|  |  |
| --- | --- |
| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 01 August 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 12.30-1.00pm | 2023 FULL 17872 | Glucagon-like peptide-1 receptor agonists in dialysis patients | Dr Tze Liang Goh | Ms Maakere Marr and Ms Joan Pettit |
| 1.00-1.30pm | 2023 FULL 18000 | Do MinDArT groups and Dementia Cafes make a difference? | Associate Professor Emma Febvre-Richards | Ms Kate O'Connor and Mr Barry Taylor |
| 1.30-2.00pm | 2023 FULL 15170 | Gold Study: Genomics of COVID-19 vaccine-related heart inflammation | Associate Professor Helen Petousis Harris | Ms Alice McCarthy and Ms Joan Pettit |
| 2.00-2.30pm | 2023 EXP 18067 | GN44993: A Study Evaluating the Effects of Different Intervals Between Lumbar Punctures in Healthy Participants | Dr Nick Cross | Ms Kate O'Connor and Mr Barry Taylor |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Ms Kate O’Connor  | Lay (Ethical/Moral reasoning) (Chair) | 13/08/2021 | 16/08/2024 | Present |
| Mrs Leesa Russell | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Apology |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Ms Alice McCarthy | Lay (the Law) | 22/12/2021 | 22/12/2024 | Present |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Present |
| Dr Amber Parry-Strong | Non-Lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Apology |
| Mr Ewe Leong Lim | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Apology |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Mr Ewe Leong Lim, Mrs Leesa Russell and Dr Amber Parry-Strong.

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 04 July 2023 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1**   | **Ethics ref:**   | **2023 FULL 17872** |
|   | Title:  | Glucagon-like peptide-1 receptor agonists in dialysis patients |
|   | Principal Investigator:  | Dr Tze Liang Goh |
|   | Sponsor:  | Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland |
|   | Clock Start Date:  | 20 July 2023 |

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. The Committee requested more clarification around where the Researcher is getting the 60% Pasifika recruitment, and how this targeted recruitment will be performed.
2. The Committee requested that the Māori consultation be more firmed up or detailed to the Committee.

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

1. Please include more information around the risks of Trulicity
2. Under who can take part, please outline they must be 18 years and over
3. If this is available outside of the study, make sure this is clear in the alternatives to taking part section
4. The Committee queried the statement that the drug is ‘useful’, and requested clarification around what that means, particularly around the medical goals of reducing CVD.
5. Please provide more detail around how any potential cardiac issues are being checked for. The Committee queried if it is just monitoring medical records and whether this is sufficient.
6. The Committee queried when they turn up for blood draws, if there are any more specific investigations concerning their heart health.
7. Please include more information about the risk of Sarcopenia.
8. Please provide more information of how there is increased monitoring as part of regular follow ups
9. It is not clear in the PIS that if there is benefit shown after a year, participants can continue a second year as part of the study. Please provide more information about the frequency of follow ups in the second year.
10. The GP yes/no optional item in the CF should not be 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 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 Maakere Marr and Ms Joan Pettit.

|  |  |  |
| --- | --- | --- |
| **2**   | **Ethics ref:**   | **2023 FULL 18000** |
|   | Title:  | MinDArT: A randomised attention-control trial compared to a Memory Cafe intervention |
|   | Principal Investigator:  | Associate Professor Emma Febvre-Richards |
|   | Sponsor:  | Massey University |
|   | Clock Start Date:  | 20 July 2023 |

Associate Professor Emma Febvre-Richards and Dr Susan Gee 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 that capacity is being assessed by expert clinicians who know the patient well, not the Researchers.
2. The Committee confirmed that the long-term plan is to spread this nation-wide, a facilitators guide is being developed
3. The Committee queried about the provision of a device to use the app. The Researcher explained that a tablet will be provided with app downloaded on it, but the device will be taken away at the end. The app will be available on other devices afterwards. A paper workbook is also available.
4. The Researcher confirmed that user data is not being collected to a cloud storage
5. It was confirmed by the Researchers retain IP over the product and that if made available more widely this would be for limited financial gain.
6. The Committee confirmed that the patient and care-partner assessments are done separately.
7. The Committee confirmed that parking is arranged for participants ahead of time, and if mobility vouchers are being used, the participants will be advised to tell them so they can help cover the other half.

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 human ethics/research office at the university needs to sign off as Sponsor and not just head of department.
2. Committee noted that if the Researchers wanted to go further beyond just mild dementia in a future study, to bear in mind that Right 7(4) would need to be met and demonstrate patient’s best interest, which the Committee would be supportive of if that argument was outlined.
3. The Researchers clarified that participants are invited to Dementia Wellington for a session and morning tea but can be some home-based if that works better for the participants. The Committee requested to see a home visit safety protocol that staff will be adhering to.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee

|  |  |  |
| --- | --- | --- |
| **3**   | **Ethics ref:**   | **2023 FULL 15170** |
|   | Title:  | Gold Study: Genomics of COVID-19 vaccine-related GBS, VITT/TTS and myocarditis/pericarditis – New Zealand’s contribution to a global study |
|   | Principal Investigator:  | Associate Professor Helen Petousis Harris |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 20 July 2023 |

Associate Professor Helen Petousis Harris, Lisbeth Alley, Karin Batty, and Dr Hannah Chisholm were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried if any data would be required to go into any US depositories and the Researchers confirmed no data will be.
2. The Researchers confirmed that tissue sent overseas to have DNA extracted will form an aggregated set of data that cannot identify a single person.
3. The Committee clarified with the Researchers that confirmation of diagnostic criteria is after consent is given.

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 human ethics/research office at the university needs to sign off as sponsor.
2. Please review advertisements for typos
3. Please provide more information around recruitment of personnel within organisations in the protocol. The Committee stressed the concern around avoiding forced enrolment.

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

1. Please make it clearer; how the saliva will be used, what its limited to, and that the DNA information is potentially identifiable but there are protections to keep it from going beyond, and that you do plan on sharing data of analysis that will be aggregate only, and data set may be shared with researchers over time, but there is a low chance someone will be personally identified.
2. Please provide reassurance around the purpose of collecting ancestry information
3. Clarify that all COVID vaccinations are valid, not just restricted to what was available in New Zealand.
4. Please provide a second avenue of contact such as text or telephone to withdraw.

**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 Alice McCarthy and Ms Joan Pettit

|  |  |  |
| --- | --- | --- |
| **4**   | **Ethics ref:**   | **2023 EXP 18067** |
|   | Title:  | EVALUATION OF THE EFFECTS OF INTERVAL BETWEEN LUMBAR PUNCTURES ON CSF AND PLASMA ANALYTES IN HEALTHY VOLUNTEERS |
|   | Principal Investigator:  | Dr Nick Cross |
|   | Sponsor:  | Genentech, Inc. |
|   | Clock Start Date:  | 20 July 2023 |

Dr Nick Cross, 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 confirmed with Researchers that this procedure is not unreasonable risk and there is exaggerated myth. A little more than a blood test with discomfort and there is anaesthetic. Risks will be properly discussed before consent. The researchers are suspecting recruitment difficulties but have already factored that into their approach.
2. The Committee noted the close expiry date of MPS certificate. The Researchers confirmed this has already been renewed
3. The Researchers confirmed that proxy consent mentioned in the protocol will not be used in New Zealand.

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 Researchers confirmed only experienced and practiced clinicians will be performing the lumbar punctures. The Committee requested an extra layer of assurance to get one of these clinicians to look through safety monitoring plan and site guidance documentation and provide reassurance to Committee that this procedure is as safe as it can be.
2. The Whole Genome Sequencing (WGS) in the protocol is presented as though it could be left out if the country or approving ethics committee doesn’t approve it. The Committee noted their stance that if it’s not mandatory for WGS to participate in any study, it can be included as an optional separate participant information sheet (PIS) away from the main PIS. If it is mandatory, then the protocol needs to have a firmer scientific rationale about why it’s needed. For it to be a mandatory part of study participation it would need to be clear that the primary research goals cannot be achieved without it.
3. Some advertisements and PIS have legacy language around this being a drug trial, such as it being reviewed by Medsafe, asking whether people are surgically sterile or post-menopausal, seeing how they respond to treatment, and experimental drug mentions, etc. There are also some items in protocol about it. Please review and remove these.

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

1. Please remove references under section 2 to treatment, and other restrictions around birth control given this is not an experimental drug trial.
2. Please provide a little more information about how assigning to cohort works
3. Reimbursements and costs don’t belong mingled with benefits, please separate.

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 Kate O’Connor and Mr Barry Taylor.

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 05 September 2023 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 2.30pm.