|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Committee:** | | | Southern Health and Disability Ethics Committee | | | |
| **Meeting date:** | | | 8 March 2022 | | | |
| **Zoom details:** | | | <https://mohnz.zoom.us/j/96507589841> | | | |
|  | | |  | | | |
| **Time** | **Review Reference** | | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** | |
| 10:30am-11:00am | 2022 FULL 11814 | | VT-1001: A Study of VERVE-101 in Patients with Heterozygous Familial Hypercholesterolemia, Atherosclerotic Cardiovascular Disease, and Uncontrolled Hypercholesterolemia | Miss Courtney Rowse | Mr Dominic Fitchett & Dr Devonie Waaka | |
| 11:00am-11:30am | 2022 FULL 12203 | | Lymphoma and Related Diseases Registry (LaRDR) | Dr Leanne Berkahn | Mr Anthony Fallon & Associate Professor Nicola Swain | |
| 11:30am-12:00pm | 2022 FULL 12118 | | Oral Lonafarnib (LNF) for Treatment of Chronic Hepatitis D (delta) | Prof. Ed Gane | Dr Devonie Waaka & Mr Jonathan Darby | |
| 12:20pm-12:50pm | 2021 FULL 11944 | | Pilot study 177Lu-DOTA-Rosopatamab (TLX591) therapy in mCRPC patients failing PSMA small molecule ligands | Dr Andrew Henderson | Mr Anthony Fallon & Ms Amy Henry | |
| 12:50pm-1:20pm | 2022 FULL 12178 | | Diabetes eye care services in Auckland and Counties Manukau | Mr Pushkar Silwal | Associate Professor Mira Harrison-Woolrych | |
| 1:20pm-1:50pm | 2022 FULL 11192 | | Pacific Child Wellbeing | Miss Ni-Lun Lois Chu Ling | Ms Helen Walker & Associate Professor Nicola Swain | |
| 2:05pm-2:35pm | 2022 FULL 11982 | | SOTERIA - A Long Term Follow Up Study of Sotatercept for PAH Treatment | Mrs Christine Tuffery | Ms Helen Walker & Associate Professor Mira Harrison-Woolrych | |
| 2:35pm-3:05pm | 2022 FULL 11228 | | A Phase 1 study to evaluate the effect of renal impairment on the pharmacokinetics of ONC201 | Start-up Associate Sharmin Bala | Mr Jonathan Darby & Ms Amy Henry | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Devonie Waaka | Non-Lay | 18/07/2016 | 18/07/2019 | Present |
| Mrs Helen Walker | Lay | 22/05/2018 | 22/05/2020 | Present |
| Mr Jonathan Darby | Lay | 13/08/2021 | 13/08/2024 | Present |
| Mr Anthony Fallon | Lay | 13/08/2021 | 13/08/2024 | Present |
| A/Prof Mira Harrison-Woolrych | Non-Lay | 28/06/2019 | 28/06/2020 | Present |
| Mr Dominic Fitchett | Lay | 05/07/2019 | 05/07/2022 | Present |
| Ms Amy Henry | Non-Lay | 13/08/2021 | 13/08/2024 | Present |
| A/Prof Nicola Swain | Non-Lay | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 10am and welcomed Committee members.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mr Jonathan Darby and Mrs Helen Walker were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 8 February 2022 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **2022 FULL 11814** |
|  | Title: | VT-1001: A Study of VERVE-101 in Patients with  Heterozygous Familial Hypercholesterolemia,  Atherosclerotic Cardiovascular Disease, and  Uncontrolled Hypercholesterolemia |
|  | Principal Investigator: | Dr Patrick Gladding |
|  | Sponsor: | VERVE |
|  | Clock Start Date: | 28 February 2022 |

Dr Patrick Gladding, Courtney Rowse, Professor Ed Gane, Dr Andrew Bellinger and Dr Scott Vafai 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 Study

1. The study aims to assess the safety of VERVE-101 in various patients effected by HeFH, ASCVD, and uncontrolled hypercholesterolemia, and to observe the pharmacokinetics and ability of VERVE-101 to lower LDL-C and PCSK9 levels in the blood.

Summary of resolved ethical issues

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

1. The Committee asked for more information regarding the processes in place to formally document whether participants provide consent for ongoing use of optional samples in the event of withdrawal from the main study. The Researcher explained that in the event of a participant withdrawing from the study, the research team would verbally ask the participant whether they consented to the ongoing use of optional samples.
2. The Researchers confirmed to the Committee that there are processes in place regarding use of optional tissue samples in the event of a participant withdrawing from the study.
3. The Committee asked for more information on the Quality-of-Life questionnaire and whether there would be timely follow-up if there are any issues indicated. The Researcher explained that the physician will follow up with participants immediately if there was anything of concern indicated and would refer the participant to the relevant specialist.
4. The Committee clarified that due to a lack of females capable of reproduction represented in the animal trials, women of reproductive age would be excluded during this phase of trials but would likely be included in the future.

Summary of outstanding ethical issues

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

1. The Committee requested that Gene Technology Advisory Committee (GTAC) review be uploaded for review upon completion.
2. The Committee clarified that the mention of optional screening for certain biomarkers was not in fact optional and that this needs to be amended to be mandatory.
3. The Committee queried the section that mentions that participants are being asked to consent to an additional mandatory study for which currently does not have a PIS. The Researcher explained that this does not refer to a separate study, it is referencing the long-term continuation of this study which will be submitted as a protocol deviation. The Committee requested that this expectation is made clear and change the wording to ‘willing and able to consider’ participation as without provision of a PIS this cannot be mandatory.

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

1. Please simplify the exclusion criteria relating to medical conditions.
2. Please remove the page of information referring the participant to Part C of the study.
3. Please simplify the concomitant medications information and check for any repetitive information.
4. Please include a statement on whether the gene editing process can be reversed should off-target edits or unanticipated adverse events occur.
5. Please clearly outline the unintended risks of gene editing and the lasting affect these may have.
6. Please remove reference to cups if blood and provide round volumes.
7. Please amend the statement that 'genetic testing is mandatory and specific to this study'. Non-study specific analyses should be listed as optional.
8. Please clarify the data referenced in the statement ‘you may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study’s scientific integrity’. As this is not an open-label study, this is not relevant.
9. Please remove the repeated information regarding ownership rights and financial benefit.

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

1. Please amend to include selected dose, and summary of Part A safety results prior to use.

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

1. Please submit any documents relating to this section with tracked changes.

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

1. Please clearly outline that participants can verbally decline participation.

**Decision**

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

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

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

|  |  |  |
| --- | --- | --- |
| **2** | **Ethics ref:** | **2022 FULL 12203** |
|  | Title: | Lymphoma and Related Diseases Registry (LaRDR) |
|  | Principal Investigator: | Dr Leanne Berkahn |
|  | Sponsor: | Monash University |
|  | Clock Start Date: | 28 February 2022 |

Dr Leanne Berkahn and Ms Eliza Chung 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 Study

1. The Australian and New Zealand Lymphoma and Related Diseases Registry (LaRDR) aims to monitor access to care, outcomes, variation in practice and trends in incidence, and survival. Included in this is a study of the factors that influence outcomes including survival and quality of life.

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 form of consent was standard for the type of registry and would be consistent with NEAC standards.
2. The Committee clarified that newly diagnosed participants would be given the opportunity to participate in the study. To do so, hospitals could screen and refer participants who would be diagnosed in the last 6 months. The brochure would then be given upon invitation, prior to consent.
3. The Committee noted that the inclusion criteria includes participants whose cause of death is listed as lymphoma and asked whether the 6 month retrospective research would apply. The Researchers explained that they would not examine further as older data could be inconsistent.
4. The Committee asked for more details on the Māori consultation process. The Committee explained that Māori approval would be sought during locality authorisation and the study would not begin without Māori consultation is completed. The Committee noted that consultation for this particular study is important given the use of non-consenting data and sending the data overseas and stressed the need to consult Māori at each locality.

Summary of outstanding ethical issues

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

1. The Committee noted that the Participant Brochure is lacking in New Zealand-specific information and suggested that the Researchers draw from the [HDEC PIS template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/). This includes adding information on the New Zealand-based research team.
2. Please include a statement on any data risks in the study (i.e., data breaches, confidentiality, risks of sending data overseas, etc).
3. Please include information what will happen to the participants data if they withdraw from the registry. Include a caveat if there is data that may be used and cannot be withdrawn.
4. Please check the document for any spelling mistakes.

**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).*

|  |  |  |
| --- | --- | --- |
| **3** | **Ethics ref:** | **2022 FULL 12118** |
|  | Title: | Oral Lonafarnib (LNF) for Treatment of Chronic  Hepatitis D (delta) |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | Eiger Pharmaceuticals |
|  | Clock Start Date: | 28 February 2022 |

Sarah Middleton and Professor Ed Gane 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 Study

1. The study aims to evaluate the safety and tolerability of Oral Lonafarnib (LNF) 50/RTV200 QD administered over a 48-week treatment period and to evaluate the effect of LNF50/RTV200 QD administered for 48 weeks, with a 24-week post-treatment follow-up period, on Hepatitis Delta (HDV) viral levels.

Summary of resolved ethical issues

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

1. The Committee clarified that the study is initiated by their colleague in Israel.
2. The Committee clarified whether the Māori exclusion criteria would prevent participants with a mother from the Western Pacific region and a Māori father from participating in the study. The Researcher stated that it would not.
3. The Committee clarified that participants’ health practitioners would be contacted about their participation in the study and that this would be a mandatory part of participation.
4. The Committee asked whether a karakia would be available at the point of disposal. The Researcher stated that as the samples will have travelled overseas at the point of destruction, a karakia will be unavailable. While this is stated in the Participant Information Sheet (PIS), please bring this statement into the earlier paragraph which regards the cultural significance of participants’ samples.
5. The Committee confirmed that the coordinating investigator, who will not be involved in participants’ clinical care, will be present to talk through the PIS.

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 clarified the role of Eiger Pharmaceuticals. Eiger Pharmaceuticals would be providing the study drug at no expense as well as some set up costs at the request of the Researchers.
2. The Committee clarified that Eiger requested the right to review publications before they are disseminated to ensure the validity of the information being published, but that they do not hold the right to veto any publications. The Committee also noted that the Researcher’s submission states under B15 that “Soroka and Eiger Pharmaceuticals may publish in peer-reviewed scientific journals, conference presentations, on website or through internal reports”. The Researcher responded that the research team should have exclusive rights to the data collected from the study. The Committee asked for clarification over whether the Eiger Pharmaceuticals have the right to publish study data themselves. The Committee specified that if they do not, then this would not be considered a commercial study.

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

1. The Committee noted that under “Who is Funding the Study”, it states that the investigators “may benefit financially” from the study. Please remove this statement from the PIS.
2. Please rectify the page numbering.
3. Please simplify the “Who Can Take Part in the Study” section by removing reference to all possible conditions that would exclude participation as the Researcher will be pre-screening the participants anyway. Replace this by stating there are some medical conditions that could make it unsuitable for participants to take part.
4. Review assessments for lay language.
5. The Committee noted there are two different Māori tissue statements, one of which discusses genetic material despite no genetic material being collected in this study. Please use only one of these statements.
6. Please remove the initial statement that identifiable information will not be accessed by anyone outside the site or site’s suppliers.
7. Please provide frequencies for the side effects given with usual categories (e.g., very common, common, uncommon, rare).
8. There is no need to repeat all the contraceptive information for male participants. Simplify this by stating participants must use two forms of contraception as stated above with female participants and explain any differences that may exist.

The Committee requested the following changes to the Data Tissue Management Plan (DTMP):

1. The Committee noted that while the application states there is no study sponsor, the DTMP has many references to a sponsor. Please review and correct this.

**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 and tissue management plan to ensure the safety and integrity of participant data and tissue (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15, 14.16&14.17).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Devonie Waaka & Mr Jonathan Darby.

|  |  |  |
| --- | --- | --- |
| **4** | **Ethics ref:** | **2022 FULL 11944** |
|  | Title: | Pilot study 177Lu-DOTA-Rosopatamab (TLX591)  therapy in mCRPC patients failing PSMA small  molecule ligands |
|  | Principal Investigator: | Dr Andrew Henderson |
|  | Sponsor: | Telix International |
|  | Clock Start Date: | 28 February 2022 |

Dr Andrew Henderson and Rosane Joseph 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 Study

1. The aim of the pilot study will be to assess ease of patient recruitment and retention, ability to deliver two doses of therapy as per protocol and to define treatment outcomes.

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 in the application form, the study claims to be using Kaupapa Māori methodology. The Researcher stated that this is not the case and the Committee determined this to be a mistake.
2. The Committee asked what consultation with Māori is planned for the study. The Researcher stated that they will be meeting with the Director of Health Outcomes from their hospital who is also Chair of a cancer agency.
3. The Committee asked for more information on the recruitment process and whether there is a possibility of undue influence from the clinician-researcher role. The Researcher explained that the study will be recruiting from a pool who have already received treatment. There is a clinical research coordinator in the team who will be the unbiased link between the participants and the clinician.

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 asked for clarification on the role of Telix in this study. The Researcher stated that Telix will supply the agent and support the study financially should the study be approved. Telix also wish support the Researcher in setting up a larger, multi-centre prospective trial. The Researcher clarified that Telix is not the study sponsor.
2. The Committee clarified that this was technically a first in human study. The query related to the Investigators Brochure which stated, "no former human administration in man". The researcher noted the production of the antibody is novel, not the antibody itself which the Committee pointed out is therefore technically the first in human trial for this novel production of this antibody. Please ensure necessary safety monitoring is in place to this effect. Please include a statement to describe the process by which Sentinel dosing would be conducted and that the justification for the safety monitoring gap is adequate and provided to participants.
3. Please provide more information on any access to data Telix will have and whether this will be used in the future.
4. Please clarify which elements of the study the sponsor is funding.
5. The Committee noted that sponsorship must be formally agreed as this impacts the participant insurance in the study. The study cannot commence until this is formalised.
6. The Committee requested more information regarding the tissue management plan. Please provide more information on what is happening to any sampled (labelling, how long they will be held, whether they form part of the clinical record, etc). Please consider using the [HDEC template.](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/)
7. Please provide information on whether karakia will be available at the time of destruction.
8. The Committee noted that in the data management plan the ‘sponsor’ is referred to throughout. Given that this has yet to be formally agreed, please amend this as appropriate.
9. Please provide more detail on the institutional data policies being followed during the study (i.e., governance, management, etc).
10. Some health data must be held for a minimum of 10 years. Please check whether this applies to data generated in the study and amend if required.
11. The Committee noted that there is a questionnaire that is mentioned in the application which is not included in the PIS. The Committee requested that this is added to the PIS and submitted for review.
12. The Committee noted that no reimbursement is being made available to participants. It is standard to reimburse participants for their time, accommodation, and any travel expenses.

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

1. Please provide a lay title with fewer technical terms. Consider creating an acronym or further summarising the study.
2. Please ensure all acronyms are spelled out with first use.
3. Please include information on future data use and an option for participants to provide consent.
4. Please include a statement outlining that any images taken during the study will become part of the participant’s clinical record.
5. Please include a statement on how long health data will be stored (10 years).
6. Please include information on who is sponsoring the research and any access or input they will have.
7. Please include information on whether blood or tissue samples will be sent overseas.
8. Please address any cultural issues that may be associated with this (i.e., whether karakia will be available at tissue destruction)
9. Please provide lay explanations of any procedures, technical words, or scans.
10. Please information on any radiation risks to the participant or others.
11. Please remove the tick box on General Practitioner (GP) notification and withdrawal of data use as this should be mandatory.
12. Please include a statement informing the participant that any information gained during the study will be included in their clinical record.
13. Please change the insurance information relating to Accident Compensation Corporation (ACC) to insurance of a commercially sponsored study.
14. Please include a statement on the first page of the PIS explicitly stating that this is the first time the study drug will be used in humans.
15. Please provide more information on reproductive risks. This information can be found in this [HDEC template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-apr20.docx)

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Anthony Fallon and Ms Amy Henry.

|  |  |  |
| --- | --- | --- |
| **5** | **Ethics ref:** | **2022 FULL 12178** |
|  | Title: | Diabetes eye care services in Auckland and Counties  Manukau |
|  | Principal Investigator: | Associate Professor Jacqueline Ramke |
|  | Sponsor: | Health Research Council NZ |
|  | Clock Start Date: | 28 February 2022 |

Associate Professor Jacqueline Ramke 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 Study

1. The study aims to identify the gaps and develop strategies to modify the monitoring process of Diabetes Eye Care (DEC) services to facilitate the routine reporting of MOH Diabetes Retinopathy (DR) indicators and to develop a package of deliverable strategies to increase access to DEC services.

Summary of resolved ethical issues

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

1. The Committee clarified that whilst there was clinical reasoning for choosing 15-year-olds instead of 16-year-olds in the research, that the researchers are happy to change to 16-year-olds to make the process easier for the researchers and the potential participants.
2. The Committee asked if everyone in the study will be providing their own informed consent. The Researchers confirmed this.
3. The Committee asked about the identifying process for potential participants of the study and if the researchers can reduce the risk of potential participants feeling obliged to take part of the study. The Researchers explained they will use different clinicians and different people in the field and that it is a small field of people all working together and took on board a letter to potential participants from the researcher for a formal invite would work.
4. Upon questioning, the Researchers clarified that they have two Maori consultors and are both named researchers on the study.
5. The Committee asked where the interviews would be done. The researchers clarified they could use consultation rooms or a community centre they already use in another study.
6. The Committee asked about the reimbursement for the service provider and why they are not getting something from the study. The Researchers explained they the service providers would be conducting interviews during their work time so would still be getting paid as per usual.

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 include expectation that privacy of other workshop members be respected.
2. Please amend the interview as it currently states that 'No clinical details will be asked/collected during the interview', however the submitted interview asks for clinical details regarding treatment plan and medications.

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

1. Please check for use of too-long words and phrases and delete where possible, so the PIS is written in simple plain English, especially for the service users who are not as familiar with health service language.
2. Please state whether the activity will be recorded (and how it will be recorded). State what happens to the recording after it is transcribed.
3. Please state how consent forms and contact details etc will be stored. (these are pieces of identifiable information that is collected).
4. Please state whether the data collected may be used for future research.
5. Please remove square brackets throughout document.
6. Please remove references to sponsor as the application states there is no sponsor on page 3.
7. Please rephrase sentence to make it clear the workshop and survey will be consented separately on page 4.
8. Please include the ability to bring a support person along with the participant to the interview.

**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).*

|  |  |  |
| --- | --- | --- |
| **6** | **Ethics ref:** | **2022 FULL 11192** |
|  | Title: | Pacific Child Wellbeing |
|  | Principal Investigator: | Dr Teuila Percival |
|  | Sponsor: | Moana Research |
|  | Clock Start Date: | 28 February 2022 |

Dr Teuila Percival & Mrs Mary Roberts 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 Study

1. The Well Child/Tamariki Ora programme is a series of health assessments and support services for children and their families from birth to five years and is an important gateway for parents to access primary and specialist health care, education, and social services.

Summary of resolved ethical issues

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

1. The Committee asked for confirmation from the Researchers about if participants show up to 1 workshop or if they show up to 3. The Researchers explained that there are 3 possible Early Childhood Education (ECE) options that people only attend once.
2. The Committee confirmed that participant feedback and improvement is important and will be implemented.
3. The Committee asked about the koha and the $100 that if 4-year-old participant and the parent will they get the $100 only once. The Researchers explained that the family would get the $100 twice as the koha is per person.
4. The Committee confirmed Moana Research are the sponsor for the trial.
5. The Committee noted the researchers acknowledged the delay in start of the trial and that it may be necessary to extend the finish date accordingly.
6. The Committee asked for testing in the target population to be done as the documents are wordy and has taken testing it first onboard.
7. The Committee asked about the ‘on the mat’ process and what the kids are going to be doing for the hour on the mat. The Researchers explained that they want the kids to do the same things they would usually do, the kid is accompanied by the same ECE teacher and explained that the time is up to an hour some kids sit for 15 minutes and some may use the whole hour. Furthermore, explaining that it’s about exploring with the kids what works well albeit books or toys.
8. The Committee asked if the researchers will be interacting with the children or just observing during mat time. The Researchers explained that the researchers will be observing, and the teacher will be interacting with the children.
9. The Committee asked if the activities on the mat are reading books or physical play and asked for clarification. The Researchers explained that they are still trying to figure that out as it is a part of the co-design work and respecting the co-design.
10. The Committee asked if the researchers have thought about giving the child participant some toys or games for Koha as that seems more appropriate for the child. The Researchers explained that they have done that in the past with another study and will take that knowledge onboard with this study.
11. The Committee asked about the photos and videos that are being taken during the trial and what they will be used for. The Researchers explained that they may use the photos for promotion of the programme and advertisement, stating they don’t have to take photos as it’s not part of data collection.

Summary of outstanding ethical issues

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

The Committee requested the following changes to the Data Management Plan (DMP):

1. Please provide named responsibility for data management & confidentiality.
2. Please outline privacy breach management.
3. Please outline ownership of data.
4. Please outline future uses of data if there is any.
5. Please provide more information on storage and who has access to/use of photographs and videos (forms of data not referenced in the Data Management Plan).

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

1. Please amend references to 6-year data retention period to 10 years if any health data is being collected.
2. Please clarify in the participant information sheet that participants will not be able to review/modify transcripts (currently states they can 'access and correct their information').
3. Please state whether data could be used for future research.
4. Please include brief statement of risk of privacy breach
5. Please amend caregiver’s information sheet: simplify aims of study per PISCF parent request.
6. Please amend Page 3: (what will happen to my information) Change ‘the participants’ to ‘you will have access to information’.
7. Please clarify what the koha provided to children at the conclusion of the 'on the mat' session is and provide more detailed information for the participants.

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

1. Please simplify aims into short, lay-friendly bullet points.
2. Please explain what a 'resource' is and whether 'exercise' means physical exercise, physical games, etc.
3. If risk of COVID is not increased above routine ECE attendance, please delete reference to this.
4. Please state whether the session will be video or audio-recorded, or whether photographs may be taken. Storage, access to and use of any images should be discussed. Permission for use of photos / videos should be addended to the main PISCF.
5. Please further explain the further statement 'you can withdraw at any time' means. Please clarify if a child's data be withdrawn once they have participated in the session? please provide more clarification.
6. Please correct reference to data retention period of 6 years; application form states 10 years after turning 16.
7. Please give an example of the On the Mat activity.
8. Please explain if the children will be asked any questions.
9. Please explain what the koha is and how/when/to whom it will be given.

The Committee requested the following changes to the Workshop Participant Information Sheet (PIS):

1. Please state why the person has been invited to take part.
2. Please provide more detail about how many workshops and how often they will take place.
3. Please provide more information about what sort of questions will be asked in the workshops.

**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 Associate Professor Nicola Swain & Mrs Helen Walker.

|  |  |  |
| --- | --- | --- |
| **7** | **Ethics ref:** | **2022 FULL 12187** |
|  | Title: | SOTERIA - A Long Term Follow Up Study of  Sotatercept for PAH Treatment |
|  | Principal Investigator: | Dr Henry Gallagher |
|  | Sponsor: | Acceleron Pharma Inc. |
|  | Clock Start Date: | 28 February 2022 |

Mrs Christine Tuffery 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 Study

1. The primary objective of this open-label, LTFU study is to evaluate the long-term safety and tolerability of sotatercept when added to background PAH therapy in adult participants with PAH. The secondary objective is to follow participants from parent sotatercept studies that were treated with sotatercept or placebo and assess continued efficacy.

Summary of resolved ethical issues

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

1. The Committee asked for more information regarding the study mobile phone application being used by participants. The Researcher stated that the application has already been downloaded on the participants mobile phones from the parent studies. The application will be used to record symptoms and note down timing of self-administered injections.

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 ensure that the information on retaining tissue for future use is consistent across all study documents, including the PIS.
2. Please remove any statements regarding genetic material, as this is not applicable to the study.

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

1. Please include a lay title.
2. Please explicitly state to participants that they are being invited to participate in the study because of another parent study they are involved in.
3. Please provide more information for participants receiving placebos, including information on unblinding, or the introduction of any medications.
4. Please provide information on any potential adverse events which may have occurred during the parent studies.
5. The Committee requested more information be given surrounding the right heart catheterization procedure and outline the potential risks.
6. Please replace the current reproductive risks section with the template provided on the [HDEC website.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-apr20.docx)
7. Please specify there will be not be access to the study drug after the end of the treatment period.
8. Please add the information on self-administering the drug earlier on in the PIS to ensure that participants are aware.
9. Please remove the statement ‘if your country laws allow’ on self-administering medication and include New Zealand specific information.
10. Please include frequencies of possible adverse effects or reactions (using data from earlier studies).
11. Please alter the table on page 9 to present the information more clearly.
12. Please explicitly state that tissue will be sent overseas
13. Please state that karakia will not be available at the time of tissue destruction
14. Please ensure that the use of first-person and second-person grammar is consistent throughout the document.
15. Please explain what exposure '4.8 - 6.4 x higher than average yearly background radiation' means in terms of increased risk.
16. Please provide a consent form option regarding receipt of lay summary of study results.

**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).*

|  |  |  |
| --- | --- | --- |
| **8** | **Ethics ref:** | **2022 FULL 12158** |
|  | Title: | A Phase 1 study to evaluate the effect of renal  impairment on the pharmacokinetics of ONC201 |
|  | Principal Investigator: | Dr Nicholas Cross |
|  | Sponsor: | Chimerix, Inc. |
|  | Clock Start Date: | 28 February 2022 |

Dr Nicholas Cross and Ms Sharmin Bala 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 Study

1. The purpose of this study is to evaluate how safe and well-tolerated ONC201 is, in patients with severe renal (kidney) impairment (dysfunction) compared to participants with normal renal function, to determine the effect of severe renal impairment on ONC201 and to measure the body’s response to a single dose of ONC201 in healthy and renal impaired participants.

Summary of resolved ethical issues

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

1. The Committee asked for more information on the study design regarding the decision to use a severe cohort and the selection of the doses. The Researcher explained that doses were chosen following data taken from the animal testing phases and testing in healthy volunteers. This indicates that the doses being given to the study group will be safe.
2. The Committee noted that in previous applications it was the case that the renal department received remuneration for the time taken to identify potential participants. The Committee asked whether this was still the case. The Researcher explained that this is no longer the case.
3. The Committee asked for clarification on whether members of the study team will be involved in the participants clinical care outside of the study. The Researcher explained that the Principal Investigator is involved would not be the active clinician during the trial.
4. The Committee asked for clarification why women of child-bearing potential are excluded from participating in the study. The Researcher explained that it is prevent any chance of harm to a pregnancy, even if using effective contraceptives.

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 more information on the scientific basis of the study, such as clearance routes of the study drug and/or it’s metabolite, and whether it is anticipated that pharmacokinetics will be significantly impacted by level of kidney infection. The Committee requested that this is made clearer in future study applications.
2. The Committee noted that the current response to C4 discusses cancers for which the drug is not being developed, and states that Māori participants may benefit 'if the drug works for them'. Please reconsider this response for the current study, which is non-therapeutic.
3. The response to C6 states that 'Finally, clinical trials make available to Pacific people drugs that are too costly to access in Aotearoa New Zealand or are not available to the general public' which is non-applicable to the current study. Please review these responses for future submissions.
4. The Committee noted that clinical trial registration is yet to be undertaken. Please ensure this is completed prior to commencing recruitment activity.

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

1. Please clarify whether alcohol screening will only be at pre-screening or throughout the study. Please ensure this information is consistent across documentation.
2. Please provide more information on timeframes of receiving Covid-19 vaccinations and how this may affect eligibility.
3. Please review all patient facing documents and use consistent lay terms where possible (i.e., changing ‘renal impairment’ with ‘severely reduced kidney function).
4. Please replace ‘subjects’ with ‘participants’ throughout the PIS/CF.
5. Please remove reference to “single period reference” and “parallel group reference” as this is not required.
6. Please remove the repetitive sections regarding ownership and financial benefit.
7. Please remove the sentence 'depending on the type and objectives of the study' and ensure that this is more study specific.
8. Please simplify in the information table (i.e., repeated explanation of PPB).
9. Please remove the final inclusion criteria bullet point as it does not apply to the health cohort and is already noted under exclusion criteria.
10. Please amend the second exclusion criteria bullet point as It is difficult to understand.
11. Please remove this statement: ‘please inform the study doctor or staff if you decide to stop having the study drug for any reason. If you stop receiving study drug for any reason (either your choice or on the advice of your study doctor) your study doctor will ask you to continue to attend the unit for follow-up assessments'. This is not applicable to a single dose study.
12. Please provide known frequencies for side effects.
13. Please remove the statements in section 5.2 as this is already explained on page 12.
14. Please confirm that data generated in the current study will not be retained for future research.

**Decision**

This application was *approved with non-standard conditions* 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).*

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 12 April 2022 |
| **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 3:10pm