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| **Committee:** | NTB Health and Disability Ethics Committee |
| **Meeting date:** | 06 May 2025 |
| **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 22261 | A 26-Week, Study to Evaluate the Efficacy, Safety, and Tolerability of Axatilimab in Subjects with Idiopathic Pulmonary Fibrosis (IPF) | Dr Michael Epton | Ms. Kate O'Connor / Mr Barry Taylor |
| 12.00-12.30pm | 2025 FULL 22522 | Usability and performance of a dual limb mask for non-invasive ventilation. | Dr Christopher Hands | Dr Joy Panoho / Mrs Leesa Russell |
| 12.30-1.00pm | 2025 FULL 22756 | The TRANSCEND study - Phase 3 study to evaluate Felzartamab compared to placebo in kidney transplant recipients diagnosed with active or chronic active Antibody-Mediated Rejection (AMR). | Dr Sophie Harmos | Ms Alice McCarthy / Dr Andrea Furuya |
| 1.00-1.30pm |  | Break (30 mins) |  |  |
| 1.30-2.00pm | 2025 FULL 22155 | SKY-0515-004-ANZ: A phase 2/3 study of SKY-0515 in Participants with Huntington’s Disease | Prof Tim Anderson | Dr Joy Panoho / Dr Amber Parry Strong |
| 2.00-2.30pm | 2025 FULL 22829 | Evaluating Glucose Control using a Next-Generation Automated Insulin Delivery Algorithm in Adults with Type 2 Diabetes: EVOLUTION2 | A/Prof Martin de Bock | Ms Maakere Marr / Dr Andrea Furuya |
| 2.30-3.00pm | 2025 FULL 22648 | An Active Comparator Safety Study Evaluating the Combination of APG777 + APG990 in Moderate-to-Severe Atopic Dermatitis | Professor Marius Rademaker | Ms Alice McCarthy / Mrs Leesa Russell |
| 3.00-3.30pm | 2025 FULL 22832 | ALLAY-HFrEF STUDY | Professor Gerard Wilkins | Ms. Kate O'Connor / Dr Amber Parry Strong |
| 3.30-4.00pm | 2025 FULL 22812 | EASi-KIDNEY (Studies of Heart & Kidney Protection with BI 690517 in combination with empagliflozin) | Associate Professor Janak de Zoysa | Ms Maakere Marr / 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 | Apology |
| 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 | Present |
| Dr Joy Panoho | Lay | 03/03/2025 | 02/02/2030 | Present |
| Dr Andrea Furuya | Non-Lay | 03/03/2025 | 02/03/2029 | Present |

## Welcome

The Chair opened the meeting at 11.00am and welcomed Committee members, noting that apologies had been received from Leesa Russell.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Andrea Furuya confirmed their eligibility and were co-opted by the Chair as a member 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 01 April 2025 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2025 FULL 22261** |
|   | Title:  | A 26-Week, Randomized, Double-Blind, Placebo-Controlled, Multi-centre Study to Evaluate the Efficacy, Safety, and Tolerability of Axatilimab in Subjects with Idiopathic Pulmonary Fibrosis (IPF) |
|   | Principal Investigator:  | Dr Michael Epton |
|   | Sponsor:  | Syndax Pharmaceuticals, Inc. |
|   | Clock Start Date:  | 24 April 2025 |

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

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried what the prognosis is for people with Idiopathic Pulmonary Fibrosis and what the current treatment options are. The Researchers noted that IPF has been described as worse than lung cancer and has around a five-year progression with no significant treatment options available.
2. The Committee noted that participants will be randomised at a one-to-one ratio and queried whether twenty-six weeks is a long time for participants to potentially be on a placebo infusion. The Researcher advised that it is not, the infusions will only occur every few weeks and this is a relatively short study in this disease setting.
3. The Committee queried whether this study would go onto an open-label phase. The Researcher advised that it could potentially but not that they were aware of at this stage.
4. The Committee queried whether electronic patient reported outcomes (ePROs) would be done during site visits. The Researcher advised that they will.
5. The Committee queried whether there is any threat to United States federal funding involved in the study. The Researchers advised that there was not to their knowledge.
6. The Committee queried whether there had been a delay in the study starting as the insurance certificate was dated to start from 2023. The Researchers advised that they were originally approached about the study in 2022 but it did not start in New Zealand straight away and they have only now been asked to start the study 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 noted for future reference, stating that Māori have the same right to participate in the study should not be presented as a benefit.

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

1. Please avoid referring to the experimental drug and placebo as treatment, rather use investigational product.
2. Please remove reference to spoons when referring to blood, use ml’s instead.
3. Please state whether the sponsor has committed to the Medicines New Zealand guidelines. If they have not, then please remove this statement.

**Decision**

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

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

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| **2**   | **Ethics ref:**   | **2025 FULL 22522** |
|   | Title:  | Usability and performance of a dual limb mask for non-invasive ventilation. |
|   | Principal Investigator:  | Dr Christopher Hands |
|   | Sponsor:  | Fisher and Paykel Healthcare |
|   | Clock Start Date:  | 24 April 2025 |

Dr Christopher Hands, Jo, and Lotte van den Heuij 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 request to have a closed meeting was declined as it only applies to trade secrets rather than intellectual property under the Official Information Act.
2. The Committee queried in what circumstances a NIV mask can be prescribed. The Researcher advised this can be anything from an acute intensive care setting to at home for sleep apnoea. The Committee questioned given that information why the intent to conduct the study in the more acute patient population. The Researchers advised that the single limb mask is designed for things such as in home use, but the dual limb mask is designed to be used with machines typically found in a critical care setting and that this is the patient population that it would be used in.
3. The Committee queried whether changing the mask twice creates any risk for the participant. The Researcher noted that they would only change the mask if it was safe for the participant to do so. The Researcher also noted that it is standard practice to remove masks briefly to allow patients to have a drink and give them a respite from the invasive feeling of the mask.
4. The Committee queried whether the Investigators Brochure relates to this specific mask and whether it has had any clinical testing. The Researchers advised that they Investigators Brochure does relate to this specific mask, but it has not had any clinical testing, only bench testing at this stage.
5. The Committee queried what had come out of the Māori consultation process. The Researchers advised that this would be part of the locality sign off process and had not occurred yet, however they would incorporate any recommendations as part of this process.

**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 per *right 7.4 of the code of Health and Disability Consumer rights*, there is not a strong argument for including participants who are unable to consent for themselves on the grounds of best interests and therefore recommend only including those participants who are able to consent, for the first stage of the trial. Once data in these participants has shown a benefit, then the best interest’s argument would be effective, and the trial could justify expanding to include those who cannot initially consent.
2. The Committee requested some rephrasing in the protocol to make it clear that this is a feasibility study aiming to prove non-inferiority.
3. The Committee noted that the scientific rationale provided in the scientific review lacks sufficient detail to support the ethical justification of the study and recommended a more comprehensive review of the existing evidence, including relevant studies or data supporting the intervention and study design, is needed to assess the risk-benefit balance. *9.25-9.32 of the National Ethical Standards*
4. The Committee noted that the response to C10 in the submission form around responsiveness to Pacific peoples came across as patronising. Please consider rephrasing to more mutually respectful language. *4.1 of the National Ethical Standards*
5. The Committee noted that the Data Management Plan needs to include more information rather than referring to the protocol. For example, what data will be collected, where and how it will be stored and that this will be consented to. When referring to identifiable data currently only consent forms are mentioned, however it is likely that collected data may include an NHI number, so should also be mentioned here. [Data and Tissue Management Plan templates | Health and Disability Ethics Committees](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/)
6. The Committee noted that clinicians will complete a survey about the use of the mask, therefore they are participants in the study and a PIS/CF will need to be developed for them.
7. The Committee noted that contingency framework will need to be put in place for un-consenting participants, which includes information on what will happen to data if a participant does not recover or discharges themselves prior to signing consent to continue. Along with processes for individuals who do not have family that can be contacted or are not in an appropriate state to comment on whether someone might be likely to wish to participate. *7.67-7.69 of the National Ethical Standards*
8. The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):
9. Please refer to the HDEC intervention template and ensure that all relevant sections are included [Participant Information Sheet templates | Health and Disability Ethics Committees](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
10. Please remove the statement about the Medicines New Zealand guidelines, as this is a device study, this does not apply.
11. The Committee recommend expanding the benefits section to include the additional oversight of a dedicated study nurse, and further explanation on intended benefit of a reduction in rebreathing, such as preventing acidosis.

**Decision**

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

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| **3**   | **Ethics ref:**   | **2025 FULL 22756** |
|   | Title:  | A Double-Blind, Placebo-Controlled, Multicentre, Randomized Phase 3 Trial Evaluating the Efficacy and Safety of Felzartamab in Kidney Transplant Recipients with Late Antibody-Mediated Rejection (AMR) (TRANSCEND) |
|   | Principal Investigator:  | Dr Sophie Harmos |
|   | Sponsor:  | Biogen Idec Research Limited |
|   | Clock Start Date:  | 24 April 2025 |

Dr Sophie Harmos and Andrew Pilmore 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 sought clarity around the prognosis for this disease and whether these individuals will be on the transplant waiting list. The Researchers advised that individuals with this condition have done all the right things post-transplant however their immune system is still rejecting the kidney, so they will be at a much higher risk of transplant failure. The participants that will be enrolled for this study will not be at the stage of requiring another transplant yet, as this process can take years.
2. The Committee queried the length of time for some participants to be on placebo. The Researchers noted that two out of three participants will be on the intervention, and for those on placebo there is no active alternative to offer instead of placebo, other than immune suppressants which they will continue. Six months is required due to this being a long-term fix and any less than six months is unlikely to achieve any benefit. Based on the inclusion/exclusion criteria all these participants are still expected to maintain kidney function for six months. After six months all participants will be on the active intervention.
3. The Committee queried whether this is an open label extension. The Researchers advised it is not, rather it is part B of the study. In part A there will be a placebo arm and the intervention will involve different dose levels. In part B everyone will be unblinded and all put on the same dose of intervention. The sponsor is considering an open label extension at the conclusion of the study once they have more data about appropriate timeframes between doses.
4. The Committee queried whether there would be follow up in writing to the participants general practitioner (GP) if there were any issues of concern, as currently it states that they will be contacted via phone. The Researchers advised that if there was something that needed to be followed up on then they would also email the GP.
5. The Committee queried the rationale for excluding people with Human Immunodeficiency virus (HIV) and Hepatitis B or C. The Researcher explained that this is due to the medication posing a risk of causing reactivation or worsening of infection. The likelihood of having a potential participant with either of these conditions is low but should someone present, it could be discussed with the medical monitor.

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

1. Personal information appears to have been conflated with identifiable data.
2. Please refer to the HDEC template for wording around compensation and data. [Participant Information Sheet templates | Health and Disability Ethics Committees](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
3. Please refrain from using treatment when referring to an investigational product.
4. Please remove the yes/no option from the consent form for things that are not truly optional, such as the one relating to pregnancy.
5. Please state that in addition to reimbursement for travel costs, participants will receive a stipend of $135 for each visit.
6. Please change ‘biohazard waste’ to ‘tissue samples’, as referring to blood as waste is not culturally acceptable.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Alice McCarthy and Dr Andrea Furuya.

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| **4**  | **Ethics ref:**   | **2025 FULL 22155** |
|   | Title:  | A Phase 2/3 Randomized, Double Blind, Placebo-Controlled, Dose Ranging Study to Evaluate the Pharmacodynamics, Safety and Efficacy of SKY-0515 in Participants with Huntington’s Disease |
|   | Principal Investigator:  | Prof Tim Anderson |
|   | Sponsor:  | Skyhawk Therapeutics, Inc. |
|   | Clock Start Date:  | 24 April 2025 |

Ms Laura Paermentier 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 there seems to be excitement in the Huntington’s community about the proposed research. The Researcher commented that there have recently been new research targets identified, and many individuals with Huntington’s are engaged in following research developments.
2. The Committee noted that the Researchers are likely to have an existing relationship with the Huntington’s community and queried whether they will be able to easily recruit the target number of forty participants. The Researcher acknowledged that they do have a relationship with Huntington’s sufferers and their families as it is often passed onto children due to its genetic nature. The Researcher felt each of the two sites should easily recruit ten participants each but are hopeful with travel and accommodation provided, that they may be able to get participants from the South Island too.
3. The Committee noted that one in four participants will be on placebo and asked for confirmation that the study would progress to an open label phase. The Researcher stated that all going well the sponsor does intend to progress to an open label phase.
4. The Committee queried whether there is any federal funding involved in this study. The Researcher confirmed there is not, Skyhawk is a private pharmaceutical company.
5. The Committee queried how results of the questionnaire will be followed up. The Researcher noted that while participants will be referred to a psychiatrist if required, the PI will continue to be involved, as this is not an uncommon requirement for people with Huntington’s.

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 reconsenting every three months is unusual and request that this is only done alongside already scheduled visits. Noting that if changes were made to the protocol and PIS/CF because of safety committee findings, reconsenting would be required anyway.
2. The Committee noted that prior to commencement the trial will need to be registered with a World Health Organisation approved clinical trials registry.
3. The Committee request that all site staff who will be giving the questionnaires undergo the Columba training.
4. The Committee noted that the Māori data sovereignty section of the Data Management Plan needs to be updated, to remove reference to data being stored in a ‘cancer registry’. It also refers to the Director of Māori Health Research across different District Health Boards (DHB’s), this it out of date, as we no longer have DHB’s and there is only one Director of Māori Health Research. Please also check for Māori spelling of words, particularly the use of macrons.
5. The Committee queried whether the medication needed to be kept refrigerated as it is being transported in a chiller bag. The Researcher advised that it does not need to be kept refrigerated, it is only kept in the chiller bag during transportation to prevent it from getting too hot while kept in the back of a vehicle for a long period. The Committee reviewed the Investigators Brochure which states “SKY-0515 drug product (active and placebo) is stored at 2-8⁰C”, and the Instructions for taking study drug, which states “Please store your bottle of SKY-0515 or placebo in the refrigerator. Do not leave out of the refrigerator for any extended time”. Therefore, the Committee request that a statement is added to the PIS advising participants of the requirement to store the investigation product in the fridge.

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

1. Please remove the word “discharged” from page 11, as the participants will not be in-patients, rather state “have left the clinic”.
2. On page 15 please state the stipend amount. Please ensure this is consistent across sites. Please remove reference to time, as this is considered payment. The Committee recommend giving participants the option or petrol or supermarket vouchers.
3. Please state clearly that blood samples, which are stored for fifteen years, may be used for future research, specifically for Huntington’s disease only.
4. Please update for site specific contact information.
5. Please state that the sponsor has agreed to the medicine New Zealand guidelines.

**Decision**

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

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

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| **5**   | **Ethics ref:**   | **2025 FULL 22829** |
|   | Title:  | Evaluating Glucose Control using a Next-Generation Automated Insulin Delivery Algorithm in Adults with Type 2 Diabetes: EVOLUTION2 |
|   | Principal Investigator:  | A/Prof Martin de Bock |
|   | Sponsor:  | Insulet Corporation |
|   | Clock Start Date:  | 24 April 2025 |

A/Prof Martin de Bock, Cecilia Ross, Indy Wellesley, and Trang 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.

Amber Parry Strong declared a potential conflict of interest and the Committee decided to excuse her from the discussion and decision for this application.

Summary of resolved ethical issues

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

1. The Committee noted that this study is a follow up from a previous study. The Researcher agreed and commented that it is positive to continue to offer options for individuals with type 2 diabetes.
2. The Committee asked for clarification about what ‘announcing meals’ means. The Researcher explained that this refers to systems that require the user to input prior to eating an approximation of the amount of carbohydrates they will be consuming, so that the system does not react to a sudden change in glucose levels and provide too much insulin. Noting that the ideal system would not require the user to announce meals and at the same time to cause peaks and troughs in insulin levels.
3. The Committee acknowledged and appreciated the advice that no US federal funding is involved in this study.

Summary of outstanding ethical issues

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

1. The Committee require an updated Medical Protection Services certificate for the Principal Investigator, as the one submitted with the application has expired.

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

1. Please state the value of the voucher that participants will receive to state it will be $100 per visit.
2. Please state that HDEC have approved the ethical standards of the study on pages 10 and 14.
3. Please remove the macron from the word taonga on pages 8 and 10.
4. Please update the relevant site contact information.

**Decision**

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

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

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| **6**   | **Ethics ref:**   | **2025 FULL 22648** |
|   | Title:  | A Phase 1b, Open-label, Randomized, Multicenter, Active Comparator Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of the Combination of APG777 + APG990 in Adults with Moderate-to-Severe Atopic Dermatitis |
|   | Principal Investigator:  | Professor Marius Rademaker |
|   | Sponsor:  | Apogee Therapeutics, Inc. |
|   | Clock Start Date:  | 24 April 2025 |

Professor Marius Rademaker, Rakesh Aher, Haley Funderburk, and Tharika Dealwis 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 some discrepancy between there being a 52 week follow up period for those finishing the study and a single visit for those choosing to exit the study. The Researcher clarified that 52 weeks follow up is the ideal but for those individuals who decide that they do not want any further involvement with the study, they need to at least have one final visit.

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 recommend establishing at least an internal Data and Safety Monitoring Committee, if not an independent committee, given that this is a phase one trial.
2. The Committee stated that requiring participants to provide receipts is burdensome, and the Committee prefer to see sites giving participants vouchers to cover costs, rather than using third party apps for reimbursement.
3. The Committee noted that if future unspecified research (FUR) may be carried out on the samples that will be stored for fifteen years, then a separate FUR PIS/CF will be required to be submitted to the Committee for approval.

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

1. Please ensure consistency about how long samples will be stored for, currently it states both no more than fifteen years and indefinitely, or if both of these are true for different samples, please make this clear for participants.
2. Please amend the statement that Dupilumab is available in New Zealand as this is not accurate.
3. Please be transparent about the fact that participants will receive different payment amounts based on how complete their diary is.
4. Please just use ethnicity rather than race.
5. Please provide a yes or no option for the statement about samples being used for future research related to atopic dermatitis.
6. Please change the wording from ‘biohazard waste’, which is culturally inappropriate, to ‘tissue samples’, when referring to disposal.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Alice McCarthy and Dr Amber Parry Strong.

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| **7**   | **Ethics ref:**   | **2025 FULL 22832** |
|   | Title:  | Safety and Efficacy of the Alleviant No-Implant Interatrial Shunt in Patients with Heart Failure and Reduced Ejection Fraction. |
|   | Principal Investigator:  | Professor Gerard Wilkins |
|   | Sponsor:  | Alleviant Medical Inc. |
|   | Clock Start Date:  | 24 April 2025 |

Professor Gerard Wilkins and Emma Cox 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 questioned the reason for the cap on participants in the US. The Researcher commented that previous cardiac studies have produced differing results in the US compared with the rest of the world.
2. The Committee queried the need for a sham arm. The Researcher commented that the placebo effect would make it difficult to tell if participants were truly experiencing benefit without the benefit of a sham arm to compare to. The Researcher also pointed out that in about two years’ time if it is apparent that the procedure is successful, this will be offered as a cross-over to the sham participants.
3. The Committee queried the prognosis for people with this disease, given that if participants have the sham procedure, they will be waiting two years before receiving the intervention, should it prove successful. The Researcher advised that mortality at two years for participants would be about ten percent. Individuals with stage four heart failure would be excluded from the study, as they would not be likely to still be alive after two years.
4. The Committee queried why the last stage of screening is blinded. The Researcher explained that this is because the last stage of screening is to conduct a trans-oesophageal echo to determine if the inter-atrial septum is thin enough for the procedure, and this is done under anaesthesia. At this point if the inter-atrial septum is thin enough, they will be randomised, and the procedure or sham performed. If it is too thick, they will not be randomised and instead woken up and advised.

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 new peer review of this protocol, as the one submitted is a few years old and does not relate to the current protocol.
2. The Committee requested that advertising material is reviewed, as currently it refers to “investigational treatment” and does not mention that there is a placebo control and is therefore overselling benefit.
3. On the poster, please rephrase to state that HDEC approve the ethical aspects of the study.
4. The Committee requested a copy of the Investigators Brochure.

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

1. Please state on the first page that there is a one in two chance of being randomised to the sham procedure and provide some information about what is involved in the sham procedure, such as that a catheter will be inserted into a blood vessel up until around the heart.
2. Please rephrase the benefit section to make it clear that there is no benefit to those randomised to the sham arm.
3. Please state that travel will be reimbursed and the process for this.
4. Please remove reference to teaspoons and use ml’s instead.
5. Please remove reference to future research if the tissue limb is not being done in this study in New Zealand.
6. Please give participants the option to have their tissue returned to them if they wish.
7. Please rephrase to state that HDEC approve the ethical aspects of the study.
8. Please check for grammar and spelling mistakes, for example, add a macron to the word whānau.
9. Please remove reference to legally authorised representative, as this is not applicable to New Zealand.
10. On page one where it states, ‘the Federal Drug Administration (FDA) has not approved’, please add ‘anywhere in the world including New Zealand’.
11. Please refrain from using treatment, instead use investigational procedure. This would also be a more appropriate term to use than ‘device’.
12. Please add some information about the companion study and the experience the surgeons have had doing this procedure, as this is reassuring for participants.
13. On page 7 please give an indication of when month twelve of the last participant reaching follow up will be.
14. Please refer to the HDEC template for wording in the ‘my information’ section. [Participant Information Sheet templates | Health and Disability Ethics Committees](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
15. On page 12, in New Zealand the sponsor may not stop the study for commercial reasons alone.
16. Please describe the process for family members being contacted if participants are lost to follow up, currently this is not mentioned until the consent form.
17. Please remove the statement from the consent from about discontinuing the study intervention, as this is a one-off procedure.
18. Please remove the reference to Medicines New Zealand guidelines, as this does not apply to 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).*

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 Amber Parry Strong.

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| --- | --- | --- |
| **8**   | **Ethics ref:**   | **2025 FULL 22812** |
|   | Title:  | Studies of Heart & Kidney Protection with BI 690517 in combination with empagliflozin: A multicentre, international, randomised, double-blind, placebo-controlled clinical trial of the aldosterone synthase inhibitor BI 690517 in combination with empagliflozin in patients with chronic kidney disease |
|   | Principal Investigator:  | Associate Professor Janak de Zoysa |
|   | Sponsor:  | Boehringer Ingelheim |
|   | Clock Start Date:  | 24 April 2025 |

Associate Professor Janak de Zoysa, Daniel O’Hara, and Chelsea Bassett were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that this is a resubmission of a previous decline and thanked the Researchers for coming back to this Committee. Reasons for previous decline included the documents having been designed overseas and not tailored to a New Zealand audience, and confusion around the trial being commercially sponsored.

Summary of outstanding ethical issues

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

1. The Committee request a certificate of currency to show evidence Accident Compensation Corporation (ACC) equivalent insurance.
2. Please review the Medsafe data sheet for empagliflozin, to see if instructions for washing twice daily need to be included in the participant information sheet.

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

1. The PIS/CF is currently quite dense and length, please simplify the information sheet, see the HDEC template for guidance. [Participant Information Sheet templates | Health and Disability Ethics Committees](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
2. Currently the Data Management section is heavily weighted to overseas jurisdictions, please make this relevant to what is happening in New Zealand.
3. Please ensure the section about what happens when the study is over clearly explains which participants would still be able to access empagliflozin and which participants wouldn’t, and that it is not funded.
4. Please remove any yes/no check boxes from the consent form, that are not truly optional.
5. Please remove teaspoons of blood, instead use ml’s.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Maakere Marr and Mr Barry Taylor.

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 03 June 2025 |
| **Zoom details:** | 965 0758 9841 |

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. **Any other business**

The Secretariat requested support from Committee Members with timely review of response to provisional approvals.

The meeting closed at 4.00pm.