensure contraception and pregnancy sections are relevant to the participants in the context of this study.
3. The Committee requested clarity of how independent cultural consultation and review is carried out for this specific study. Clarification that more broad cultural consultation takes place continuously across document templates can be provided in tandem with details of study specific consultation.

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

1. Please revise wording indicating that the study medicine is not approved in New Zealand’ to be clear that the study drug is not approved anywhere.
2. Please clarify up front in the PIS that this is potentially a four-and-a-half-year study
3. Please revise document to replace ‘drug’ with ‘investigational medication, or investigational medicine’ where necessary.
4. Ensure any statements about routine pregnancy testing, and other statements about contraception etc relate to these participants

**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 Alice McCarthy and Dr Kate Parker.

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| **8** | **Ethics ref:** | **2025 FULL 18549** |
|  | Title: | A Phase 1, Single Dose, Open-label Study to Assess the Pharmacokinetics of GEn-1124 after Single Oral Dosing in Healthy Subjects |
|  | Principal Investigator: | Dr Christopher Wynne |
|  | Sponsor: | GEn1E Lifesciences, Inc. |
|  | Clock Start Date: | 22 May 2025 |

Dr Christopher Wynne, Lucy Druzianic, Kayla Malate, Julia O’Sullivan and Kody Shaw 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 exclusion of females from this study is to limit the variability in results, as it is a small study, and the absorption of the material because there may be a difference in gender absorption of the drug, confining the population of the study to a very specific group can minimise the number of people exposed to the dose. The Researchers also indicated that this study has no therapeutic benefit for participants.
2. The Researchers confirmed that there is no sentinel dosing because of the short half-life of the drug, and because no unknown adverse events are expected, clarifying that while this is a phase one study in New Zealand it is a known medicine
3. The Researchers clarified that ethnicity data is being collected more so to obtain data on who is applying for clinical trials and for reporting to HDEC as opposed to the study itself analysing data based on ethnicity.
4. The Researchers clarified this study is in healthy participants which would mean anyone with disabilities associated with a disease would be excluded.
5. The Researchers clarified that the amount of compensation provided is in $USD.
6. The Researchers clarified that the indication that this molecule may reactivate tuberculosis is because any molecule that has an impact on inflammatory processes may potentially impact immunity. This provision is not because of anything unique to the molecule.

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 any references to pregnancy testing in the documentation and references to breastfeeding in the pre-screening section be removed.
2. The Committee requested that options that are not relevant to the study are removed from the advertising materials.
3. The Committee requested that the digital media section identify the best email address for contact within New Zealand
4. The Committee expressed its preference for reassurance, in writing, that there is no United States government funding for this study.

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

1. Please revise wording “you must get a partner pregnant”
2. Please remove the word ‘and’ page 8, fourth tick, second line
3. Please ensure participants are aware that in any photos that are taken during the study faces are obscured to ensure participants are not identifiable.
4. Please ensure ‘investigational medication’ is provided in place of ‘drug’

**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).*
* 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).*

## General business

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

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| --- | --- |
| **Meeting date:** | 1 July 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 4:10pm.