|  |  |
| --- | --- |
| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 08 July 2025 |
| **Zoom details:** | 812 7953 3520 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 10:00am-10:30am |  | Committee Welcome |  |  |
| 10:30am-11:00am | 2025 FULL 23157 | ASCEND First in Human Study | Dr Andrew Holden | Dr Maree Kirk / Dr Nicola Swain |
| 11:00am-11:30am | 2025 FULL 22943 | Acquired Stuttering: Characteristics and Treatment | Ms Kate Tyson | Ms Dianne Glenn / Dr Geoff Noller |
| 11:30am-12:00pm | 2025 FULL 23292 | A study comparing two formulations of thioguanine in healthy participants (HDEC) | Dr Noelyn Hung | Ms Neta Tomokino / Dr Nicola Swain |
| 12:00pm-12:30pm |  | *Break (30 mins)* |  |  |
| 12:30pm-1:00pm | 2025 FULL 23332 | A study of BBT001 in Adults with Moderate to Severe Eczema | Dr Arna Letica | Dr Maree Kirk / Dr Geoff Noller |
| 1:00pm-1:30pm | 2025 FULL 23366 | Brain Network Stimulation for Internalizing Psychopathology | Prof Dirk De Ridder | Ms Dianne Glenn / Dr Tristan Sames |
| 1:30pm-2:00pm | 2025 FULL 21981 | GOROX | Doctor Bryony Simcock | Ms Neta Tomokino / Dr Geoff Noller |
| 2:00pm-2:15pm |  | *Break (15mins)* |  |  |
| 2:15pm-2:45pm | 2025 EXP 20364 | Protocol of a Pilot Study to Estimate HbA1c from Glucose Monitoring  | Associate Professor Arindam Basu | Ms Dianne Glenn / Dr Nicola Swain |
| 2:45pm-3:15pm | 2025 FULL 23326 | KRIYA-586-101 (the RECLAIM study): A Study to Evaluate VV-14305 in Patients with Thyroid Eye Disease | Dr Rohit Katial | Ms Neta Tomokino / Dr Tristan Sames |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Mr Dominic Fitchett  | Lay (the Law)  | 05/07/2019  | 05/07/2022  | Apologies |
| Dr Tristan Sames | Non-lay  | 09/06/2025 | 08/06/2028 | Present |
| Dr Nicola Swain | Non-lay  | 22/12/2021 | 08/06/2030 | Present |
| Ms Dianne Glenn | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Neta Tomokino | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Dr Geoff Noller | Non-Lay | 03/03/2025 | 02/03/2029 | Present |
| Dr Matthew Moore | Non-Lay | 09/06/2025 | 08/06/2028 | Apologies |

## Welcome

The Acting Chair, Dr Nicola Swain, opened the meeting at 10.00am and welcomed Committee members, noting that apologies had been received from Mr Dominic Fitchett and Dr Matthew Moore.

Neta Tomokino opened with a karakia.

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 10 June 2025 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1**   | **Ethics ref:**   | **2025 FULL 23157** |
|   | Title:  | Aneurysm SaC ManagemENt Device for Abdominal Aortic Aneurysms First-in-Human (ASCEND) Study |
|   | Principal Investigator:  | Dr Andrew Holden |
|   | Sponsor:  | Life Seal Vascular Inc |
|   | Clock Start Date:  | 26 June 2025 |

Dr Andrew Holden and Miss Cynthia Corne 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 application was originally scheduled to be reviewed by the Central HDEC but was withdrawn before the meeting. Most of the original issues raised by the Central committee members have been resolved before submitting for review by this Committee.
2. The Committee noted that the CI is a shareholder in the commercial sponsor company but were satisfied that any conflict of interest is being well managed.

Summary of outstanding ethical issues

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

1. The Committee queried whether the potential participants clinician could advise them about the trial at the point when they have been approved for surgery.
2. The Committee noted that a further PIS/CF would be required before any potential explant surgery.

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

1. Please note that a single line can be used for offering an interpreter, rather than the tables on both forms.
2. Please add a yes/no option to the consent form for future unspecified research.

**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).*

|  |  |  |
| --- | --- | --- |
| **2**   | **Ethics ref:**   | **2025 FULL 22943** |
|   | Title:  | Acquired Stuttering: Exploring Behavioural Characteristics, Response to Treatment and Brain Changes Associated with Stuttering. |
|   | Principal Investigator:  | Ms Kate Tyson |
|   | Sponsor:  | University of Canterbury |
|   | Clock Start Date:  | 26 June 2025 |

Ms Kate Tyson 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 there are three arms to the study and queried at what point the consent process occurs. The Researcher advised that consenting would occur before participants enter arm one and will be consented for all three arms. During the course of the study assessments, it may be uncovered that the individual’s speech disfluency is not in fact acquired stuttering, in which case they would not complete all of the study arms.
2. The Committee queried whether individuals would be able to participate if they have a power of attorney who can consent on their behalf. The Researcher advised that participants need to be able to practice the intervention at home, so would need to be able to consent for themselves.

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 given the limited funding available for the study, how the costs will be covered for overseas participants to complete the MRI portion of the study. The Researcher noted that overseas participants will not be eligible for the MRI portion of the study. The Committee noted that this should be clear in the protocol and PIS.
2. The Committee queried whether funding would be available for people with disabilities for transportation. The Researcher advised that they have insufficient funding to cover transportation costs for all participant’s but that they would discuss with their supervisor and department to see if it is possible to get funding for services such as Driving Miss Daisy.
3. The Committee noted that participants must be fluent in English to be included in the study and queried whether this point was discussed as part of the Māori consultation process. The Researcher advised that it was not discussed and that as none of the Research team are fluent in Te Reo Māori, whilst they could provide support to individuals who are not fluent in English, they would be unable to participate in the study. The committee noted that this needs to be clear in the PIS.
4. The Committee noted that storing video recordings of children indefinitely which may be used in future research is quite vague and does not highlight potential risks, with what is a significant decision. The Researcher advised that this is discussed in depth during the consenting process and that it is explained these recordings may be used for teaching purposes or at conferences. The Committee felt that this warrants separate consenting and contact to advise of the intended uses at the time when this will occur. Given the children in the study are experiencing stuttering which may be in relation to another condition, this makes them a vulnerable population group and consideration should be given to this.
5. Please amend the statement on the poster to be clear that HDEC review the ethical standards and do not approve all aspects of the study.
6. The Committee raised the point that speech therapy is very expensive, making this study very appealing for parents who have children who stutter. The Researcher noted that there would be a limited number of children in the study as acquired stuttering is relatively rare in children. The intent of this study to gain evidence in this area to try and improve access to treatment. Developmental stuttering is different and has funding for treatment through the education system, although wait times are significant. The Researcher noted that they are likely to have individuals referred to the study who have many different types of speech disfunction that are not suitable for inclusion in this study and wondered whether it would be appropriate to keep a record of the different types of presentation that they reviewed and what referrals were made for these individuals. The committee agreed that this would be useful data to gather.
7. The Committee noted that the protocol requires more detail about international participants.
8. Please check all documents for spelling and typos, for example “number” is spelt incorrectly in the advertising.

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

1. Please consider labeling the assent forms “younger child” and “older child” rather than having age ranges, as this allows them to be used with more discretion.
2. Please state that individuals with aphasia may participate in the study.
3. Please state that supported decision making may be available when necessary.
4. Please amend the statement to be clear that HDEC review the ethical standards and do not approve all aspects of the study.
5. Please review for spelling and grammar, for example under the image “taken” is spelled incorrectly.
6. Please add the option for future research to all consent forms, as it is currently only on one.
7. Please include a statement about access and removal of barriers for participants with disabilities. If funding for transport for participants with disabilities is available, please state this.
8. The protocol mentions the risk of distress associated with a TBI; this point should be included in the risk section of the parents PIS.
9. Please state that extra support with speech therapy will be at no cost to the participant.

**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 Dianne Glenn and Dr Geoff Noller.

|  |  |  |
| --- | --- | --- |
| **3**   | **Ethics ref:**   | **2025 FULL 23292** |
|   | Title:  | A single dose, randomized, two-treatment, three period, three sequence, partial replicate, reference-scaled, crossover, bioequivalence study comparing 1 × 40 mg R-211 tablet (Douglas) with 1× 40 mg Tabloid® tablet (Aspen Global Inc) in healthy participants under fasting conditions. |
|   | Principal Investigator:  | Dr Noelyn Hung |
|   | Sponsor:  | Douglas Pharmaceuticals Ltd |
|   | Clock Start Date:  | 26 June 2025 |

Dr Noelyn Hung, Linda Folland, and Dr Jason Long 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 process for consultation is. The Researchers advised that a representative comes to the site and reviews the documentation and provides feedback.
2. The Committee queried the exclusion of pregnant and breastfeeding people. The Researchers noted that this is manufacture recommendation due to risks for fetal abnormality and post-natal development.
3. The Committee noted that information in the submission was unclear around whether consenting would be done individually. The Researchers advised that there would be a group information session but consenting would be done individually.
4. The Committee queried the person who has signed the sponsor authorisation does not work for the sponsor. The Researcher advised that as CRO he has delegated authority from the sponsor to sign and that the form is still shared with the sponsor.
5. The Committee noted that the submission states the trial will not be registered with a clinical trials registry. The Researcher advised that is incorrect and it will be registered.
6. The committee enquired about NZ level ethnicity data, and the researchers confirmed that this was collected and will be reported to HDEC.
7. The Committee noted that locality sign off has been completed, however Māori consultation is not complete and sign off should not occur until this is complete.

Summary of outstanding ethical issues

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

1. The Committee noted that the submission stated that “this study may provide an option to patients who do not respond to currently available treatments” and that this should be phrased as a potential outcome of study, as research cannot be called treatment.
2. The Committee note that the insurance certificate is expired. Please provide a current insurance certificate.
3. The Committee noted that as it is not always feasible for karakia to be given when tissue is disposed of, could karakia be offered at the time of blood draw instead.
4. The Committee noted that the response in the submission stating pacific issues are the same as Māori issues, is not a sufficient response.
5. Please include information about the facilities available and things that people can do while on site. The Researchers noted that they have a separate information sheet that they give to participants. The Committee noted that as this is a participant facing document it should be submitted to HDEC for review.

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

1. Please review for technical terms and ensure lay language is used throughout, with any medical terms defined.
2. Please review for spelling and typos.
3. Please include examples of exclusion criteria.
4. Please change Central to Southern for the HDEC who has approved the ethical aspects of the study.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Neta Tomokino and Dr Nicola Swain.

|  |  |  |
| --- | --- | --- |
| **4**   | **Ethics ref:**   | **2025 FULL 23332** |
|   | Title:  | A Randomized, Blinded, Placebo-controlled, Single- and Multiple-ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, Pharmacodynamics and Exploratory Clinical Activity of BBT001 in Healthy Volunteers and in Adult Patients with Atopic Dermatitis |
|   | Principal Investigator:  | Dr Arna Letica |
|   | Sponsor:  | Bambusa Therapeutics Inc. |
|   | Clock Start Date:  | 26 June 2025 |

Dr Arna Letica Thang Ho, Lisa Li, Wenbing Hu, Wei Lin, Michelle Tang, Venesha Retham, Kshemina Mhaskar and Cheryl Glover 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 rescue treatment will be and whether this will impact participation in the trial. The Researchers advised it will be topical corticosteroids and if this proves to be ineffective and the participant requires oral or IV treatment then they will conclude the study at that point.
2. The Committee queried why participants are not able to receive their results from the study. The Researcher advised that they would go through with participants any clinically significant results but information about pharmacokinetics will be blinded, so not available at an individual level.
3. The Committee queried the recommendation that participants phone 111 or attend an emergency department if they experience side effects after receiving a dose and leaving the study site. The Researcher advised that this is because they are only open business hours and that if it is life threatening, they do not want to delay the participant from seeking treatment. Participants will be given a card with an on-call phone number and information about the study that can be presented to clinicians.

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 197 days is a long time to be on placebo for those individuals with severe eczema and would like further consideration to be given to this timeframe and justification for its requirement. The Researcher noted that rescue treatment is permitted after 97 days and that this will be highlighted as a potential risk to all participants during screening.
2. The Committee asked for clarification about how much the stipend will be and whether this also covers other costs such as transport and meals. The Researchers noted that the amounts are all inclusive, however meals are provided on site, and have been finalised and submitted via correspondence. As no amendments can be made to applications after submission and prior to review at the meeting, this document will need to be submitted as part of the non-standard conditions.
3. The Committee queried what “support” means for people who test positive for Hepatitis C. The Researcher advised that this includes notifying the Ministry of Health, as it is a notifiable disease, advising the participant of the diagnosis and referring them to their GP for appropriate treatment. The Committee noted that Hepatitis C is commonly contracted by intravenous drug use and therefore there can be stigmatisation around this disease, so it would be appropriate to gain the participants consent before informing their GP.
4. The Committee queried having substance abuse disorder in the PIS as an exclusion, although this is not in the protocol. There needs to be a clear definition included.
5. The Committee queried the rationale for excluding people who use cannabis, noting that it can be prescribed in New Zealand. The Researcher noted that this is to avoid contraindication, and because it is unknown whether cannabis provides any treatment effects.
6. The Committee noted that it is a requirement to collect New Zealand ethnicity data which may be different from the ethnicity data that the sponsor intends to collect.
7. The Committee noted for future reference regarding the response for cultural considerations the answer provided was not specific for this participant population which it should be.

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

1. Please change marijuana, to cannabis.
2. Please state the reasons for excluding cannabis use.

**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).*

|  |  |  |
| --- | --- | --- |
| **5**   | **Ethics ref:**   | **2025 FULL 23366** |
|   | Title:  | A Triple Network Stimulation Approach for the Treatment of Internalizing Psychopathology: A proof-of-concept study |
|   | Principal Investigator:  | Prof Dirk De Ridder |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 26 June 2025 |

Ms Cindy van Sleeuwen and Divya Adhia were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried whether data about participants disabilities will be collected. The Researchers stated that disability data will be collected at screening.
2. The Committee queried whether it is necessary to notify Medsafe of the conclusion of the trial. The Researcher advised that as it is a device trial they do need to notify Medsafe when the study commences and concludes.

Summary of outstanding ethical issues

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

1. The Committee noted that this study will need to be registered in a World Health Organisation approved clinical trials registry before commencing.
2. The Committee noted that some individuals may be considered too unwell to participate and queried the process for providing support to these individuals. The Researcher advised that there is an on-call psychiatrist who would be contacted to arrange emergency care for these individuals. The Committee requested that this detail be added to the protocol.
3. The Committee queried why pregnant people and recently pregnant people are excluded. The Researcher advised that pregnancy and/or birth may have influenced the internalizing psychopathology of the individual, so this is to remove that as a confounding factor.
4. The Committee noted that most lay people will not know what internalizing psychopathology means, so recommend changing the language on the advertising to depression or anxiety.
5. The Committee queried what follow up will be done with participants. The Researcher stated that they can add a follow up phone call or email as a wellbeing check, two weeks and a month after completion of the trial.
6. The Committee queried whether a registered medical practitioner would be present during the administration of the intervention. The Researcher advised that the intervention would be performed by a PhD student. The Committee would like it confirmed that a registered health professional will be supervising the intervention.

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

1. Please revise to ensure understanding for lay people.
2. Please state that you expect participants to feel better and how long you anticipate these results to last and that then participants will likely return to their pre-study levels.
3. Please state that access to the interventional product will not be available at the end of the study and provide some explanation for why not.
4. Please state that participants may have whanau present during study visits.
5. Please state that participants may attend visits on weekends if they are unable to attend during the week.
6. Please change the statement to say that HDEC review the ethical standards, rather than approve the study.
7. Please clarify the koha is the only payment participants will receive, aside from providing disability transportation. Also remove mention of time, as time is taxable.
8. Please provide an explanation about what will happen when the device is in use and what brain stimulation is.
9. In the contact information Professor Glue is listed as a psychologist, please change to psychiatrist.
10. Please state that karakia is available at the start and end of each visit.

**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 Dianne Glenn and Dr Tristan Sames.

|  |  |  |
| --- | --- | --- |
| **6**   | **Ethics ref:**   | **2025 FULL 21981** |
|   | Title:  | Quality of life and adherence to post-operative thromboprophylaxis following surgery for gynaecological cancers: rivaroxaban vs low molecular weight heparin – The Gynaecology Oncology RivarOXaban acceptability study |
|   | Principal Investigator:  | Dr Bryony Simcock |
|   | Sponsor:  | Te Whatu Ora Waitaha |
|   | Clock Start Date:  | 26 June 2025 |

Dr Bryony Simcock and Faye Riley were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried whether participants would consent to deidentified data being shared with other researchers or if this was a requirement. The Researchers advised that it is an option on the consent form for participants to consent to their deidentified data being shared with researchers in Australia.
2. The Committee noted that throughout the submission the language “we believe” is used and sought reassurance that there is in fact sufficient scientific evidence to justify the trial. The Researcher noted that there have been similar studies which had good evidence but were underpowered, and that it is approved by Pharmac for use in an orthopaedic setting.
3. The Committee noted that one of the outcomes is looking at clot prevention but queried whether the study is powered to test this. The Researcher stated that they are not, and this is just an exploratory outcome at this stage, as it is easy to gather.
4. The Committee queried who will make the first approach to potential participants. The Researchers advised that there is a research nurse who will identify potential participants and advise their clinician who will advise them of the trial and ask if they would like to be contacted by the research nurse.

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 that the QoL questionnaires will be reviewed within 2 weeks and noted that within twenty-four hours would be more appropriate to screen for signs of serious distress requiring follow up.
2. The Committee noted that written confirmation of withdrawal is not required in New Zealand, verbal notification is all that is needed.
3. On page 5 it states if you start to feel unwell, please contact a doctor. This is probably insufficient given wait times for GP appointments. Please offer a study contact number and provide participants with a card they can give to medical professionals to advise them of their participation in the trial.

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

1. Please review to ensure that this is written for a lay audience and any medical terms defined.
2. The Committee would like to see the information from 13.6 of the protocol included in the PIS, as they felt this is reassuring to participants.
3. Please soften the language around “instructing” participants to discuss with their GP.

**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 Neta Tomokino and Dr Geoff Noller.

|  |  |  |
| --- | --- | --- |
| **7**   | **Ethics ref:**   | **2025 EXP 20364** |
|   | Title:  | Development and validation of Human Digital Twins for reversing Type II Diabetes |
|   | Principal Investigator:  | Associate Professor Arindam Basu |
|   | Sponsor:  | University of Canterbury |
|   | Clock Start Date:  | 26 June 2025 |

Associate Professor Arindam Basu and Karaitiana Taiuru 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 queried the rationale for using GPs for recruitment, as there are increasing numbers of New Zealanders who do not have a GP and whether social media could be another option. The Researchers felt that as this is a pilot study and only a small number of participants are required that they could achieve their target through the GP, especially as it involves using a continuous glucose monitor.

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 any advertising material will need to be submitted to the Committee for review before use.
2. The Committee asked for the rephrasing of “the diabetic”, rather state “the person with diabetes”.
3. The Committee noted that there is mention of a website but that this was not included in the application and queried whether e-consent would be used. The Researchers advised that they intend to have a QR code and website with e-consent, but this had not been finalised with the sponsor at the time of making the application. The Committee advised that these need to be provided to the Committee for review.
4. The Committee queried the notification of the GP and suggested stating in the PIS that if an individual’s results are of concern, you will discuss these with them, and this could include notifying their GP.

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

1. Please state at the top of the form that translation is available for Māori and any other language that you can offer. Also state if there are other languages it can be read to the participant in.
2. Please remove the black box warning as this is not required for this study as it is not a first in human trial of a new medicine.
3. Please state the aims of the study in plain language, i.e. that the intention is to collect a small amount of data to train an algorithm to predict blood glucose levels.
4. Please include information for potential participants who already use a continuous glucose monitor, that explains how they could participate in the study.
5. Please review to ensure that information provided is relevant to the participants in this study, for example this study is not using AI to control and reverse diabetes.
6. Please remove italics, unless for special emphasis.
7. Please state that karakia will be available at the time of tissue disposal or collection depending on which is possible.
8. Please amend the statement to say that HDEC approve the ethical aspects of the study rather than the entire study.
9. Please state clearly that the blood test is essential, so potential participants should not consent if they are not willing to have a blood test.
10. Please include an option in the consent form for participants to consent to the future use of deidentified data for research.
11. Please clarify which costs will be covered by the study and state the process for obtaining reimbursement.
12. Please remove the benefits section as there are no benefits to the participant for this study.
13. Please simplify the costs section.

**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 Dianne Glenn and Dr Nicola Swain.

|  |  |  |
| --- | --- | --- |
| **8**   | **Ethics ref:**   | **2025 FULL 23326** |
|   | Title:  | KRIYA-586-101 (the RECLAIM study): A Study to Evaluate VV-14305 in Patients with Thyroid Eye Disease |
|   | Principal Investigator:  | Dr Rohit Katial |
|   | Sponsor:  | Kriya Therapeutics, Inc. |
|   | Clock Start Date:  | 26 June 2025 |

Dr Rohit Katial, Lucy Druzianic, Dr Chris Wynne, Samantha Nie, Kayla Malate and Julia O’Sullivan 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 the time frame of the study. The Researchers stated that the two-year period is for all of the cohorts, but participants will only be in the study for fifty-six weeks.
2. The Committee acknowledged and expressed appreciation for the inclusion of the paragraph explaining how the study would affect the participants whakapapa.

Summary of outstanding ethical issues

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

1. Please review to ensure this is written in lay language and any technical terms are explained. For example, Orbitopathy, anti-IGF1R antibody, microbicide, etc.
2. Please move the statement around the optional long term follow up to after the risk section, to improve the flow of readability.
3. On page 16 please change ‘monkey’ to ‘non-human primate’.
4. Please add ‘natural remedies’ to the statement asking participants to disclose supplements.
5. On page 2 of the optional genetic research sub study PIS, there is reference to a sample, please state what type of sample e.g. blood.
6. On page 3 of the optional sub study, there is a typo, an extra ‘t’ in the statement about karakia.
7. On page 6 of the optional sub study, point 10 ‘what if something goes wrong’ please copy the information from the main PIS.

**Decision**

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

* 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).*

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 12 August 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.

The meeting closed at 3.00pm.