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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 12th April 2022 |
| **Zoom details:** | https://mohnz.zoom.us/j/9481145912 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Assigned Lead Reviewers** |
| 10:30am – 11:00am | 2022 FULL 12083 | A phase 3 study evaluating the safety and efficacy of VX121 triple combination therapy in Cystic Fibrosis (VX20-121-103) | Dr Mark O’Carroll | Mr Anthony Fallon & Associate Professor Nicola Swain |
| 11:00am – 11:30am | 2022 FULL 11901 | A phase 3 study evaluating the safety and efficacy of VX121 triple combination therapy in Cystic Fibrosis (VX20-121-103) | Dr Mark O’Carroll | Mr Anthony Fallon & Associate Nicola Swain |
| 11:30m – 12:00pm | 2022 FULL 12301 | The XanaFX study | Dr. Andrew Marshall | Mr Dominic Fitchett & Ms Amy Henry |
| 12:00pm – 12:30pm | 2022 FULL 12482 | A PHASE 1/2A STUDY EVALUATING THE EFFECTS OF ARO-MUC5AC INHALATION SOLUTION IN HEALTHY SUBJECTS AND PATIENTS WITH ASTHMA | Dr Mark O’Carroll | Ms Catherine Garvey & Dr Devonie Waaka |
| 12:30pm – 12:50pm |  | ***Break (20 minutes)*** |  |  |
| 12:50pm – 1:20pm | 2022 FULL 12531 | The effect of positive pressure treadmill training in young people with cerebral palsy | Mr. Pablo Ortega-Auriol | Catherine Garvey & Associate Professor Mira Harrison-Woolrych |
| 1:20pm – 1:50pm | 2022 FULL 11813 | Low Dose Naltrexone To Help Treat Depression | Dr Joanne Lin | Mr Dominic Fitchett & Associate Professor Nicola Swain |
| 1.50pm – 2:20pm | 2022 FULL 12212 | Fanau ola manuia programme | Dr Ridvan Firestone | Mr Anthony Fallon & Ms Amy Henry |
| 2:20pm – 2:50pm | 2022 FULL 12393 | MT1002 in PCI | Dr Jithendra Somaratne | Ms Catherine Garvey & Dr Devonie Waaka |
| 2:50pm – 3:00pm |  | Break (10 minutes) |  |  |
| 3:00pm – 3:30pm | 2022 FULL 12280 | Peripheral chemoreflex in hypertension: rest and exercise | Miss Ana Luiza Sayegh | Mr Dominic Fitchett & Associate Professor Mira Harrison-Woolrych |
| 3:30pm – 4:00pm | 2022 FULL 12480 | APL-101-03: A Study Comparing two different capsule formulations of APL-101 and PLB-1001 in Healthy Chinese and Caucasian Participants | Ms Julia O'Sullivan | Mr Anthony Fallon & Ms Amy Henry |
| 4:00pm – 4:30pm | 2022 FULL 11658 | Improving continence management for people with dementia in the community (PHASE 3) | Professor Vanessa Burholt | Ms Catherine Garvey & Dr Devonie Waaka |
| 4:30pm – 5:00pm | 2022 FULL 12229 | PREVISION First in Human Study | Ms Cynthia Corne | Mr Dominic Fitchett  & Associate Professor Mira Harrison-Woolrych |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Devonie Waaka | Non-lay (intervention studies) | 18/07/2016 | 18/07/2019 | Present |
| 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 | Present |
| 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 |
| Associate Prof Nicola Swain | Non-lay (intervention & observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Ms Catherine Garvey | Lay (Law) | 11/08/2021 | 11/08/2024 | Present |

## Welcome

The Chair opened the meeting at 10:00am 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. Ms Catherine Garvey confirmed their eligibility and 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 8th April were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2022 FULL 12083** |
|  | Title: | A phase 3 study evaluating the safety and efficacy of VX121 triple combination therapy in Cystic Fibrosis (VX20-121-103) |
|  | Principal Investigator: | Dr Mark O’Carroll |
|  | Sponsor: | Vertex Pharmaceuticals Australia Pty Ltd & Adjutor Healthcare (NZ) Limited |
|  | Clock Start Date: | 31st March 2022 |

Dr Mark O’Carroll and Ms Maye Hamed 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.

Devonie Waaka declared a potential conflict of interest and the Committee decided that Devonie would not engage with the discussion. The Committee remained quorum.

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 2022 FULL 12083 and 2022 FULL 11901 are being conducted under one research team and study conduct is extremely similar, with the main difference being different types of genetic mutation in the study population. Because of this, the Committee comments applied to both studies and this is reflected in the minutes.
2. The Committee noted that the Pregnancy PISCF has not been reviewed or approved, as this is reviewed on an as-needed basis.
3. The Committee asked for information on the process which would take place should a participant experience distress on questionnaire completion during the at-home sections of the study. The Researcher explained that the Study Coordinator would be contactable if needed for the participants, as well as a nurse specialist who is linked into a multidisciplinary team who would be able to assist in the event of distress.
4. The Committee requested more information on the future availability of the study drug following the conclusion of the study. The Researcher noted that there is a possibility of participants from the study being able to join an open-label study which would allow for access to the study drug, however this has not been confirmed.

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 if CRF reporting does not collect ethnicity data relevant to NZ, additional relevant data per Stats NZ levels is collected in source documents. This is required for future reporting to HDEC. The Committee noted the continued use of the Study Data and Samples’ section of the PIS that the statement “The sponsor will use the information and samples in the research and development of the Study Drug and other medicines and diagnostics. You will not own any of the information or the samples.” implies future unspecified research outside the parameters of this study. The Committee suggested that either this sentence should be revised to state samples will only be used within the study parameters, or this statement may be deleted and moved to the section Future Research Using Your Information.
   1. The committee noted that the Researchers have uploaded a separate PIS for future research. This may be mentioned in the main PIS section Future Research Using Your Information, emphasising that it is optional to agree to having samples used for future research.
2. The Committee requested that optional unspecified future research involving potential broad genetic analysis is restricted to those able to provide independent informed consent, as once genome sequencing has been undertaken for unspecified research it may be impossible to delete the data in the future.

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

1. Please provide more lay-friendly titles.
2. Please remove the technical language and ensure that the information provided is lay-friendly.
3. Please provide blood measurements as millilitres instead of teaspoons or cups.
4. Please revise the Reproductive Risks section and consider using the [HDEC template.](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/) Please remove the statement in the child’s assent form requesting that they be on birth control.
5. The Committee noted that informing the participants GP is not optional – please remove the yes/no tick box.
6. The Committee noted that stopping a trial due to commercial reasons is not a viable reason in New Zealand. Please remove this statement.
7. Please include a statement explaining the study sponsor and their role in the study. Please then remove mention of the sponsor where it is not relevant.

ASSENT FORM FOR CHILDREN 12 – 18

1. Please alter the statement around all female participants needing to take a pregnancy test
2. Please include information on providing a same-gender clinician and bringing a support person to clinician visits.

**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).*

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| **2** | **Ethics ref:** | **2022 FULL 11901** |
|  | Title: | A phase 3 study evaluating the safety and efficacy of VX121 triple combination therapy in Cystic Fibrosis (VX20-121-103) |
|  | Principal Investigator: | Dr Mark O’Carroll |
|  | Sponsor: | Vertex Pharmaceuticals Australia Pty Ltd & Adjutor Healthcare (NZ) Limited |
|  | Clock Start Date: | 31st March 2022 |

Dr Mark O’Carroll and Ms Maye Hamed 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.

Devonie Waaka declared a potential conflict of interest and the Committee decided that Devonie would not engage with the discussion. The Committee remained quorum.

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 2022 FULL 12083 and 2022 FULL 11901 are being conducted under one research team and study conduct is extremely similar, with the main difference being different types of genetic mutation in the study population. Because of this, the Committee comments applied to both studies and this is reflected in the minutes.
2. The Committee noted that the Pregnancy PISCF has not been reviewed or approved, as this is reviewed on an as-needed basis.
3. The Committee asked for information on the process which would take place should a participant experience distress on questionnaire completion during the at-home sections of the study. The Researcher explained that the Study Coordinator would be contactable if needed for the participants, as well as a nurse specialist who is linked into a multidisciplinary team who would be able to assist in the event of distress.
4. The Committee requested more information on the future availability of the study drug following the conclusion of the study. The Researcher noted that there is a possibility of participants from the study being able to join an open-label study which would allow for access to the study drug, however this has not been confirmed.

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 if CRF reporting does not collect ethnicity data relevant to NZ, additional relevant data per Stats NZ levels is collected in source documents. This is required for future reporting to HDEC. The Committee noted the continued use of the Study Data and Samples’ section of the PIS that the statement “The sponsor will use the information and samples in the research and development of the Study Drug and other medicines and diagnostics. You will not own any of the information or the samples.” implies future unspecified research outside the parameters of this study. The Committee suggested that either this sentence should be revised to state samples will only be used within the study parameters, or this statement may be deleted and moved to the section Future Research Using Your Information.
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6. The Committee noted that stopping a trial due to commercial reasons is not a viable reason in New Zealand. Please remove this statement.
7. Please include a statement explaining the study sponsor and their role in the study. Please then remove mention of the sponsor where it is not relevant.

ASSENT FORM FOR CHILDREN 12 – 18

1. Please alter the statement around all female participants needing to take a pregnancy test
2. Please include information on providing a same-gender clinician and bringing a support person to clinician visits.

**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).*

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| **3** | **Ethics ref:** | **2022 FULL 12301** |
|  | Title: | The XanaFX study |
|  | Principal Investigator: | Dr. Andrew Marshall |
|  | Sponsor: | Worldwide Clinical Trials Pty Ltd (on behalf of Actinogen Medical Limited) |
|  | Clock Start Date: | 31st March 2022 |

Dr. Andrew Marshall was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that the Welfare Guardian/Legally Acceptable Representative PISCFs and Sleep-Wake Diary for over 18 year olds are not applicable to study conduct in New Zealand, the NHI Toolbox is out of scope for review, and the pregnancy follow-up PISCFs are to be submitted only in the event of a participant or partner pregnancy. These documents have not been reviewed or approved with the current submission.
2. The Committee asked for more information on the consenting process. The Researcher noted that it is likely that most participants will have an intellectual disability which will impact their ability to give informed consent. The Researchers clarified that all participants will be under the age of 18. The Researcher explained that intellectual disabilities are common in those with Fragile X syndrome, and this would inform the consent process. Because of this, the researchers will gain consent from the participants parents or caregivers and assent from the participants themselves. The Committee requested further information regarding the use of the placebo run-in as a means for participants to adjust to the study and ensure they are able to comply with study requirements. The Researcher explained that in the event of a participant not complying to protocol-required levels, they would try to make changes to accommodate them before withdrawing them from the trial.
3. The Committee asked for clarification on the recruitment process and how many participants would be involved in the trial. The Researcher explained that due to the low numbers of Fragile X Syndrome in New Zealand, many potential participants are already known to the study team and would be recruited through existing channels. The Researcher explained that there would be a minimum of 3 participants, but would be aiming for approximately 15 participants.
4. The Committed asked what provisions would be made should a participant be struggle with aspects of the trial, such as blood taking or wearing the acti-monitor. The Researcher explained that they would make any practical changes possible after discussion with the Sponsor, which would be recorded as a protocol deviation.

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 therapeutic studies cannot be terminated in New Zealand solely due to financial reasons and requested that any mention of this be removed.
2. E6 of the application form states that not all elements of Accident Compensation Corporation (ACC)-equivalent compensation will be available to participants in the event of study-related injury. The study cannot be approved in the absence of the Sponsor agreeing that compensation will be potentially available for all entitlements available through ACC. Please provide written confirmation from the Sponsor that compensation provisions in event of injury are at least ACC-equivalent. The Committee noted that the study insurance is close to expiry.
3. Please ensure that advertisements used in New Zealand refer to 13 – 18 years olds, not 13 – 21-year-olds.
4. The Data Management Plan retains a number of template options in square brackets. Please review and select a study-specific option in each case and remove the square brackets.
5. The Committee noted that as this is an international protocol, the routine ethnicity data collected is often not applicable to a New Zealand study population. If this is the case, please ensure that New Zealand-appropriate ethnicity data is collected for the final report to the Health and Disability Commissioner (HDC). Please ensure that participants receive koha for an acknowledgement of their time.

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

1. Please review the document for readability and ensure it is lay-friendly. Please also check all PIS documents for spelling or grammar mistakes.
2. Please remove the yes/no tick box to inform the participants GP in the event of any abnormal results, as this is not optional.
3. Please explain the process of the ‘needle scratch’.
4. Please add new hepatitis B and C diagnosis to notifiable diseases.
5. Please review documents for repetitive information.
6. Please remove teaspoon blood volume measurements and replace with millilitres.
7. Please explain where the listed risk frequencies have been drawn from, i.e. how many healthy participants and other population groups have received the study drug.
   1. Please review the listed frequencies for adverse events, as they do not seem to clearly equate to information provided in the Investigator’s Brochure. It is possible that the frequency descriptions for very common and common are incorrect.
   2. Please ensure the risk section references the report of DILI in a participant receiving 20 mg, and discuss the potential significance of ALT elevations for participants.
   3. The Committee noted that the reported small nerve fibre density skin biopsy changes are not explained in terms of potential significance. The reported frequency may also be incorrect; '9/30 subjects (30%) in the Xanamem group' experienced changes in one study, and skin biopsies do not appear to have been repeated in subsequent trials. Please amend to include the correct information.
8. In the Adult FUR PIS, please remove the statement regarding compensation in the event of injury as this is not applicable to this part of the study.
9. Please remove the statement "Actinogen Medical, not the study doctor, will be conducting the future scientific or genetic research'. Ensure it is instead made clear that no genetic research will be undertaken.

**Decision**

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

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

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

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| **4** | **Ethics ref:** | **2022 FULL 12482** |
|  | Title: | A PHASE 1/2A STUDY EVALUATING THE EFFECTS OF ARO-MUC5AC INHALATION SOLUTION IN HEALTHY SUBJECTS AND PATIENTS WITH ASTHMA |
|  | Principal Investigator: | Dr Mark O'Carroll |
|  | Sponsor: | Arrowhead Pharmaceuticals Inc & Novotech (New Zealand) Limited |
|  | Clock Start Date: | 31st March 2022. |

Dr Mark O'Carroll, Ms Courtney Rowse and Ms Sharmin Bala 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 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 the study’s use of group e-consent and requested further information on the process. The Researcher explained that the use of e-consent by NZCR is the standard protocol for healthy volunteer studies, although there are opportunities for participants to request an in-person discussion. The Researcher further explained that potential participants can request a one-to-one remote conversation with the consenter prior to providing informed consent.
2. The Committee noted that every potential participant should have a one-to-one discussion with the consenter prior to providing informed consent. Please ensure the provided document is amended to state that each participant will have a one-on-one discussion with the consent or to discuss any questions or concerns, prior to signing consent. Please amend the name of the document to reflect that while study information is provided in a group setting, consenting will be undertaken on an individual basis.
3. The Committee noted that group study information provision should apply only to healthy participants, and not to the asthmatic cohort.
4. The Committee noted that whilst they have received the content of the advertising, they are not shown the final advertisement which may display information differently (i.e. the reimbursements feature heavily in the final advertisement). The Committee noted *National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.13* which highlights that remunerations cannot be emphasised, especially when potential participants are vulnerable to financial incentives. Please provide the final advertisement to be reviewed by HDEC.
5. The Committee requested that they are informed of the final name that the study is listed under on the NZCR website.
6. The Committee asked whether participants who have undergone the bronchoscopy at screening will receive compensation for their time, even if they are not eligible or are not required to join the study. The Researcher confirmed that these participants would receive compensation.
7. The Committee requested that the compensation figure for bronchoscopy is provided to HDEC for review.
8. The Committee made a note that the study Certificate of Insurance (COI) lists 42 potential participants, however the submission lists “approximately 50”. Please be sure to update the study insurance if more than 42 participants enter screening

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

1. Please include more information on the bronchoscopy, such as where it will be performed, who will be performing it, and how long the procedure and associated visit will take
2. Please provide more information on the data monitoring safety arrangements in place in the study.
3. Please remove references to ‘subjects’ and replace with participants.
4. Please provide a clear indication on whether reserves are planned for this study, rather than the statement ‘depending on the type and objectives of the study’.
5. Please simplify the assessment table and delete repeated explanations of assessments.
6. Please explain what antibodies and biomarkers are, the first time these terms are used.
7. Please provide more information on the 24-hour urine collection.
8. Please rephrase ‘early termination’ to ‘early study withdrawal’.
9. Please include a statement regarding the chest x-ray risks, such as radiation in pregnancy.
10. Please remove reference to teaspoons or cup blood volumes.
11. Please remove section 5.2, ‘What Could Happen to me by Giving these Biological Samples?’
12. Please review documents for any spelling or grammar mistakes, for example ‘Urine samples to test excreted into urine collected over a period of 24 hours’.
13. Please include more information on how long standard of care bronchodilators will be withheld.

**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 Dr Devonie Waaka & Ms Catherine Garvey.

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| **5** | **Ethics ref:** | **2022 FULL 12531** |
|  | Title: | The effect of positive pressure treadmill training in young people with cerebral palsy |
|  | Principal Investigator: | Mr. Pablo Ortega-Auriol |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 31st March 2022 |

Mr. Pablo Ortega-Auriol was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that this study is a resubmission of a previously declined study (2021 FULL 11871) and reminded the Researcher that previous declines should be acknowledged on the HDEC application form.
2. The Committee asked whether the Researcher anticipates that participants may find the treadmill exercises difficult or potentially distressing. The Researcher explained that the inclusion criteria for the study states that the participants are able to walk unassisted and explained that the participant will be making 20 strides on the treadmill, which should not be overly difficult or distressing if the participant can walk unassisted. Within the high support training, participants can take breaks and recommence the activity whenever they are comfortable to do so.
3. The Committee asked whether there would be a private place for participants to have the sensors placed and get changed, and whether same-gender members of the research team could be made available if the participant wished. The Researcher explained there will be private areas to place the sensors and the parents of participants can place the sensors on the study team’s behalf with instructions.

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 it is mandatory for participants’ general practitioners (GPs) to be informed that their patients are participating in the study, and of any significant abnormal results. Please ensure this contact is made directly by the study team.
2. Please ensure that good quality ethnicity data is collected. This is required for the final study report submitted to HDEC.
3. The Committee requested that the submitted flyers need to be edited for readability. Please also temper the statements on the benefits of the study, as benefit cannot be promised.

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

1. Please state that the participant’s GP will be informed that they are participating in the study, and of any significant abnormal findings
2. Please review the patient-facing documents and remove any jargon that may not be easily understood. Please be sure the documents are written in lay language.
3. Please remove references to the costs of the assessments.

**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).*

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| **6** | **Ethics ref:** | **2022 FULL 11813** |
|  | Title: | Low Dose Naltrexone To Help Treat Depression |
|  | Principal Investigator: | Dr Joanne Lin |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 31st March 2022 |

Dr Joanne Lin was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted that the study was not yet registered on a WHO-approved clinical trial registry and asked whether this process was underway. The Researcher confirmed that they are in the process of registering the trial.
2. The Committee asked for further information on recruitment, noting that this will be done on social media and through a database. The Researcher explained that participants in previous studies could indicate whether they were interested in future studies through the database. This would include participants who did not fit the inclusion criteria in previous studies. The Researcher also noted that recruitment is also sometimes through flier drops at general practitioner (GP) offices.
3. The Committee noted that throughout the application documents “students” are referred to as collecting data and asked for more information, specifically on outlining which stages of the study students will be involved in. The Researcher explained that there will be two PhD students (registered pharmacist and neuroscience) involved in the study who will be involved throughout the study (engaging with participants, screening, EEG/MRI data, follow-ups, etc) with oversight from senior members of the study team. All clinical aspects of the study will be conducted by a research nurse.

Summary of outstanding ethical issues

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

1. The Committee asked whether the study will be using C-reactive protein (CRP) or high-sensitivity C-reactive protein (hs-CRP). The Researcher stated that they would be using hs-CRP. The Committee noted that the study protocol references CRP, which is reported differently to hs-CRP. Please ensure that the correct test is referred to.
   1. The Committee noted that the CRP ranges differ between different parts of the protocol (Section 4,1, Figure 1, and Section 5.1). Please ensure that these ranges are reviewed and corrected.
   2. Please clarify in the protocol whether participants re-screened on the basis of hsCRP will have only the re-screened figure used for eligibility, or whether the average of all 3 results will be calculated.
   3. Please comment in the protocol on the percentage of potential participants likely to fail on CRP; this would likely be significant particularly for healthy controls requiring a CRP of less than one.
2. Eligibility criteria for healthy participants are not included in the protocol. Please ensure this omission is corrected. The Committee noted that naltrexone is approved by Medsafe and commercially available in 50 mg tablets, but not the lower doses intended for use in the protocol. The study capsules will contain 4.5 mg of naltrexone hydrochloride with microcrystalline cellulose (MCC) within a gelatine capsule shell. This constitutes a new dose formulation and Standing Committee on Therapeutic Trials (SCOTT) approval must be sought (*National Ethical Standards for Health and Disability Research and Quality Improvement*, *para 14.44).* 
   1. The Committee noted that there is no description of the manufacture of 3mg and 1.5 mg naltrexone capsules in Section 6.1.2, however these are to be administered in the event of intolerability of the 4.5 mg dose. Please address this in the protocol.
   2. The Committee noted that the potential risks of naltrexone were not addressed as required in Question E.1 of the application form. Please ensure this is addressed in any future submission.
3. Please clarify whether chronic low-dose naltrexone administration may reduce or block analgesic effect if required in an acute setting such as trauma.
   1. Please provide participants a card to present to health care providers stating they may be on naltrexone.
   2. Please state whether someone from the study team will be available 24 hours to advise treating health care professionals about dose adjustment or to break blind in the event opioids are required for acute analgesia.
4. The Committee noted that the study will be testing hsCRP and Erythrocyte Sedimentation Rate (ESR) which if significantly elevated may require further investigation. Please clarify the timeliness of result review, who will make the initial determination regarding the potential significance of the result, and how appropriate follow-up will be arranged if indicated.
5. The Committee queried the mandatory inclusion of data in the open-source data bank (Figbank), noting that the kinds of data to be included are not specified and that participants are not given an opportunity to decline their data being added to this database. Please reconsider this and how this section may impact other study documentation (i.e., in the PIS it is stated that only members of the study team will have access to the data. If the database is open source, this will not be the case). Please amend study documentation and ensure information is consistent throughout.
6. The Committee asked for more detail in the Data Tissue Management Plan (DTMP) (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.8 – 12.13)*
   1. The Committee noted that the DTMP mentions tissue samples being restricted to those specified in the ‘applicable optional information form’ but noted that an optional information form has not been uploaded for review. Please clarify what is intended.
   2. The Committee noted that no tests for notifiable diseases are being undertaken per study protocol. Please delete reference to this in Section 8.1
   3. The Committee noted that Section 13 references incorrectly numbered sections of the DTMP and does not match information provided in other documents submitted. Please review and amend.
   4. Question G6 of the application form states that 'participant may withdraw their data by contacting a member of the study team and letting them know they would like to withdraw their data'. The DMP suggests mandatory inclusion of data in an open-source databank, from which data cannot be withdrawn for future (unspecified) use, which is a significant ethical issue. Clarify what is intended and ensure consistency between documents.
7. The Committee noted the inconsistencies regarding the biomarkers being collected between the PIS and the study protocol. The PIS states there will be “over 10 biomarkers collected”, whilst the protocol specifies which tests will be conducted. Please ensure the number of tests is included in the PIS.
8. Please ensure that the study duration of healthy participants is outlined in the advertisements, and that study duration is corrected for all participants in the MDD cohort.
9. Please amend the protocol to include the collection of good quality ethnicity data.(*National Ethical Standards for Health and Disability Research and Quality Improvement*, *para 9.20)*
10. The Committee noted that the recruitment would be through a phone call and e-consent and queried whether there would be an opportunity for face-to-face discussion. The Researcher explained that these will be offered to the participants, as well as a Zoom call if preferred. Please ensure that this is added to the study protocol and PIS (*National Ethical Standards for Health and Disability Research and Quality Improvement*, *para 9.7 – 9.8*).

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

1. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).* Please consider using the [HDEC template.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)
2. Please include a statement on the likelihood of failure to enrol based on CRP results.
3. Please include contact details for the research team indicating their availability to provide information to other health care professionals in an emergency situation including potential lifting of the blind for safety.
4. Please include information on the CRP and ESR results, noting the process to manage significant abnormal results, and including a statement that ESR will not be analysed for some time after collection
5. Please review the patient-facing documents for lay language and explain any technical terms.
   1. Please simplify the eligibility criteria. Please reconsider the language stating that participants with major psychiatric disorders will be excluded from the study.
   2. Please explain the use of placebos in the study, such as whether treatment allocation is blinded to participants and researchers, and state whether the blind can be broken if required.
   3. Please soften and reconsider the language around exclusion from the study due to ‘acute risk of suicide’. Please include resources to refer the participant to.
6. If mRNA will be collected (and note that it is not specified in the protocol), please explain what mRNA is in lay language.
7. Please provide more information on the study pilot, such as how many were in the trial and anything of note that came out of the study (i.e., potential side effects).
8. Please state how 'effective contraception' will be assessed. Please consider using the [HDEC Reproductive Risks template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-apr20.docx)
9. Please provide an explanation to the healthy volunteers explaining the tests they will be involved in and their role in the study.
10. Please explain the use of MRI in the study and state that whilst it is not a clinical MRI, anything of significance will be reported to the participants GP.
11. Please rephrase the statement regarding accessing GP and hospital records to state that access is limited to that required for study purposes.
12. Please remove ‘conversations about mental health’ as a benefit of the study as this is not a listed benefit of clinical participation.
13. Information about use of information requires significant revision, particularly given data entry into an open-source databank. Please review the HDEC PISCF template and ensure all aspects covered in the template are adequately addressed.
14. Please clarify who can access the databank, whether there are restrictions to the research that may be undertaken, whether checks are in place that these restrictions are adhered to, and whether data entered into the databank can be withdrawn. State also whether EEG and MRI data will be accessible in the database. Please ensure that the information on who will have access to the data is consistent across all study documentation.

**Decision**

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

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| **7** | **Ethics ref:** | **2022 FULL 12212** |
|  | Title: | Fanau ola manuia programme |
|  | Principal Investigator: | Dr Ridvan Firestone |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 31st March 2022. |

Dr Ridvan Firestone 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 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 presenting all 3 projects at the same time may be too much information to present at once to parents, especially if the majority of participants will not go on to Projects 2 or 3 after Project 1. The Committee suggested that information on the Projects could be separated, with mention in Project 1 that a small number (20) will be asked to take part in Project 2 and 3 and briefly what that may involve. Information for Project 2 and 3 should then be presented later to the small number sought for participation for this.
2. The following protocol statement was noted: 'We also aim to obtain information on non-participants, defined as those who: declined participation; or completed the questionnaire and did not meet the criterion outlined above, and non-respondents, defined as those who: did not return the study packs; or did not complete the screening questionnaire. Appended to the screening question there will be a ‘decline to participate’ slip, where a number of tick box questions on demographics (sex, ethnicity, name of street/road and postal code); and whether their child is already under medical care for either overweight and obesity, prediabetes or T2DM. We will use this data to compare with the group of children having new prediabetes and T2DM diagnoses as identified through our targeted screening approach'. The Committee raised the following concerns that need to be addressed:
   1. The Data and Tissue Management Plan (DTMP) does not address inclusion of this data or where it will be obtained from, especially any medical information.
   2. The Participant Information Sheet (PIS) does not state that those who decline to participate will still have data used.
   3. The extent of data collection is unclear, for example how information be collected about those that do not return the slip.
   4. Please clarify that medical data or data in general will not be collected from individuals who decline participation and without consent.
   5. General Practitioner involvement (GP) is unclear in study documentation. Further, please outline follow-up provided where a participant has not provided GP contact details. The Committee suggested making it mandatory for participation.
3. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17)*:
   1. Refer to Privacy Act 2020 (Section 2)
   2. Health information generated in the study must be retained for at least 10 years after the participant turns 16. Amend documentation accordingly.
   3. Individual comments made during group sessions (workshops, panels etc) are not usually able to be withdrawn as they can alter the context of other comments. This should be acknowledged in the PIS and DTMP.
4. Recruitment material for the study is intended, however no documents have been uploaded for review. Pleas ensure all recruitment material is submitted for HDEC approval prior to use.
5. The committee noted that there is no assent form for Project 1, and the current assent form provided is not fit for purpose to describe participation for this part of the study. There needs to be an opportunity for the children to give assent to have measurements and blood taken.
6. The Committee noted that anyone who turns 16 can be given the main PIS and consent form to reconsent rather than the one submitted.
7. Please specify the amount given as koha to participants for each Project, given the large time burden of Project 2 in particular. Please also clarify what the small koha for children will be.

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

1. The Committee noted there are missing sections of the participant information sheet in order to obtain fully informed consent as required by the National Ethical Standards (2019). The Committee recommended the Researcher adapt or use as a guide the [PIS template available on the HDEC website.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) Assent templates are also available and should be referred to.
2. Please clarify that intravenous bloods are taken, not a finger prick.
3. Please state whether a karakia will be available for the destruction of samples.
4. Please state the number of questionnaires participants will be expected to complete.
5. Please state blood will be analysed at (Wellington SCL) lab.
6. Please state how results will be returned to the participant.
7. Include a full description of what each part of the study involves and the approximate time commitment for each study
8. Please address the access to health data by stating what data will be used e.g., B4 school check, dental record.
9. Please include a cultural tissue statement, see the HDEC template for guidance.
10. Please include Māori support contact details.
11. Please note health data should be kept for 10 years after the youngest participant turns 16.
12. Please specify exactly what the carer is consenting to: their own participation, the index child's, their siblings etc.
13. Review for technical terms ('non-invasive assessments of body measurements', 'body mass index' etc) and replace with simple lay language.
14. Please note that a blood test is invasive (the PIS currently states it is not invasive).
15. Please state what happens to the results obtained in Phase 1, specifically whether the results will be made part of the child’s clinical record and if the family will be told the results routinely. Please also specify who will be reporting these results and how these will be sent to a GP.
16. Please summarise potential risks / inconveniences associated with each part of the study.
17. Please provide information about access to, security and use of data (identifiable and coded) and withdrawal of data.
18. Please provide information about intention to data-link with other clinical information, why data-linking is needed, and any associated risks (e.g. increased risk of re-identification).
19. Please correct reference to the Central HDEC approving the study to Southern HDEC.
20. Please amend the ACC compensation statement to the current HDEC-approved wording.' Please refer to the [HDEC PISCF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) for this.

The Committee requested the following changes to the Project 2 Assent Forms:

1. Please provide more information as to the nature of the participation required and where the workshop and panels may be held or distributed timewise. If there is nothing yet decided upon, please outline that this will be developed in time.
2. Please specify who will be invited to the workshops or panels.
3. Please amend the assent forms to be appropriate for the individuals who will be reading it. Currently there is no difference between the younger and older forms and that this will need amending before commencing this part of the study as appropriate.
4. Please specify the nature of the study and what will be expected in the second phase of the project as in the protocol.
5. Repeated references to 'supporting your family' may place undue pressure on young family members to participate.
6. Please reword statements 'no-one will be angry with you' and 'no-one will know if you take part'
7. Please delete 'I understand that whatever I decide, my legal rights will not be affected'.

**Decision**

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

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

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

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| **8** | **Ethics ref:** | **2022 FULL 12393** |
|  | Title: | MT1002 in PCI |
|  | Principal Investigator: | Dr Jithendra Somaratne |
|  | Sponsor: | Shaanxi Micot Technology Co. Ltd & Labcorp New Zealand Limited, C/O RSM New Zealand (Auckland) |
|  | Clock Start Date: | 31st March 2022. |

No Researcher was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. Clarify the site selection process used by the Sponsor and CI. Confirm that Nelson Hospital is adequately resourced for a study of this nature.
2. The Committee raised the following about standard of care (SOC) and treatment delay:
   1. Please outline SOC at study sites. The Committee queried if unfractionated heparin (UFH) / bivalidurin is routinely used at the sites with non-ST-elevation myocardial infarction (NSTEMI) percutaneous coronary intervention (PCI) as described in the protocol.
   2. If anticoagulant is routinely used, clarify whether with-holding SOC for 60 minutes in the event of the investigational product not achieving the desired anticoagulant effect poses additional risk to the participant. The Committee queried if this an issue when heparin is required for 'bail-out therapy' during PCI.
   3. If anticoagulant not routinely used, clarify whether adding study drug poses additional bleeding risk for participant.
   4. UFH effects can be reversed in the event of bleeding; the Committee queried if the same true for the investigational product.
3. Discuss why two Serious Adverse Events (SAEs) related to study drug in a cohort of six participants is required to trigger de-escalation per the stopping criteria. Justify how more than one study drug-related SAE per cohort is considered acceptable from a safety perspective (B3 of application form, protocol page 30). Please also explain why the stopping criteria state that two or more study drug-related SAEs triggers de-escalation to a lower dose, but also state that the same events will result in the study being stopped; these are two very different outcomes. Please clarify which is correct.
4. The Committee requested the following changes to the protocol:
   1. It is stated that there are 'no anticipated risks' associated with the investigational product (p26). The Committee queried if bleeding, anaphylactoid reaction / increased bone marrow haematopoiesis (preclinical studies) are anticipated risks. Please amend to include.
   2. The schedule of activities includes a number of assessments that will be conducted as part of standard care. Clarify whether SOC results can be used or whether all assessments will be repeated (demographic, con meds, exam, vital signs, ECG, many of the blood tests, etc.), which places significant additional burden on patients.
5. Patients with acute coronary syndrome usually present to and are treated at public hospitals. Explain how health care resources will not be used, as stated in Question B10, when all study procedures will be undertaken in (presumably) the emergency department and coronary care wards.
6. Please ensure the patient's treating physician does not conduct the entire recruitment and informed consent process.
7. Clarify how much time patients will be given to be presented with study information, consider participation, and discuss with whānau.
8. The Committee requested the following changes to the Data and Tissue Management Plan (DTMP) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17)*:
   1. Section 3 references New Zealand Clinical Research (NZCR) policies and Standard Operating Procedures (SOPs). Clarify NZCR's involvement in the study. Ensure data governance policies / SOPs for the site localities are addressed in Section 2.
   2. Review and edit square-bracketed DTMP template language with study-specific information.
   3. G2 of the application form states no data will be stored in identifiable form, however it appears that protocol-specified laboratory tests are entered into the clinical record. Clarify what is intended.

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

1. Please use a lay title that makes sense to patients.
2. State in a black box on page 1 that this is the second time the drug has been studied in humans (please see the HDEC PIS/CF template statement for guidance).
3. Please bullet point the dosing details to make these more readable (page 2)
4. State whether another treatment would usually be given instead of the study drug (page 2), or whether the study drug will be administered in addition to standard care.
5. State whether tests in the assessment table will be repeated if they have already been performed as part of standard of care.
6. Delete reference to aspirin and clopidogrel if these are part of standard care.
7. Simplify explanation of assessments significantly as there is currently far too much detail provided (page 6).
8. Reporting Adverse Event frequency as 'once in each study group' is not helpful when the number of study groups is not known. Replace with total numbers (e.g., 4 of 30 participants) (page 7)
9. Make it clear that additional optional consent will be sought to collect participant pregnancy follow-up data (page 8).
10. Clarify whether abciximab, eptifibatide, tirofiban are approved for use and funded. If not used at the New Zealand study sites, reference to these drugs should be removed (page 9)
11. As the study does not test for infectious diseases, delete reference to the Medical Officer of Health (page 10)
12. Statements about personal data are confusing when included in the 'coded information' section and reads as though the sponsor will in fact have access identifiable information. Please review, and clearly split into identifiable and de-identified subsections. Remove repetitive statements.
13. Data linking is referenced as a risk but does not appear to be used in this study. Delete (page 11)
14. Delete optional tick boxes for GP notification of abnormal results in the consent form.

**Decision**

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

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

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

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| **9** | **Ethics ref:** | **2022 FULL 12280** |
|  | Title: | Peripheral chemoreflex in hypertension: rest and exercise |
|  | Principal Investigator: | Dr James Fisher |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 31st March 2022. |

Dr James Fisher and Ana Luiza Sayegh were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that no personal physicians of the potential participants are investigators.
2. The Committee confirmed that the koha amount is correct in the study documentation but incorrect in the application form.
3. The Committee confirmed that the questionnaire will be completed after participants have consented.

Summary of outstanding ethical issues

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

1. Please review for consistent fonts and layout.
2. Please provide a diagram showing the mask and probes in place.
3. Please describe whether any of the assessments are painful or uncomfortable.
4. Please state there are no individual benefits to being in this experimental study.
5. Please review for jargon and amend to make lay-friendly (i.e., what ‘clinically significant’ means).
6. Please state that participants will not know the order of the infusions.
7. Please remove references to collecting blood.
8. Please remove the statement that dopamine will not be available after the study, as this is not relevant in a non-therapeutic trial.

**Decision**

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

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

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| **10** | **Ethics ref:** | **2022 FULL 12480** |
|  | Title: | APL-101-03: A Study Comparing two different capsule formulations of APL-101 and PLB-1001 in Healthy Chinese and Caucasian Participants |
|  | Principal Investigator: | Dr Paul Hamilton |
|  | Sponsor: | Apollomics Inc & LabCorp |
|  | Clock Start Date: | 31st March 2022. |

Dr Paul Hamilton, Julia O’Sullivan, and Courtney Rowse were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified the rationale behind restricting to Chinese and Caucasian ethnicity. The researcher confirmed that Caucasian ethnicity is self-reported
2. The Committee was satisfied with the justification for length of participant in-house stay for compliance reasons.
3. The Researcher confirmed that cultural consultation for Asian populations is undertaken for NZCR studies.

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 the study’s use of e-consent and requested further information on the process. The Researcher explained that the use of e-consent by NZCR is the standard protocol for healthy volunteer studies, although there are opportunities for participants to request an in-person discussion. The Researcher further explained that potential participants can request a one-to-one remote conversation with the consenter prior to providing informed consent.
2. The Committee noted that every potential participant should have a one-to-one discussion with the consenter prior to providing informed consent. Please ensure the provided document is amended to state that each participant will have a one-on-one discussion with the consenter to discuss any questions or concerns, prior to signing consent. Please amend the name of the document to reflect that while study information is provided in a group setting, consenting will be undertaken on an individual basis.
3. The Committee requested to see the layout of the final advertisements.
4. Section 8.4 of the Data and Tissue Management Plan states that 'De-identified tissue will be used by the Sponsor for future medical or scientific research for purposes which are related to the item and/or condition under study' and 'De-identified tissue may be made available to other researchers on request for future research as specified above...' . This is at odds with the application form. Please correct to clarify there is no future use on tissue.
5. The Committee queried why women are excluded from this study. After discussion, the Committee requested the Sponsor provide a justification for the exclusion of women.

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

1. Please explain why the study is specifically targeting Caucasian and Chinese participants (page 2).
2. Delete repeated bracketed explanations of each assessment from table (page 4)
3. Delete repeated information regarding ownership rights and financial benefit (page 3/13)

**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.

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| **11** | **Ethics ref:** | **2022 FULL 11658** |
|  | Title: | Improving continence management for people with dementia in the community (PHASE 3) |
|  | Principal Investigator: | Professor Vanessa Burholt |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 31 March 2022 |

Professor Vanessa Burholt was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee was assured capacity to consent is constantly checked each visit, and capacity to consent is required in order to participate in interviews.
2. The Committee was assured appropriate follow-up will be made if a participant raises concerning health issues in interviews.
3. The Committee clarified with the Researcher that they have an established researcher safety plan for home visits.
4. The Researcher clarified that the “up to 75” supporters participating in interviews was an overestimation to be inclusive of whānau some participants living with dementia may want present.
5. The Committee was satisfied that the debrief sheet submitted with the application will be given to participants at an appropriate 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 clarified with the Researcher that access to identifiable transcripts is limited to the CI. The Committee requested this is detailed in the participant information sheet (PIS).
2. The Committee requested the following changes to the Data Management Plan (DMP)*:*
   1. Please check whether cognitive information collected from questionnaires qualifies as health information that would need to be retained for a minimum of 10 years per New Zealand Law (currently 10 years for health data that relates to an identifiable individual).
   2. Reference applicable institutional data governance policies / SOPs.
   3. Address management of privacy breach
   4. Clarify whether de-identified data generated in the study may be used / shared for future research.

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

1. Repeated use of multiple bracketed words throughout the documents reduces readability. Only use medical terminology (cognition etc) when necessary. Consider splitting paragraphs into shorter paragraphs and increasing white space.
2. Address ongoing participation if capacity to consent lost (person living with dementia (PLWD)
3. Explain whether the PLWD may only participate if a supporter also takes part (and vice versa).
4. Address process to manage potentially significant health disclosures such as speaking to the carer or medical members of the research team, who will inform health professionals if required.
5. Clarify statement that 'We will only keep a copy of your interview, without your name or any other information that might identify you'. At odds with application statement that 'The only data stored in an identifiable form will be consent forms, transcripts and audio files'.
6. Address risk of privacy breach. The paragraph in the HDEC PIS template can be used as a guide.
7. State that ethical aspects of the study have been approved by the Southern HDEC.
8. Review and shorten longitudinal PIS/CFs, participants are aware of the nature of the study as they have already completed one interview.

**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).*

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| **12** | **Ethics ref:** | **2022 FULL 12229** |
|  | Title: | PREVISION First in Human Study |
|  | Principal Investigator: | Dr Andrew Holden |
|  | Sponsor: | Becton, Dickinson and Company (BD) |
|  | Clock Start Date: | 31 March 2022 |

Dr Andrew Holden and Cynthia Corne were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee confirmed the only current New Zealand site is in Auckland.
2. The Researcher discussed the recruitment process with the Committee and how the role of clinicians is separated from research. After discussion, the Committee was satisfied the conflict is managed and the potential participant has adequate time to consider their participation.
3. The Researcher confirmed the Australian sites have already received ethical approval.

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 formalize the ‘pause’ between procedures discussed by the Researcher in study documentation.
2. Please ensure the Sponsor insurance includes the formal protocol title or protocol number.
3. Delete references to future unspecified tissue research from Section 8.5 of the Data and Tissue Management plan as none is planned for this study.

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

1. Please review for jargon and amend to make lay-friendly (such as explaining 'immunosuppression' and 'azoospermia' in lay terms).
2. Please include a lay-title.
3. Please give an approximate time for how long the procedure would take and more clarity around the procedure. Please consider using bullet points to list information.
4. Please move the black box warning to under the header so it cannot be missed.
5. Role of the Sponsor’s representative is not clear to a lay-person. Please describe what a Sponsor is and who the representative is and their role.
6. Please describe risks in lay terms.
7. Please use a Contraceptive subheading as opposed to Pregnancy as this section predominantly relates to contraceptive advice.
8. Clarify that the livestream is not recorded.
9. Please remove “which you normally wouldn’t have” when referring to the assessments participants undergo before discharge from hospital.
10. Clarify whether the statement 'Currently, there are only two sirolimus DCBs commercially available in Europe' refers to FPS catheters (page 2).
11. Please ensure it is clear that those who are no longer enrolled/participating in the study still receive standard of care follow-up.

**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:** | 10th May 2022. |
| **Zoom details:** | To be determined |

The following members tendered apologies for this meeting:

* Mira Harrison-Woolrych

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.