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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 12 November 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 10.30-11.00am | 2024 EXP 20797 | Deep learning analysis to determine outcome following stroke intervention - a follow-up study | Dr William Diprose | Mr Dominic Fitchett and Dr Amy Henry |
| 11.00-11.30am | 2024 FULL 21300 | Transplant and Cellular Therapies (TCT) Registries | Dr Andrew Butler | Dr Maree Kirk and Dr Nicola Swain |
| 11.30am-12.00pm | 2024 FULL 19639 | The VIGILANT study | Professor Geoffrey Shaw | Ms Dianne Glenn and Dr Devonie Waaka |
| 12.00-12.30pm | 2024 FULL 21127 | ORKA-001-111: A Study to Evaluate ORKA-011 in Healthy Volunteers Following A Single Dose. | Dr Chris Wynne | Ms Neta Tomokino and Dr Amy Henry |
| 12.30-1.00pm | *Break* |  |  |  |
| 1.00-1.30pm | 2024 FULL 21501 | Phase 3 Low-Grade Serous Ovarian Cancer Trial (Ramp 301) | Dr Michelle Wilson | Mr Dominic Fitchett and Dr Nicola Swain |
| 1.30-2.00pm | 2024 FULL 21091 | TransShield Embolic Protection System | Dr Sanjeevan Pasupati | Dr Maree Kirk and Dr Devonie Waaka |
| 2.00-2.30pm | 2024 FULL 21269 | BIOCONCEPT.CorSky Family | Dr Matthew O'Connor | Ms Dianne Glenn and Dr Amy Henry |
| 2.30-3.00pm | 2024 FULL 21213 | A study to evaluate efficacy and safety of belzupacap sarotalocan (AU-011) in subjects with primary indeterminate lesions or small choroidal melanoma (CoMPASS Study) | Dr Riyaz Bhikoo | Ms Neta Tomokino and Dr Nicola Swain |
| 3.00-3.30pm | 2024 AM 13080 | CIRCA NZ: Investigation and Research of Patients with Immune Dysfunction (AMENDMENT) | Dr Ignatius Chau | Mr Dominic Fitchett and Dr Devonie Waaka |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Devonie Waaka | Non-lay (Intervention studies) | 18/07/2016 | 18/07/2019 | Present |
| Mr Dominic Fitchett | Lay (the Law) (Chair) | 05/07/2019 | 05/07/2022 | Present |
| Dr Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Dr Nicola Swain | Non-lay (Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | 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 |

## Welcome

The Chair opened the meeting at 10.00am and welcomed Committee members followed by a karakia, noting that no apologies had been received.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 15 October 2024 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2024 EXP 20797** |
|  | Title: | Deep learning analysis of intra- and post-procedural imaging to determine outcome following stroke clot retrieval - a follow-up study |
|  | Principal Investigator: | Dr William Diprose |
|  | Sponsor: | Te Whatu Ora - Auckland |
|  | Clock Start Date: | 31 October 2024 |

Dr Kaustubha Ghate was present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

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

**Summary of resolved ethical issues**

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

1. The Researcher confirmed all data would come from the national stroke database and individual patient medical files would not be accessed. The Researcher confirmed the data available to the computer scientist who developed the model is deidentified.
2. The Researcher clarified the model would include the data of about 800 patients.
3. The Researcher confirmed the model is open-access on Github and will not be commercialised.
4. The Committee queried why a log to link data back to the patient is required. The Researcher stated the outcome data from the model would need to be linked with the code back to the patient to analyse trends and identify further variables to feed into the model. The Researcher explained this is to prevent the patient’s identifiers being put into the model.

**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 Researcher confirmed ethnicity data would be captured in the database. The Committee queried if the model would include this ethnicity data. The Researcher stated the model would deidentify patient demographics including gender and ethnicity. The Committee queried how the study would address ethnic inequities if this data is not included. The Committee expressed concern at not including this variable as this may miss an important variable to help the model predict an individual’s outcome. The Committee noted this would be important for the New Zealand population especially as the model will be using New Zealand data. The Researcher agreed to consult with model’s developer.
2. The Committee encouraged the Researcher to include gender in the model as well to reduce the risk of introducing bias.
3. The Committee advised the importance of including Māori perspectives into the design, development and testing of the model and this should be done before the model is deployed so appropriate cultural recommendations can be incorporated.
4. The Committee advised future use of data is not appropriate as this has not been consented to. The Researcher clarified it meant future research using the same data from the database in future applications with ethics approval. The Committee requested Section 8.5 of the data management plan is amended to reflect this as it currently reads as open access for use of the data. The Committee advised future research using this would require new applications.
5. The Committee requested the data management plan specifies that clinical outcome data will be analysed to see whether the model is working.
6. The Committee requested section 4 of the data management plan is updated to refer to current NEAC standards for both data management and AI.
7. The Committee queried if the study would be presented to NAIAEAG as it involves a national dataset. The Researcher stated this was not currently planned and agreed to discuss with the other investigators. The Committee recommended checking local hospital requirements for submitting to NAIAEAG.
8. The Committee noted the peer review is from a registrar and requested an additional peer review from a consultant radiologist is supplied.
9. The Committee discussed the need for a social licence to undertake research of this nature and requested the Researcher check if the registry has a patient advisory group. If so this or another applicable consumer group should be consulted on use of the data.

**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 supply an additional peer review from a suitable expert eg consultant radiologist.
3. 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).*
4. Please update the data management plan. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15*).

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Dr Amy Henry.

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| **2** | **Ethics ref:** | **2024 FULL 21300** |
|  | Title: | Transplant and Cellular Therapies (TCT) Data Collection and Management Registries |
|  | Principal Investigator: | Dr Andrew Butler |
|  | Sponsor: | Te Whatu Ora - Waitaha |
|  | Clock Start Date: | 31 October 2024 |

No researcher 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.

The Committee advised it would be useful to have the Researchers attend the discussion of the resubmission.

**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 it was unclear if this was a research activity as there does not appear to be a proposal to use the data, only collect it for unknown use by others. This could potentially be a quality improvement activity and require transparency and informing consumers under the NEAC National Ethical guidelines. This would also require informing consumers that some data will be uploaded even if they decline to participate.  *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 18.11)*
2. The Committee noted it was unclear whether the application is requesting the existing registries are added to the international registries listed or if it is to consent new patients.
3. The Committee requested clarification on the current status of registry enrolment and if enrolments have proceeded in all three registries after 2020 when it was recognised HDEC approval is required.
4. The Committee noted the only protocol provided is for the CIBMTR. Please provide protocols for the ANZTCT and NZBMDR.
5. The Committee requested the rationale for not requesting locality approval as an additional site for registries that have already received HDEC approval. It is entirely usual for a CI to have oversight of a registry at multiple New Zealand sites while being clinical lead at one centre only; in those cases the local clinical leads are referred to as PIs.
6. The Committee noted there does not appear to have been any formal consultation process with Māori regarding the registries themselves. Please ensure this is undertaken prior to further enrolment of participants.
7. The Committee requested a description of the enrolment process for adults lacking capacity to provide independent consent (per D1 in the HDEC application form).
8. The Committee requested information on how participants enrolled into the study prior to HDEC approval will be managed (e.g. will consent be sought if the site is able to contact the patient).
9. The Committee requested the following changes to the Data Management Plan (DMP) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*:
   1. Please clarify why, in a purely observational study, participants cannot request the withdrawal of their data from the registry database (G6 of the application form). Note the response is at odds with the participant information sheet/consent form (PIS/CF) which states withdrawal of data is permitted, with the caveat that it cannot be removed from previous analyses.
   2. The data management plan submitted states that some data will still be submitted to CIBMTR and the ANZTCT even for participants who do not consent. Please clarify what data is submitted to the CIBMTR. Please also clarify whether patients are specifically informed that some data will be submitted regardless of their consent.
   3. Please clarify why first letter of first name and surname, and date of birth are submitted as part of the ANZTCT form. If these details are required access should be restricted to site-only. Please confirm if this is the case.
   4. Please clarify the statement that consent is not required for in-house CDHB databases used for research purposes. Note also that a superseded version of the Health Information Privacy Code is referenced.
   5. The submitted data management plan does not address many of the requirements listed in Standard 12.15a of the NEAC Standards. Please provide a document that fulfils these requirements. If necessary, a separate data management plan should be submitted for each registry.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please state more clearly who has access to each form of data.
2. Please state the risks associated with data being stored and analysed overseas.
3. Please state whether genetic data will be recorded.
4. Please state how long data will be retained for.
5. Please include information on data linkage and whether participants agree to be contacted for future research.

**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:** | **2024 FULL 19639** |
|  | Title: | VIsualisation of critical care aGItation and sedation with higher resoLution Assessments and evaluation of a fitNess Tracker: The  VIGILANT study |
|  | Principal Investigator: | Professor Geoffrey Shaw |
|  | Sponsor: | University of Canterbury |
|  | Clock Start Date: | 31 October 2024 |

Professor Geoffrey Shaw, Professor Geoff Chase, and Isaac Flett 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 an error in the application form which stated all participants would give consent which missed the preceding part of the study with unconscious participants. The Researcher explained clinical or research staff would identify eligible patients and a researcher would discuss with the family and obtain their assent for the unconscious participant to participate, then once consciousness is regained they would be approached for consent. The Committee noted research involving activities done to participants such as drawing blood would require something more formalised than familial assent such as a welfare guardian or enduring power of attorney. The Researcher clarified the only intervention that happens other than gathering data is placing a heart watch on the participant’s wrist and then taking blood samples from existing cannulae. The Researcher stated this is standard in an intensive care research environment. The Researcher clarified the blood would only be used once the participant has awoken and given consent.
2. The Committee queried how enrolment would be in the best interest of the participant. The Researcher stated they would have increased monitoring of their agitation and sedated state and more information will be available in their condition which may lead to better care.
3. The Committee queried the process if a participant does not regain the capacity to give consent and what happens to their data/samples. The Researcher stated if the assent from whānau is given and the participant does not survive the data would be used as its removal would bias the study results.
4. The Committee stated it was satisfied the best interest’s test may be met; the only exception is the use of blood samples from participants who do not survive. The Committee queried which subset of participants would have blood samples. The Researcher stated participants who are anaemic or would be adversely affected by having extra blood taken would not be included otherwise they would be enrolled if they were expected to be in the full duration of the assessment, e.g. mechanically ventilated for up to a week but at least 48 hours. The Researcher clarified samples would not be analysed until later for logistics reasons and so samples where participants did not give later consent could be excluded.
5. The Researcher confirmed data from the watch is wiped from the device after use by each participant and no third party would use it for other purposes.
6. The Researcher clarified the AI component was for deep machine learning in the analysis of the data after collection.
7. The Researcher clarified the poster was intended for hospital staff.

**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 the following changes to the Data Management Plan (DMP) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*:
   1. Sections 7 and 8.1 to state samples will be labelled with a participant code only
   2. Section 7.3 to state this is not applicable as data will not be collected anonymously.
   3. Section 8.1 to state GPs will not be notified, as this is not intended per the application form.
   4. Specify that future unspecified research will not be undertaken.
   5. Please include a section under deidentified data to discuss management of smartwatch data (eg they are numbered, livestreamed and no data is retained by the third party).
2. The Committee requested the Researcher develop an information sheet and consent form for participants who regain consciousness to consent to ongoing use of their data and samples.

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

1. Please include more information on how data from the smart watch will be managed (e.g. how it is labelled, downloaded, stored and information that no third party will sell it).
2. Please correct ‘which’ to ‘whom’ on page 2.
3. Please insert a missing word to the incomplete sentence on page 2 e.g. “and therefore lead to a more focused *awareness* on finding the optimal sedation level”.

**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 data management plan. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).
4. Please supply an information sheet and consent form for participants who regain consciousness.

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

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| **4** | **Ethics ref:** | **2024 FULL 21127** |
|  | Title: | A Double-Blind, Placebo-Controlled, Single Dose Escalation Study to Evaluate the Pharmacokinetics, Safety and Tolerability of ORKA-001 in Healthy Participants |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: | Oruka Therapeutics |
|  | Clock Start Date: | 31 October 2024 |

Dr Chris Wynne, Kayla Malate, Julia O’Sullivan, and Lucy Druzianic 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 there cannot be true equipoise in a healthy volunteer trial as there are risks but no prospect of therapeutic benefit.
2. The Researcher clarified the reason for collecting immigration status is to confirm participants are legally able to work in New Zealand and they will be paid for their participation and this is taxed.
3. The Committee noted the exclusion of tattoos would exclude many Pasifika participants due to traditional cultural tattooing of the abdomen. The Researcher explained the reason for the exclusion was a safety concern as during a phase 1 study the researchers must be able to assess any skin or subcutaneous reaction associated with the injection. The Researcher clarified an individual would only be excluded if there was no site on the skin able to be assessed for reaction.

**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 advised study advertisements should be limited to basic study information and the supplied advertisements contain statements such as “Join a trial and do the things you love”, “rest and relax”, “take a break and join a trial”. The Committee advised advertisements which emphasise social or recreational aspects of clinical trials are not appropriate as they do not convey the risk of participating in an early phase trial of an experimental drug that may not have been tested in humans before. Please amend the recruitment material accordingly.
2. The Committee requested the advertisement line “Help progress research for obesity” is removed.
3. The Committee requested information related to the Wellington site is removed as this will not be used.

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

Optional PIS:

1. As no additional blood draws are involved please refer participants to the compensation section in the main sheet to avoid duplication.
2. Please state whether the whole genome will be tested. If the whole genome will be tested, please state whether there is a risk of matching across genetic databases (e.g. law enforcement).
3. Please review the use of information section and delete statements covered elsewhere in the sheet. If the information is the mainly the same as the main sheet state the points of difference, otherwise state that the participant’s data will be treated as per the information provided in the main sheet.

**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 advertising pack to remove inappropriate emphasis regarding social and recreational benefits of participating in a clinical trial *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.11 & 11.12).*

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| **5** | **Ethics ref:** | **2024 FULL 21501** |
|  | Title: | A Phase 3, Randomized, Open-Label Study of Combination Therapy with Avutometinib plus Defactinib Versus Investigator’s Choice of Treatment in Patients with Recurrent Low-Grade Serous Ovarian Cancer (LGSOC) |
|  | Principal Investigator: | Dr Michelle Wilson |
|  | Sponsor: | Verastem Inc |
|  | Clock Start Date: | 31 October 2024 |

Dr Michelle Wilson and members of the study team 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 no specific risks are listed in question E1 of the application form and requested important or common risks are included in future applications.
2. The Committee noted one of the termination criteria was that the drug is shown to work and does not need further testing. The Committee queried if participants receiving therapeutic benefit from the drug would continue to have access. The Researcher confirmed this was their understanding.
3. The Researcher confirmed the Sponsor would pay for all tests and procedures that are not part of standard of care, however some tests that would be standard of care are paid for by the health system. The Researcher confirmed participants would not incur any costs for tests. The Committee noted for future studies if something is happening part of the study and is required to fulfil the study protocol then all those costs should be covered by the commercial sponsor, rather than come out of the local hospital’s budget.

**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 all investigator choices were standard of care in New Zealand. The Researcher stated they were except for pegylated liposomal doxorubicin that is not funded in New Zealand. This is standard of care internationally. The Researcher stated they were negotiating with the Sponsor to arrange funding for this. The Committee requested a paragraph in the information sheet to explain what is funded in New Zealand and what people would normally receive if they do not join the study.
2. The Committee advised the Researcher of the requirement to collect New Zealand ethnicity data and requested this is collected at a site-level for final reporting to HDEC.

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

1. Please amend ‘treatment’ and ‘treatment period’ to state ‘dosing’ and ‘dosing period’ to avoid therapeutic misconception.
2. Please undertake a general revision to remove any repetition (e.g. information about allergic reaction on page 16 and 20; information about withdrawal of data on page 23 and 26; information on ownership rights and financial gain on page 26 and 28).
3. Please revise the information on page 13 on costs of the study. This is covered more clearly on page 28.
4. Please remove section 10 on reimbursement as this is covered more clearly on page 28.
5. Please ensure the sheet contains information applicable to New Zealand (e.g. remove the reference to Medicare on page 13).
6. Please include an optional ‘yes / no’ tickbox for participants to receive a lay summary of study results.
7. Please amend the sample storage duration for local laboratory tests on page 15 if they are not intended to be held this long.
8. Please review the optional sheets for the points above. Participants may be referred back to the main information sheet when the information is the same (e.g. regarding compensation) and this may be removed from the optional sheets.

**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 ensure New Zealand specific ethnicity data is collected at a site level
* 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:** | **2024 FULL 21091** |
|  | Title: | Prospective, Multi-centre, Single Arm Feasibility Study of the TransShield Embolic Protection System |
|  | Principal Investigator: | Dr Sanjeevan Pasupati |
|  | Sponsor: | TransAortic Medical, Inc. |
|  | Clock Start Date: | 31 October 2024 |

Dr Sanjeevan Pasupati and Gypsy Francis 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 Researcher confirmed participants would be reimbursed for travel expenses for the final visit.
2. The Committee queried the role of Box. The Researcher explained it is used to upload study related documents such as information sheet and investigator’s brochure as well as deidentified images. The Researcher confirmed it is secure access. The Researcher confirmed there was no AI component to 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 advised the Researcher of the requirement to collect New Zealand ethnicity data and requested this is collected at a site-level for final reporting to HDEC.
2. The Committee requested the Researcher supply the patient satisfaction survey.
3. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP).
4. Please update section 4 to remove statements not relevant to the study e.g. that explicit consent will not be obtained and participants will be offered opt-out consent.
5. Please update or remove section 7.3 if this is not applicable.
6. Please remove section 8.5 if future use of data is not applicable.
7. Please remove square brackets throughout the document.

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

1. Please include more information on what is available as part of standard of care in New Zealand and what is not available.
2. Please include more information on development of the device and the amount of people who have undergone procedures with it.
3. Please summarise in lay language any specific safety issues related to previous versions of the device, their outcomes and how frequent they were.
4. Please state whether a commercial device would be used if the patient did not participate in the study and if so state differences between devices, e.g. if a commercial device would be used would it include a contralateral femoral puncture.
5. Please amend the use of data section to include HDEC and regulatory access to identifiable data for audit purposes, GP notification of study participation and significant abnormal results and the potential for privacy breach. These may be adapted from the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates).
6. Please state whether data will be used for future research.
7. Please remove the 0800 4 ETHICS phone number as this is no longer in use. The current HDEC template has appropriate contact information.
8. Please note on page 6 that karakia will not be available at the time of tissue destruction.

**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 data management plan. (*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 Maree Kirk and Dr Devonie Waaka.

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| **7** | **Ethics ref:** | **2024 FULL 21269** |
|  | Title: | BIO|CONCEPT.CorSky Family: First in Human study for the CorSky ICD family |
|  | Principal Investigator: | Dr Matthew O’Connor |
|  | Sponsor: | BIOTRONIK Australia Pty. Ltd |
|  | Clock Start Date: | 31 October 2024 |

Dr Matthew O’Connor, Mandy Fish and Cherie Something? was present via videoconference for discussion of this application.

**Potential conflicts of interest**

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

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

**Summary of resolved ethical issues**

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

1. The Researcher confirmed Māori consultation will be undertaken as part of locality process.
2. The application form states participants will have option for future use of their data, but then it is not included in the participant information. The Researchers clarified that this is not being done, so it won’t be put in consent form.

**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 the consenting process and how potential pressure to participate when the researcher is their treating clinician will be managed and mitigated. After discussion, it was clarified that the clinician will introduce the study before the research nurse consents them, but there is potential for the research nurse to make first contact. The Committee stated that the treating clinician should mention the research first, not the research nurse.
2. The Committee requested the following changes to the Data Management Plan (DMP) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a):*
   1. There is template language of participants under the age of 16 left in. Please remove.
   2. For identifiable data under 9.1, please state where it will be stored.
   3. Section 7.3 states consent form and contact details are not linked in any way with study data, but then says that investigator is retaining a log that links this information. Please clarify what is intended and amend accordingly.
3. The Committee noted the following peer review comment: “peer review is not materially affected by closeness to the research” The Committee queried if this means they are involved but perceive themselves not affected, or are they independent and this was phrased strangely. The Researchers confirmed this person is associated with the sponsor of the study. The Committee requested a review from an expert independent of the study, including the sponsor.
4. The Committee stated that notification to GP of participation should be mandatory. Please amend all documentation accordingly.

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

1. The participant information is overall quite technical and dense for a layperson to understand. Diagrams to aid in understanding can help comprehension and not all information is relevant to participants. Please review and amend.
2. The PIS states that the study has potential benefit to participants but doesn’t say what those potential benefits may be. Please state these.
3. Page 6 contains a duplicate paragraph. Please remove.
4. Please clarify what will happen if someone had to relocate and any risks associated with this, such as will they need a new device, will it only impact the researcher being able to check the device, etc.
5. “You will be implanted with this device whether you participate in this study or not” – please review the wording as patients still have choice and the statement must align more closely with the Code of Rights. It should be clearer that they will have a defibrillator device regardless of participation, it currently reads that they get the study device regardless of their choice.
6. Page 9 refers to article 62 of medical device regulation. If this has no relevance to New Zealand, please remove it.
7. Please correct the HDEC committee to Southern and delete the repeated ethics approval statement.
8. The data protection section (pages 14-16) is currently confusing and should be folded into the body of the PIS rather than being included as a separate appendix. If participants are expected to consent to it, it needs to be incorporated into the information sheet in a way the participants can understand, especially as there is a lot of legal jargon, and parts may not be relevant to New Zealand. Ensure information isn’t duplicated and ensure rights to access and correct information is included.
9. Please remove the statement about the Medicines NZ guidelines, as they do not apply to device manufacturers.
10. The risk of privacy breach not included. Please include, noting the [HDEC PIS template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates) paragraph can be used and duplicate information removed.

**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 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 Ms Dianne Glenn and Dr Amy Henry.

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| **8** | **Ethics ref:** | **2024 FULL 21213** |
|  | Title: | A Phase 3 randomized, masked, controlled trial to evaluate efficacy and safety of belzupacap sarotalocan (AU-011) treatment  compared to sham control in subjects with primary indeterminate lesions or small choroidal melanoma |
|  | Principal Investigator: | Dr Riyaz Bhikoo |
|  | Sponsor: | Aura Biosciences Inc |
|  | Clock Start Date: | 31 October 2024 |

Clare Arandjus and Alice Noone 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 outstanding ethical issues**

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

1. Please consider a simpler lay title across documentation.
2. The Committee raised the following regarding answers in the application form:
   1. B18 – States that ‘Funding of this Trial as agreed in the Clinical Trial Agreement between study site and sponsor’, however the Committee have not been provided with information on the value of koha/reimbursement/payment.
   2. D10.1 – There was no information in the uploaded PIS mentioning anything about Māori Research Review Committees specific recommendations, as referenced in this response. Please bear this in mind for future submissions that the Committee would like to see recommendations made and if these were taken on board.
3. The Researchers clarified that standard treatment is not being withheld, but this is not well demonstrated in the submission, especially in the PIS with “the doctor may offer standard of care if it grows, worsens, AND meets further criteria.” Some places also state these patients will not have treatment, and other places that they ‘may not’ have treatment. The Committee queried if the study is approaching patients where the only other option for them is watch and wait, or whether they are approaching patients who have other radiation options. The Researchers clarified these will be the ‘watch and wait’ patients. The Committee requested conflicting statements are reviewed and amended for clarity.
4. Please consider the impact of Rail closures for 96 days during the Treatment, study and follow-up periods, and the potential impact of traffic delays for participant and driver attending to this New Zealand site. Reimbursement should be sufficient to account for additional costs incurred as a result of the closures.
5. The Committee requested the following changes to the Data Management Plan (DMP) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*:
   1. Please tidy up the contents page (multiple instances of “Error! Bookmark not defined”).
   2. Please remove reference to under 16s at section 6.1 as all participants will be 18+.
6. The Committee requested the word ‘treatment’ is not used in the information sheet or other participant documents where possible when referring to an experimental unproven drug to avoid therapeutic misconception. The Committee suggested study medicine, study intervention or investigational product may be used instead. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* 7.19c)
7. As the current MPS Certificate will expire before the study commences, please confirm that the CI has applied to renew MPS membership.
8. In the doctor letter, please make it clear that referrals should be made only after the participant has agreed to their details being passed to the research team.
9. Please clarify whether the long-term observational study will run in New Zealand, and if applicable its approval status.
10. All researchers should collect good quality ethnicity data unless there is a particular justification for not doing so. Ethnicity data for New Zealand sites is provided to HDEC at the time of the final report; please collect at a site level if not required for the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.20)*.
11. The Committee noted that therapeutic trials in New Zealand should not be terminated early for purely commercial reasons (E8).
12. Sponsor authorisation has been provided by M. Stanley however the global sponsor is listed as J. Hoevenaars and no local sponsor is provided. Please clarify who the signature has been provided by and clarify whether they are acting as the study's local sponsor.

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

1. If there is going to be a CRA in New Zealand, please put them in the PIS instead of the Australian CRO.
2. Please review the first paragraph of page 2 and consider simplifying language. The Committee suggested bracketed descriptions to keep language lay and simple to understand.
3. Please review for font and formatting such as page 3, point 5 which has big blank spaces between paragraphs.
4. On pages 4-6, please add into the Assessment of procedures table the expected length of time for each Visit.
5. On page 13 - Point 11 cross referenced with Submission question D22 - please clarify participants payments, reimbursement & acknowledgement of time. Please make this information clear in the PIS, study guide, and study brochure, and clarify the following:
   1. Whether Visa-Gifts cards are being offered through Greenphire.
   2. Whether the stipend is for reimbursement or acknowledgment of participants time, and whether the stipend is still to be taxed.
6. Please be clear about the blood collection for PK and ADA testing. Consider adding this to the Table of Assessments and at each Visit indicate the length of time.
7. Page 14 has detailed information about copayments but is not fully relevant to the New Zealand context. Please amend the Section 11 (Costs to You) to accurately reflect the New Zealand health system. Please also note that the costs of all protocol-specified assessments, regardless of whether they are also standard of care, should be borne by the Sponsor.
8. Please make sure it is clear for participants/whānau/driver who they can call about the study.
9. Please advise on page 8 that a karakia will not be available at time of tissue destruction.
10. The Committee requested the removal of the ‘yes / no’ tick boxes from the consent form unless it is for a clause that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study). The two items with them in the CF aren’t or shouldn’t be optional. Please do however include an optional consent clause for participants to indicate if they wish to receive a lay summary of study results, once available.
11. Please mention if there would be any sample analysis by a local laboratory.
12. Please replace the words efficacy (effectiveness) and subjects (participants, people, adults) in the lay title.
13. Please remove references to treatment and treatment period, as noted above.
14. Please delete tablespoons and teaspoons references for blood volumes.
15. Please delete 'with participant consent’ from the statement regarding GP notification; this should be a mandatory component of study participation.
16. Please delete the bullet point regarding local laboratory staff; per the application form all laboratory samples are analysed and reported overseas.
17. Please state that the sponsor, ethics and regulatory access to identifiable information is limited to access for audit purposes as currently stated access is far too broad.
18. Please replace Institutional Review Board with Ethics Committee.
19. Please clarify why participants cannot access individual study assessments while on-study, as stated on page 17.

**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 Ms Neta Tomokino and Dr Nicola Swain.

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| **9** | **Ethics ref:** | **2024 AM 13080 (Application: 2023 FULL 13080)** |
|  | Title: | CIRCA NZ: Investigation and Research of Patients with Immune Dysfunction |
|  | Principal Investigator: | Dr Ignatius Chau |
|  | Assigned to meeting: | 18 October 2024 |

Dr Ignatius Chau, Dr Annaliesse Blincoe, and Tess Howard were present via videoconference for discussion of this amendment submission that seeks to add minors as active participants where they may be vulnerable, thus qualifying it for full Committee review at the Chair’s request.

**Potential conflicts of interest**

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

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

**Summary of resolved ethical issues**

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

1. The Researcher clarified the rationale behind the site location adjustment with helping with their recruitment populations.

**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 amendment relates to including paediatric participants in the study. The Committee raised the following regarding the consent procedures:
   1. Anyone 16 and over is assumed to have capacity to provide their own informed consent.
   2. Anyone 15 and under should be assessed for capacity to provide their own informed consent.
   3. Anyone under 16 who cannot provide their own informed consent should provide their assent alongside parental/guardian consent if appropriate instead.
   4. The process in the protocol for assessing capacity and consenting minors should be stepped out.
2. No assent forms have been provided for review. Please develop a simplified information and assent form for those who are younger or less reading comprehension, and an information sheet and assent form for older children/higher reading comprehension.

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

1. The Committee requested the removal of the ‘yes / no’ tick boxes from the consent form unless it is for a clause that is truly optional (i.e. the participant can answer ‘NO’ and still participate in 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 provide assent forms, 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 Mr Dominic Fitchett and Dr Devonie Waaka.

## General business

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

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| --- | --- |
| **Meeting date:** | 10 December 2024 |
| **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 3.30pm