|  |  |
| --- | --- |
| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 14 December 2021 |
| **Zoom details:** | <https://mohnz.zoom.us/j/86077775718> |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers**  |
| 10.30 – 11.00am | 2021 FULL 11256 | Lymphoma and Related Diseases Registry | Dr Leanne Berkahn | Dominic / Mira |
| 11.00 – 11.30am | 2021 FULL 11416  | MK3475-B96 Pembrolizumab/placebo plus paclitaxel with or without bevacizumab for platinum-resistant recurrent ovarian cancer  | Dr Michelle Wilson | Sarah / Amy |
| 11.30am – 12.00pm | 2021 FULL 11628 | Feasibility and acceptability of the Moves4LilMindsProgramme. | Associate Professor Kelly Jones | Helen / Kate |
| 12.00 – 12.30pm | 2021 FULL 10993  | Integrity Study – Glaukos infinite vs Hydrus to reduce eye pressure in patients with glaucoma | Dr Dean Corbett | Dominic / Patries |
| **12.30 – 12.50pm** |  | **BREAK (20 MINUTES)** |  |  |
| 12.50 – 1.20pm | 2021 FULL 11650 | A clinical trial in Familial Chylomicronemia Syndrome (FCS) | Dr John Baker | Sarah / Mira |
| 1.20 – 1.50pm | 2021 FULL 11094  | SCIP RHD | Dr Julie Bennett | Helen / Amy |
| 1.50 – 2.20pm | 2021 EXP 11147 | Pharmacokinetics of high dose quercetin | Dr Leon Yu-An Huang | Dominic / Kate |
| 2.20 – 2.50pm | 2021 FULL 11766 | Safety and Effectiveness of the Zenflow Spring System - A Minimally Invasive Treatment for LUTS associated with BPH - BREEZE study | Professor Peter Gilling | Sarah / Patries |
| **2.50 – 3.00pm** |  | **BREAK (10 MINUTES)** |  |  |
| 3.00 – 3.30pm | 2021 FULL 11846  | Tuning in to Teens in Aotearoa NZ | Ms Zara Mansoor | Helen / Mira |
| 3.30 – 4.00pm | 2021 FULL 11386 | TEMPO-2 – A randomised clinical trial of tenecteplase thrombolysis versus standard treatment for minor stroke with brain artery occlusion | Dr Teddy Wu | Dominic / Amy |
| 4.00 – 4.30pm | 2021 FULL 11430 | Diabetes eye care services in Auckland and Counties Manukau | Associate Professor Jacqueline Ramke | Sarah / Kate |
| 4.30 – 5.00pm | 2021 FULL 11790 | Understanding Child Abuse Victims, their Caregivers and Clinicians Experience of Trauma Focused Cognitive Behavioural Therapy | Miss Audrey Kusasira | Helen / Patries |

 **Southern HDEC members**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Dr Sarah Gunningham | Lay (other) |  05/07/2016 |  05/07/2019 | Present |
| Dr Devonie Waaka | Non-lay (intervention studies) |  18/07/2016 |  18/07/2019 | Apologies |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies)  | 28/06/2019 | 28/06/2020 | Present |
| Mr Anthony Fallon | Lay (consumer/community perspectives) | 13/08/2021 | 13/08/2024 | Apologies |
| Mr Dominic Fitchett | Lay (the law) | 05/07/2019 | 05/07/2022 | Present |
| Ms Amy Henry | Non-lay (observational studies) | 13/08/2021 | 13/08/2024 | Present |

 **Co-opted HDEC members**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Mrs Helen Walker | Lay (consumer/community perspectives) |  22/05/2018 |  22/05/2020 | Present |
| Dr Patries Herst | Non-lay (intervention studies) |  22/05/2020 |  22/05/2023 | Present |
| Dr Kate Parker | Non-lay (observational studies) | 11/11/2015 | 11/02/2023 | Present |

## Welcome

The Chair opened the meeting at 10.00am and welcomed Committee members, noting that apologies had been received from Mr Anthony Fallon and Dr Devonie Waaka.

Mrs Helen Walker was the co-opted Acting Chair (Central HDEC). Dr Patries Herst (Central HDEC) and Dr Kate Parker (Northern A HDEC) were the co-opted non-lay members for this 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 09 November 2021 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1**   | **Ethics ref:**   | **2021 FULL 11256** |
|   | Title:  | Lymphoma and Related Diseases Registry |
|   | Principal Investigator:  | Dr Leanne Berkahn |
|   | Sponsor:  | Monash University |
|   | Clock Start Date:  | 25 November 2021 |

Professor Erica Wood, Eliza Chung, Sophie Goodger, Neil Waters, and Dr Leanne Berkahn 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 aims of the Australian and New Zealand Lymphoma and Related Diseases Registry (LaRDR) are to:
	* Monitor access to care
	* Benchmark outcomes nationally and internationally
	* Explore variation in practice, process and outcome measures
	* Monitor trends in incidence and survival
	* Explore the factors that influence outcomes including survival and quality of life
	* Act as a resource for clinical trials.

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 about what the researchers are planning to do with this study and how the Lymphoma and Related Diseases Registry will work. The researchers explained that it aims to collect a comprehensive dataset of people with lymphoma and the researchers have been managing the registry in Australia since 2016.
2. The Committee asked about recruitment processes and the follow up procedures. The researchers confirmed this and added that all patients with lymphoma would be eligible to be in the registry and will be followed up during that time period adding that some of these participants need therapy and the group of people are diverse.
3. The Committee asked why the researchers are not asking for informed consent. The researchers explained that the type of consent they are using for this registry is a type of informed consent which does not require the patient to sign their name on the consent forms, adding the advantage it is likely to allow most people to participate.
4. The Committee explained that the difference with this study is that it is a research project as there are follow ups throughout the years and the survey, explaining that this study asks about the participants’ experiences of lymphoma and informed consent forms should be used in this case. The researchers explained that getting the outcome data is a challenge, but they are always open to making the process easier and gathering more data.
5. The Committee asked how the data is managed. The researchers explained that the data is taken from medical records and the data entered is identifiable because of the collection of the patient’s name. If the researchers are doing analysis with those records it is de-identified, stored and analysed as de-identified data.
6. The Committee asked if the researchers could split the registry from the questionnaire. The researchers replied that they will see if it can be managed separately.
7. The Committee asked about the questionnaires and what the procedure is when the responses come in. The researchers explained that the registry is not a real time activity and is not asking participants to answer the questions on the day, it is primarily an epidemiology study, the information is not being collected to manage the individual patient.

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 Participant Information Sheet and Consent Form (PIS/CF):

1. The Committee asked for greater detail around the management of data in the New Zealand part of the study to be added either to the study protocol or to a separate data management plan. This should meet the requirements set out in paragraph 12.15 of the *National Ethical Standards for Health and Disability Research and Quality Improvement 2019*. For guidance, please refer to the HDECs [Data Management Plan template](https://ethics.health.govt.nz/system/files/documents/pages/data-only-management-template-oct2020.docx).
2. 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 2019*, para 9.7).
3. The Committee decided to decline this application to allow for a cleaner process as the researchers intended to take it back to their steering committee to decide if they want to use informed consent and submit a consent form, noting that timewise it would not make a difference. The researchers explained that they do want to take it back to the steering committee to make sure that the comparison is correct and updated, whilst submitting a consent form. The Committee noted that this is not a rejection of the study, but to make sure that the proper processes are put in place.

**Decision**

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

|  |  |  |
| --- | --- | --- |
| **2**   | **Ethics ref:**   | **2021 FULL 11416** |
|   | Title:  | MK3475-B96 Pembrolizumab/placebo plus paclitaxel with or without bevacizumab for platinum-resistant recurrent ovarian cancer  |
|   | Principal Investigator:  | Dr Michelle Wilson |
|   | Sponsor:  | Merck Sharp & Dohme (Australia) Pty Limited Authorising on behalf of NZ Sponsor Merck Sharp & Dohme (New Zealand) Ltd |
|   | Clock Start Date:  | 23 November 2021 |

Dr Michelle Wilson, Mrs Sonya Merry, and Mrs Shuli Yang 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. This trial is testing pembrolizumab (pembro) plus paclitaxel, with or without bevacizumab, in women with ovarian cancer.
2. Pembro is an experimental treatment. It has been approved by some health authorities for treating various cancers. It has not been approved for ovarian cancer. Pembro is also known as KEYTRUDA® (MK-3475). Paclitaxel and bevacizumab are approved treatments for ovarian cancer.
3. The trial will compare pembro plus paclitaxel, with or without bevacizumab, against placebo plus paclitaxel, with or without bevacizumab.
4. This trial is being done to:
* Test the safety of pembro plus paclitaxel, with or without bevacizumab
* See how well pembro plus paclitaxel, with or without bevacizumab, works to control ovarian cancer*,* compared to placebo plus paclitaxel, with or without bevacizumab
* See if participants who get pembro plus paclitaxel, with or without bevacizumab, have a better quality of lifecompared to those who get placebo plus paclitaxel, with or without bevacizumab

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 about the genetic and biomarker testing, wondering if they are an optional part of the study or if it should be in the follow up future research study. The researchers explained that it is a main part of the study and is a mandatory part of the study.
2. The Committee asked if the study is a registered clinical trial. The researcher explained that it is now registered, and they are able to provide proof and information that it is registered.
3. The Committee asked about the teletrial and if this would cause any issues other than what is normal in this process. The researchers explained that the teletrial is using a very clear supervision that outlines first response calls for each part of the trial alongside multiple meetings with the team and has been proven very effective in Australia. The researchers further added they are using the teletrial to eliminate the three-hour trip some participants would need to take to get to the health centre as the participants can go to their local District Health Board to participate in the study.
4. The Committee asked about the information sheet regarding treatment and its risks and benefits. The researchers explained that the types of treatments vary from participant to participant and they are able to amend the wording to further reflect this.

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 explain in lay language and more detail what the teletrial exactly is and what it means for potential participants.

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

1. Please explain in lay language what specific biomarkers are being tested for, and if the participant would like to donate the rest of the sample, they would be required to sign the optional future unspecific research form.
2. The Committee asked for greater detail around the management of tissue and data in the New Zealand part of the study to be added either to the study protocol or to a separate tissue and data management plan. This should meet the requirements set out in para 12.15 of the *National Ethical Standards for Health and Disability Research and Quality Improvement 2019*. For guidance, please refer to the HDECs [Data Management Plan template](https://ethics.health.govt.nz/system/files/documents/pages/data-only-management-template-oct2020.docx).
3. Please amend the PIS to reflect that if participants wish to withdraw from the trial they should be asked if they also want to be withdrawn from the future biomedical research.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the PIS/CF, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, paras 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 2019, para 9.7)*

|  |  |  |
| --- | --- | --- |
| **3**   | **Ethics ref:**   | **2021 FULL 11628** |
|   | Title:  | Feasibility and acceptability of the Moves4LilMinds Programme. |
|   | Principal Investigator:  | Associate Professor Kelly Jones |
|   | Sponsor:  | Auckland University of Technology |
|   | Clock Start Date:  | 25 November 2021 |

Leanne Seniloli and Associate Professor Kelly Jones 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. Primitive reflexes are automatic stereotyped movements, which develop into postural reflexes by the age four. Continued primitive reflexes beyond four-years-old has been linked to educational underachievement, delayed motor coordination and emotional immaturity. Specific exercise programmes have reduced the presence of primitive reflexes and enhanced educational achievement. Moves4LilMinds is one such programme.
2. This randomised pilot study will examine the feasibility and acceptability of the Moves4LilMinds programme, delivered over a reduced 12-week period. Moves4LilMinds is a systematic, daily (15 minute) movement programme suitable for four to six-year-olds, delivered over one-year aimed at reducing primitive reflexes and aid the transition to developing more mature postural reflexes.

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 if the research gathered from this study will be used to promote the researcher’s business later. The researcher explained that this is not likely, the study is being used to gather information and data.
2. The Committee asked about the use of videos and how they will be blinded. The researcher explained that they will be blinded to what group they are in and see the full 20 children’s neuromotor scores. The video will be handed off to an external moderator to determine how the assessment process went. The video is for the neuromotor assessments.
3. The Committee asked about the questionnaires and if the parents can see what the teachers wrote about their children. The researchers explained that they are all confidential.
4. The Committee asked if the lead researcher will see the videos and raised concern as if the researcher was to watch the video, they could identify participants. The researcher made it clear that they will not watch the videos.
5. The Committee asked if the children in the two groups will be in the same room or near each other. The Committee explained that it will be up to the early childhood setting and would be better to negotiate with the owners first.
6. The Committee asked about the Māori consultation email where someone was going to come to the study sites. The researchers explained that they are keen to take up the offer but have not thought it through yet and were waiting for ethical approval first.
7. The Committee asked what if a teacher leaves during the study. The researcher explained that the programme can still continue with a one-hour training with a new teacher with consent.

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 explain who the external blinding moderator is.
2. Please explain how the researcher will prevent children from participating in both interventions given the space limits of many preschools.
3. Please explain how the researcher will control children who only attend preschool part-time.
4. Please amend all language throughout to make it more inviting to the children and the parents.
5. Please amend statistical language to reflect lay language and make it easier to understand for parents and the children.

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

1. Please provide a consent form for the early childhood centre/setting.

CHILD PIS:

1. Please explain what will happen to the video recording of the child.
2. Please amend the child PIS to make it easier for younger children to read and understand as there is a lot of text it may be too much for a four-year-old to read.
3. Please include more pictures and bullet points into the child PIS.

DATA MANAGEMENT PLAN:

1. All data needs to be kept for 10 years post the youngest participant turning 16-years-old (not 6 years).
2. Please make clear how the researchers will be blinded to video data.

PARENT PIS:

1. Please amend the PIS to explain in lay language what the aims of Moves4LilMinds are.
2. Please explain what ‘primitive reflexes’ are in lay language.
3. Please remove all references in the PIS as they need to stand alone and be self-explanatory.
4. Please amend the wording for the explanation of the programme in lay language.
5. Please explain if the child neuromotor assessment is done at the start or the end of the programme as this is not clear in the study processes.
6. Please explain if videos are going to be used and if they are supply information on how they will be protected.
7. Please note that obtaining a degree is not a benefit of the study for the participant.

PARENT PIS/CF:

1. Please amend the consent form if the general practitioner needs to be informed and if so, explain in the PIS why this will occur.
2. Please remove information that is also in the PIS for example, videos, contacting the ECC to follow up later etc.

QUESTIONNAIRES:

1. Please make clear that questionnaires are confidential in both teacher and parent PISs as this may affect responses.

PEER REVIEWS:

1. Please provide an independent peer review of the study.

ADVERTISEMENT:

1. Please include the HDECs Ethics approval number/reference in the advertisement.

**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 2019, paras 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 2019, para 9.7*).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Kate Parker and Mrs Helen Walker.

|  |  |  |
| --- | --- | --- |
| **4**   | **Ethics ref:**   | **2021 FULL 10993** |
|   | Title:  | Integrity Study – Glaukos infinite vs Hydrus to reduce eye pressure in patients with glaucoma |
|   | Principal Investigator:  | Dr Dean Corbett |
|   | Sponsor:  | Glaukos Corporation |
|   | Clock Start Date:  | 25 November 2021 |

Dr Dean Corbett, Claire Arandjus, and Tony Mann 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. This is a prospective, randomised, controlled, comparative multi-centre parallel group, two-arm, open-label study. Approximately 150 eyes of approximately 150 participants will be enrolled at up to five study sites. Both eyes will be screened for eligibility. Participants that consent to take part and that meet eligibility criteria will complete washout periods of their pressure-lowering eye medicine before returning for a baseline visit. Participants that meet the screening and baseline visit criteria will be eligible to receive study treatment. Randomisation will be used to determine which study treatment (iS3 infinite® or the Hydrus®) the study eye will receive in a 1:1 allocation.
2. There are two treatment groups:
	* Participants with both eyes enrolled in the study will be treated with either:
		+ first eye implanted with iS3 infinite® and second eye implanted with Hydrus®, OR
		+ first eye implanted with Hydrus® and second eye implanted with iS3 infinite®
	* Participants with one eye enrolled in the study will be treated with either:
		+ iS3 infinite®, OR
		+ Hydrus®.
3. If both eyes of a participant are eligible, the Coordinating Investigator will determine the first eye to be treated by selecting the worst of the two eyes. If both eyes are equivalent, the left eye will be randomised and treated first. The other eye will receive the opposite treatment at a later time. Note that under no circumstance will both eyes of the same participant be implanted with the same study treatment.
4. Participants will be followed for 24-months following device implantation for safety and effectiveness evaluations. Measurements of unmedicated diurnal intraocular pressure (DIOP) will be conducted at Baseline, Month six, Month 12 and Month 24 exams. IOP will be determined using the two-person method to reduce bias, i.e., Observer 1 (masked to real time IOP reading) will look through the slit lamp and turn the dial with reading being masked, and Observer 2 will read and record the IOP readings.

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 how randomisation will be done. The researcher stated that randomisation is done via electronic case report form, which is the system where all patient data are entered.
2. The Committee asked if the washout period of four weeks for some of the eyedrops participants will be using before trial participation may have the potential to increase the intraocular pressure to dangerous levels. The researcher stated that it is a normal washout period for any clinical study undertaken for glaucoma. It is a standard when looking at other interventions. In that period of time, unless the optic nerve is severely compromised, it is not considered to be a significant risk to the patient. Further, they will not enrol people with advanced glaucoma.
3. The Committee asked if the insurance is protocol specific. The researcher confirmed this and directed the Committee to the description of operations section of the insurance certificate, which includes the study number.
4. The Committee asked if the comparator device is standard of care in New Zealand. The researcher confirmed this but advised that due to market availability it is not being used often. The Committee asked why Hydrus device is being used as the comparator. The researcher stated that this is in order to clarify published results. When it came to the market, Hydrus results exceeded those of the eye stent. Glaukos wants to clarify results by carrying out this study only in patients who have had lens replacement surgery.
5. The Committee noted that participants can have either one or both of their eyes treated in the study. The researcher confirmed this and advised that they will not do two eyes at the same time.

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 stated that if participants are also patients of the Coordinating Investigator(s), the clinician should provide the patient with an initial introduction to the study and ask patients if they might be interested in participating. However, the person who carries out the consent process should be an investigator who is not the treating clinician in order to mitigate conflict of interest between the roles.
2. The Committee noted that women of reproductive age are excluded from the study; from an equity and fairness perspective, this does not meet the National Ethical Standards for Health and Disability Research and Quality Improvement 2019. The Committee asked whether women of reproductive age could be included in the study, and the researcher provides reproductive risk advice and a list of adequate contraception as per the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-apr20.docx). The researcher advised that they would discuss this matter with Glaukos.

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

1. Please provide a title in lay language on page 1.
2. Please review the document for spelling, grammatical, and formatting errors.
3. Please provide information on how many participants have already received the new device.
4. Please provide more information about the Hydrus stent.
5. Please be consistent in referring to the Hydrus stent as ‘the Hydrus stent’ only, not the ‘competitor device’ or ‘competitor implant’.
6. Please explain clearly that this study will compare the Hydrus and Glaukos stents and explain the different number of stents that each insert.
7. The Committee noted that the stent contains tissue from pigs. Some people may take issue with this from a personal, religious, or cultural perspective. Please inform participants that the product contains a small amount of animal (pig) material.
8. On page 9, please list the commercial sponsor’s name.
9. Please clarify that reimbursement will be for costs as they are incurred, not just reimbursement at the end of the study.
10. In the CF, please remove any ‘yes/no’ tick boxes for anything that is not truly optional.

**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 PIS/CF, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, paras 7.15 – 7.17).*

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

|  |  |  |
| --- | --- | --- |
| **5**   | **Ethics ref:**   | **2021 FULL 11650** |
|   | Title:  | A clinical trial in Familial Chylomicronemia Syndrome (FCS) |
|   | Principal Investigator:  | Dr John Baker |
|   | Sponsor:  | Arrowhead Pharmaceuticals, Inc |
|   | Clock Start Date:  | 25 November 2021 |

Dr John Baker, Roger Tran, Minh Le, Magdy Gado, and A Barbour 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. This primary study question is to evaluate the efficacy of the study drug ARO-APOC3 amongst adult participants with Familial Chylomicronemia Syndrome (FCS). As such, this study will adopt a double-blinded approach in which eligible participants will be randomised 2:1:2:1 to the study arms (AROAPOC3 25mg, volume-matched placebo, ARO-APOC3 50mg or volume-matched placebo) via subcutaneous injection.

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 how many participants in New Zealand will be recruited for this study. The researcher stated that they aim for five participants.
2. The Committee asked how participants will be invited into the study. The researcher advised that they have a database of individuals who consented to their details being stored following Phase 1 of the study. These people will receive a text, and if they wish to obtain more information about the study/are interested in participating, the research team can provide this. They will not cold call people. Consent will be obtained in person.
3. The Committee noted that in addition to use of the database, the researcher will use advertisements to recruit participants. The researcher stated that they will advertise on the Counties Manukau District Health Board (DHB) intranet. The researcher advised that copies of the advertisements are available on the Ethics Review Manager; however, were uploaded incorrectly under the ‘Other’ category. The researcher also clarified that Middlemore Clinical Trials is independent from the hospital, with its own staff employed who are separate from the DHB staff, so potential conflicts will be mitigated.
4. The Committee asked if there is a data monitoring committee. The researcher advised that as per the protocol at section 7.4.1, there is a safety review committee. The safety review committee will review all participants on the active drug and placebo for adverse events and serious adverse events and will meet weekly.

Summary of outstanding ethical issues

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

1. The Committee noted that pregnancy is a contraindication to participation in this study. The Committee recommended that the wording in the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-apr20.docx) is used in all of the Participant Information Sheets and Consent Forms (PIS/CFs) to outline the reproductive risks and contraceptive methods available in New Zealand.
2. The Committee has not reviewed or approved the Pregnancy/Pregnant Partner PIS/CF as this should be provided and adapted to each situation of pregnancy, at the time a pregnancy occurs. If this occurs, a Pregnancy/Pregnant Partner PIS/CF needs to be submitted to the Committee as an amendment.
3. The Committee queried whether only people with the genetic condition can participate in the study. The researcher clarified that the study is not limited to inclusion of people with the genetic condition only. The study will also include people with the phenotype as not everyone will be aware they may have the genetic mutation. Please explain this clearly and in lay language in the Participant Information Sheet. This information will need to be clear about how these people can be included in the study even without knowing the genetic condition, and also make less intimidating the information about what the genetic condition might involve.
4. The Committee noted that there is an option for future unspecified research and a separate PIS/CF was provided. The Committee asked the researchers to confirm if this will include genetic research. If so, it is important to include this information (whether it will include genetic research or whether it will not, the implications of the genetic test result, how the result will be communicated to the participant and their family/whānau – particularly their children). The Committee also acknowledged that this information is particularly important for Māori.
5. The Committee asked the researcher to provide clear information about the risks of being in the placebo arm of the study, and whether at a later time they might offer the study drug to people who were on the placebo. The researcher raised that it is a placebo-controlled study for participants on background therapy. The Committee acknowledged this; however, stated that the PIS/CF also needs to be written from a lay person’s perspective. The participants need the information to be set out more clearly on page 1 of the PIS/CF, for example (but not limited to) that:
	* participants are invited to the study as someone who has been diagnosed with hypertriglyceridemia
	* they might be experiencing possible complications already
	* they might not know that they have a genetic condition
	* they are invited to be screened for the possible genetic condition.
6. The Committee asked if a travel vendor will be used. The researcher stated that all of the paperwork for the travel vendor is currently being reviewed internally. They will be made available to the Committee for review as soon as it is available.

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

1. Please review each PIS/CF and convert the content into lay language. The language is currently very technical and may be difficult to understand. For example, on page 2 under ‘Purpose’, the content appears to have been copied directly from the protocol rather than written for prospective participants. The Committee recommended that the researchers ask lay people to review the document to confirm that they can understand the content.
2. Please provide a lay definition for ‘genotype’ the first time the term is used.
3. Please check the documents for repetition and delete any unnecessary text.
4. Please review the layout of the documents. For example, page 6 of the main PIS/CF is mostly blank.
5. Please consider using more white space / review the formatting of the document to make it easier to read.
6. Please review for any spelling or grammatical errors.
7. Please mention how many participants might be enrolled in New Zealand.
8. Please state that notification of positive results of Hepatitis B and C are required in New Zealand.
9. Participants should be offered the option to receive the lay summary of study results. Please include a ‘yes/no’ option for participants to receive 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 PIS/CFs, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, paras 7.15 – 7.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Sarah Gunningham and Associate Professor Mira Harrison-Woolrych.

|  |  |  |
| --- | --- | --- |
| **6**   | **Ethics ref:**   | **2021 FULL 11094** |
|   | Title:  | SCIP RHD |
|   | Principal Investigator:  | Dr Julie Bennett |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 25 November 2021 |

Dr Julie Bennett and Erik Anderson 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

Primary aims of the Study

1. To demonstrate safety and tolerability of high dose (20.7mL/10.8MIU) Bicillin® L-A administered by subcutaneous infusion in children/young adults with ARF who are currently receiving regular intramuscular benzathine penicillin G (BPG) injections.
2. To demonstrate acceptability of high dose subcutaneous Bicillin® L-A in children/young adults with acute rhematic fever currently receiving regular intramuscular BPG injections.

Secondary aims of the Study

1. To demonstrate pharmaco-equivalence of high dose Bicillin® L-A administered by subcutaneous infusion when compared with expected intramuscular concentrations.
2. To measure pain experienced by participants following high dose Bicillin® L-A administered by subcutaneous infusion.
3. To measure the time (in days) that penicillin concentrations remain above the minimum inhibitory concentration (0.02mg/mL) for Streptococcus pyogenes following high dose Bicillin® L-A administered by subcutaneous infusion.
4. To explore perceptions, attitudes and training of health workers delivering regular BPG and how this could impact the patient experience.
5. To measure the frequency and types of adverse events related to high dose Bicillin® L-A administered by subcutaneous infusion.

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 age range of children is quite broad and queried whether the study should focus on older children to minimise risk. The researcher stated that it would be ideal to have the children be as old as possible; however, they also wish to obtain as broad a range of those being treated with injectable penicillin, so they want input from as many children who are already on the intramuscular injections.
2. The Committee asked if there is a comparator group for the study. The researcher stated that phase 1 of the study was carried out with healthy adults. However, they were not on regular intramuscular injections. The study will compare against other already published data as this will be done based on pharmacokinetics.
3. The Committee asked if participants’ general practitioners (GPs) will be informed of their participation in the study. The researcher stated that they will not directly inform the GPs because two members of the research team are the treating paediatricians.
4. The Committee noted that pregnancy is a listed exclusion criterion. The Committee asked if participants will be able to inform the research team in private and without their parent(s)/guardian(s) present if they do become pregnant. The researcher confirmed this.

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 if the trial has been reviewed by the Standing Committee on Therapeutic Trials (SCOTT). The researcher confirmed this and advised that they will provide a copy of the correspondence from SCOTT confirming that their review/approval is not required.
2. The Committee recommended that a study participation card should be provided to participants. Please also provide a copy to the Committee for approval.
3. The Committee noted that efficacy data is not being collected in this study and the researcher stated that they can change the study to collect this information.
4. The Committee referred to D12 of the application form. The Committee clarified that assent forms for under 16-year-olds should only be used for those who are incapable of providing consent. Please also note that it is parent(s)/guardian(s) who can provide consent, not caregivers. The Committee also highlighted that if there are 15-year-olds in the study (who were consented via an assent form), they would need to sign a consent form after they turn 16-years-old.

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

1. Please check the formatting of the document. When printed in hardcopy some of the formatting changes.
2. In the PIS/CF for 11 to 15-year-olds, please make the wording more neutral in regards to ‘inviting’ the child to participate in the study, rather than asking them to ‘help’ as this may feel coercive.
3. On page 3, there is an ‘X’ where a name is missing.
4. Please state how long each visit will take in total so that people can plan ahead.
5. Please inform participants that blood samples will be sent overseas, plus the implications around this.
6. Please include a statement that the child can decline to participate even if the parent(s)/guardian(s) consent.
7. Please replace the word ‘tummy’ with ‘stomach’.
8. On page 4, please refer to the right to correct personal information, as well as referring to the right to access information.
9. On page 4, please provide more information about the tissue samples.
10. Please remove any yes/no tick boxes on the CF unless they are truly optional.
11. In the assent form, please review the statement about study information being provided to parents if the child would like this to happen. Since this is an assent form, the parent(s)/guardian(s) are actually providing the consent so it is assumed that they would be provided with this information regardless.

**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 PIS/CFs, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, paras 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 2019*, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by Helen Walker and Amy Henry.

|  |  |  |
| --- | --- | --- |
| **7**   | **Ethics ref:**   | **2021 EXP 11147**  |
|   | Title:  | Pharmacokinetics of high dose quercetin |
|   | Principal Investigator:  | Dr Leon Yu-An Huang |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 25 November 2021 |

Dr Leon Yu-An Huang and Dr Conroy Wong 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 primary aim of this study is to determine the blood quercetin level following 6 weeks of high dose quercetin supplementation. We will also be assessing the types and rate of adverse events associated with high dose quercetin, and assessing changes in renal and liver function, inflammatory marker (C-reactive protein levels), and adherence.
2. This study is an open-label, dose-ranging (2 dosing arms), uncontrolled, randomised pharmacokinetic/feasibility study. The investigators and the study participants will be aware of the dose of quercetin supplement received (two dose groups). The participants will be randomised into two groups of equal numbers receiving either 2g or 4g of quercetin supplementation for 6 weeks. There will be no placebo or control arm.

Summary of resolved ethical issues

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

1. The Committee queried whether the researcher is comfortable with the safety profile of the high dose. The researcher responded that there is limited evidence on this dose amount and that it needs to be established in the population.
2. The Committee confirmed with the researcher that they will undertake consultation with Māori before commencing this study.
3. The Committee confirmed with the researcher that they will not be storing any tissue for future unspecified research in this study.
4. The Committee queried the koha amount. The researcher responded that they are limited by budget constraints but are planning for approximately $50 per person in total. The Committee noted that this is a low figure and will not reimburse the participant for their time and travel. However, the Committee was satisfied so long as the researchers inform the participant of the koha amount in 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 noted that the application form says that there are no risks other than the blood tests. Please state the risk of the high dose.
2. The Committee requested that the researcher upload the adverts to recruit volunteers.
3. The Committee requested that the researcher check with SCOTT whether this study needs to be reviewed by them. Please upload a confirmation email.
4. The Committee requested that the researcher remove reference to the study possibly working with SARS-CoV-2.

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

1. Please include the risks of the high dosage, and other risks involved with this study, for example data risks.
2. Please state the koha amount.
3. Please inform the participant of all questionnaires.
4. Please inform the participant about tissue analysis.
5. Please inform the participant about what will happen in the event of abnormal results in the blood tests.
6. Please inform the participant that you will be informing their GP of their participation in the study.
7. Please inform the participant about using appropriate contraception for the duration of the study. Please see the [HDEC reproductive risks information sheet template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-apr20.docx) for guidance.
8. Please inform the participant about withdrawal rights.
9. Please include more information in the data management section, as per the [HDEC PISCF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc).
10. Please include more information about data risks and rights to access information, as per the [HDEC PISCF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc).
11. Please ensure that all the relevant information from the [HDEC PISCF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) is included.
12. Please give a general proofread.
13. Please refer to the correct HDEC.

**Decision**

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

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

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

|  |  |  |
| --- | --- | --- |
| **8**   | **Ethics ref:**   | **2021 FULL 11766** |
|   | Title:  | Safety and Effectiveness of the Zenflow Spring System - A Minimally Invasive Treatment for LUTS associated with BPH - BREEZE study |
|   | Principal Investigator:  | Professor Peter Gilling |
|   | Sponsor:  | Zenflow Inc |
|   | Clock Start Date:  | 2 December 2021 |

Rachael Hamill and Deborah Bell 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 objectives of the study are to demonstrate the safety and performance of the Zenflow Spring System in relieving the symptoms of LUTS associated with Benign Prostatic Hyperplasia (BPH).
2. The study is a prospective, multi-centre, multinational 2:1 randomized, single-blinded controlled clinical trial of the Zenflow Spring System.
3. In this randomized clinical trial, subjects are either randomized to the Zenflow Spring Treatment Arm or to the Control Arm (Sham) at the time of treatment and results will be compared at the 3-month follow up.
4. Subjects will be blinded as to which arm they are randomized into until they reach the 3-month timepoint.

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 researcher’s answer to question b.22 of the application form states that there is no coercion as it is a standard doctor patient relationship. However, due to the unequal power dynamic present in this relationship, there is a potential for coercion. The Committee requested that the researcher be aware of this.
2. The Committee noted that in c.4 and c.7 of the application form (cultural section), the Committee was looking for statistics about the prevalence of BPH in Māori men. The Committee responded that whilst BPH may be more prevalent in Māori men, it may be underreported.
3. The Committee noted than in question c.5 of the application from (issues for Māori), they should have noted that blood samples are taonga. Furthermore, there may be whakamā associated with having BPH as the symptoms may involve urinary and erectile dysfunction.
4. The Committee queried the recruitment process and whether first contact with the potential participant can be by a research nurse rather than someone directly involved in the study. The researcher responded that potential participants would be referred by urologists at the DHB or the patient’s GP. The research team will contact them and then, if interested, the PI will consent them.
5. The Committee queried how quickly the quality-of-life questionnaires will be reviewed by the research team, and what procedures will be in place to support participants in need of mental health support. The researcher responded that the research nurse will see the questionnaires straight away and inform the PI of any concerning answers, as well as encouraging the participant to seek help from their GP.
6. The Committee queried what would happen if at the end of the study the participant chose to keep their device in but later wanted or needed to get it removed. The researcher responded that this would require a biopsy and can be safely done within 5-6 years since initial implantation.
7. The Committee noted that there is not a person specifically named as a Māori contact person. The researcher noted that the contact had asked not to be specifically named, but confirmed that cultural support would be available to participants if they called this number.

Summary of outstanding ethical issues

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

1. The Committee noted that the researchers need to undergo formal consultation with Māori. Notification is not the same thing as consultation. This will need to occur before the study can commence and will also be required for locality approval.
2. Please provide a data management plan (DMP). (*National Ethical Standards for Health and Disability Research and Quality Improvement*, para 12.15). See the HDEC DMP template for guidance.

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

1. Please inform the participant of the number of participants and sites in NZ.
2. Please add a cultural statement. See the HDEC PISCF template for guidance.
3. The Committee noted that there are a range of device sizes, and the participant will be given the one that ensures optimal fit. The Committee requested that the researcher not tell or show the participant the different sizes, as this may be mentally distressing for some participants. Please delete this paragraph and figure 1. Rather, say something like “there are various device sizes, and we will pick the one most appropriate for you”. Keep figure 2.
4. Please provide more information about what will happen to the participant’s data, including the optional videos. See the HDEC PISCF template for guidance.
5. On page 12, please remove the following paragraph, as this will not be occurring in this study:

*Tissue samples taken from around the implant at explant may be sent to Zenflow for analysis. This tissue sample will be de-identified, will not be used for any other purpose and will be destroyed once analysis is complete. In addition, your doctor may choose to send any prostate tissue samples for routine laboratory testing.*

1. Please provide more information about what is going to happen to the sham group, especially that they are going through a similar procedure will all the associated risks, but none of the benefits.
2. In the risk section, please remove the side effects that have never been observed in this device. This is an FDA requirement which does not apply in NZ. Please also remove information about non-observed adverse events.
3. Please use the term rectum rather than back passage.
4. Please proofread, e.g. page 9 says ‘rate’ rather than ‘rare’.
5. Please note that no karakia will be available at the time of tissue destruction.
6. Please remove the yes/no tick boxes for aspects of the study that are not optional if the participant wishes to participate.
7. Please inform the participant how long the study procedures will take.

**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 2019, paras 7.15 – 7.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Sarah Gunningham and Dr Patries Herst.

|  |  |  |
| --- | --- | --- |
| **9**   | **Ethics ref:**   | **2021 FULL 11846** |
|   | Title:  | Tuning in to Teens in Aotearoa New Zealand |
|   | Principal Investigator:  | Ms Zara Mansoor |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 2 December 2021 |

Zara Mansoor, Elliot Bell and James Stanley 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 main aim of the current study is to evaluate the impact of Tuning in to Teens (TINT) as an addition to care for young adolescents presenting to Child Adolescent Mental Health Services (CAMHS) in Aotearoa New Zealand (NZ).
2. The objectives are:
	* To determine meaningful outcomes from a service-user perspective when evaluating the programme (Co-design of outcome measures).
	* To compare TINT (as an enhancement to usual care) to usual care alone for young adolescents in CAMHS (Pilot randomised control trial).
3. Part I will use a co-design methodology and involve working with service users to determine outcomes for the evaluation.
4. Part II will be a two-armed pilot Randomised Control Trial (RCT) comparing usual care in CAMHS to usual care plus TINT.
5. Due to the nature of the intervention, participants and clinicians will not be blind to allocation. Researchers collecting outcome measures will be blinded to allocation.

Summary of resolved ethical issues

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

1. The Committee commended the researcher for having addressed the comments from the previous HDEC review to a high standard.
2. The Committee and researcher discussed the fact that part I of the study will inform part II. The Committee noted that they can only approve part I of the study. Part II will need to be submitted as a substantial amendment to the study once the protocol has been developed.
3. The Committee queried how confidentiality will be managed in the group workshops. The researcher responded that informing the participants of the confidentiality risks will be part of the informed consent, and at the beginning of the workshops the importance of privacy and confidentiality and the associated risks will be discussed.
4. The Committee noted the $150 reimbursement per participant in part I of the study, commenting that this is quite high, especially for children. The researcher responded that this is because participants in part I of the study are involved in co-design, which means they are being used for their expertise. Therefore, they are being paid a market rate for their expertise. Furthermore, the researcher noted that it is important that children are not underpaid on the basis of age. She noted that participants in part II will be paid $20, which is reimbursement for their time rather than expertise, because they are filling out a questionnaire rather than contributing to co-design.
5. The Committee queried the consent process and whether the young people and parents will be consented together or separately. The researcher responded that this will be dependent on the personal preference of the children, as to whether they want a parent or support person with them through the consenting process. The researcher confirmed they will ensure the young participants to not feel pressured to participate.
6. The Committee queried how clinical care will be distinguished from research within the study, to ensure there is a separation of roles between researchers and clinicians. The researcher responded that the initial recruitment will not be coming from the participants’ care team.
7. The Committee noted the study title ‘Tuning in to Teens’ is not relevant for many of the participants, as the age group is 10-14. The researcher noted the difficulty in changing the study title across their documentation but will consider use a more appropriate lay title for participant-facing documentation. However, the programme is called Tuning in to Teens which is a trademark protected title so reference to the programme cannot be changed.

Summary of outstanding ethical issues

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

1. In the demographic questionnaire, please correct the spelling of ‘Niuean’.

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

1. The Committee noted a printing error in the PISCF and asked the researcher to check / correct for this if necessary.
2. Please check for lay language. For example, participants may not know what co-design means. Please explain what co-design means before starting to use this term widely in the PISCF.
3. On the first page of the PISCFs, please include researcher name and locality, and ethics approval number, version numbers and date at the bottom.
4. Please modify each CF to clarify throughout the document whether it is the participant *assenting* or *consenting*, or the parent/guardian/researcher consenting for the *child’s* participation, or for their *own* participation in the study. Please ensure that there are separate and distinct forms for each scenario. Ensure that each sheet has a place to sign. Please refer to parents or guardians rather than caregivers.

**Decision**

Part I of this study 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 2019, paras 7.15 – 7.17).*

Please submit part II as a study amendment once the protocol has been developed.

|  |  |  |
| --- | --- | --- |
| **10**   | **Ethics ref:**   | **2021 FULL 11386** |
|   | Title:  | TEMPO-2 – A randomised clinical trial of Tenecteplase thrombolysis versus standard treatment for minor stroke with brain artery occlusion |
|   | Principal Investigator:  | Dr Teddy Wu |
|   | Sponsor:  | The University of Calgary |
|   | Clock Start Date:  | 2 December 2021 |

Dr Teddy Wu and Kathleen Bremmer 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 will assess the safety and effectiveness of Tenecteplase to treat minor ischaemic stroke patients with minor stroke symptoms and a proven blockage of a major vessel in the brain.

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 restrictions placed on the publication of the study were based solely on the fact that the lead investigator and the steering committee require consultation prior to publications being made and that there is very low likelihood of this impacting the publication of results.
2. The Committee clarified that there would be no tissue samples taken for the study and that the only samples would be as part of routine treatment.
3. The Committee clarified that there was no likelihood of participants who could not consent.

Summary of outstanding ethical issues

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

1. The Committee requested that the Data Management Plan (DMP) be expanded on so that data breach and Māori data sovereignty are addressed as per the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/data-only-management-template-oct2020.docx).

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

1. Please include a statement about pregnancy being an exclusion criterion and how/if this will be tested.
2. Please review for spelling errors.
3. Please remove the title of the study on the first page.
4. Please amend the statement on page 5 concerning contact of the family doctor to be mandatory, the word “may” should be removed from this statement.
5. Please amend to include the 90-day follow up procedure.
6. Please clarify if identified or deidentified data will be sent overseas and include a statement on the risks of 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 2019, paras 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 2019, para 9.7*).

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

|  |  |  |
| --- | --- | --- |
| **11**   | **Ethics ref:**   | **2021 FULL 11430** |
|   | Title:  | Diabetes eye care services in Auckland and Counties Manukau |
|   | Principal Investigator:  | Professor Jacqueline Ramke |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 2 December 2021 |

Dr Jacqueline Ramke and Pushkar Silwal 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 identify the barriers and enablers of access to diabetes eye care (DEC) services and develop strategies to modify the monitoring process of DEC services to facilitate the routine reporting of Ministry of Health Diabetic Retinopathy (DR) indicators, and to develop a package of deliverable strategies to increase access to DEC services.

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 detail in the Protocol as the information provided is not sufficient *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, paras 9.7a and 9.8)*.
2. The Committee recommended use of the HDECs templates for the [Patient Information Sheet and Consent Forms (PIS/CF),](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) and [Data Management Plan (DMP)](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/data-only-management-template-oct2020.docx).

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please provide information as to the rationale, intent, and risks of the study *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, paras 7.15 and 7.16)*.
2. Please review for lay language and increased clarity *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, para 7.16)*.
3. Please specify the amount of time required by the participants to take part in the study *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, para 7.19)*.
4. Please amend the document to provide the additional information that the participants could be contacted about *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, 7.16)*.

**Decision**

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

|  |  |  |
| --- | --- | --- |
| **12**   | **Ethics ref:**   | **2021 FULL 11790** |
|   | Title:  | Understanding Child Abuse Victims, their Caregivers and Clinicians Experience of Trauma Focused Cognitive Behavioural Therapy |
|   | Principal Investigator:  | Miss Audrey Kusasira |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 25 November 2021 |

Audrey Kusasira 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 contribute to the growing body of research that is aiming to fill the gap of the data deficit of the user experience of the Trauma Focused Cognitive Behavioural Therapy (TF-CBT) model as well as to possibly afford information form the user experience that might assist in enhancing this treatment model.

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 the process by which the co-design would occur and the procedures in place for approaching the five individuals.
2. The Committee clarified that the first part of the study is the only applicable section for this review.
3. The Committee clarified that the clinicians on hand would be there to support issues with both participants and their parents/guardians during the study.
4. The Committee clarified that the parents and guardians would not be interviewed in step one of 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 noted that there was an error in reference to “Caregivers” being able to give consent for a child in the study. This will need to be amended to ‘Parent or Guardian’ as per New Zealand law.
2. The Committee queried the use of “Child” and “Children” in the study documentation when in fact many of the participants are teenagers or young adults. The Committee recommends changing this to reflect or better encapsulate the different ages of those taking part.
3. The Committee informed the researcher that data would need to be kept for 10 years after the youngest participant turns 16-years-old as per New Zealand law and this needs to be reflected in the Data Management Plan (DMP).
4. Please review the DMP for missing sections and information, please see the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/data-only-management-template-oct2020.docx) for a guide on the information required for submission.
5. The Committee requested that there be a consent form for young people participating make transcripts available to guardians and parents.
6. The Committee forwarded the notion that there could be a removal of age bands for consent forms and instead have a consent form and an assent form based on maturity/capacity to consent for themselves or assent.
7. The Committee requested that there be a statement as to what will happen to the audio tape data that is collected.
8. Please remove mention of the study contributing towards a PhD from the benefits section as it is not a benefit to the participants.

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

General Comments for all PIS/CFs:

1. Please clarify further the reasoning behind the research for the sake of participant understanding.
2. Please clarify if there will be a clinician nearby and the extent of the support that participants can receive in the event of a significant effect on the mental health of a participant.
3. Please include a Māori cultural support contact.
4. Please remove all consent tick boxes that are not for truly optional questions.
5. Please include a consent form for participants under the age of 16 who have capacity to consent for themselves.
6. Please specify in the children’s consent forms that it is their right to say no to participate in the study and not the decision of their parents to enrol them in the study.

PIS/CF Step One 8-11:

1. Please amend the statement concerning the notification of a clinician in the event of cases of significant distress to be more like the other PIS/CF statements to this effect and worded to be less heavy-handed.

PIS/CF Step One Caregiver:

1. Please note that this needs to be titled and directed for parents and guardians, as caregivers cannot give consent in this case.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, paras 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 Dr Patries Herst and Helen Walker.

## General business

1. The Committee and Secretariat thanked Dr Sarah Gunningham for her service on the Southern HDEC. This was Dr Gunningham’s final meeting.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting:

|  |  |
| --- | --- |
| **Meeting date:** | 08 February 2022 |
| **Zoom details:** | TBC |

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 5.00pm.