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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 07 May 2024 |
| **Zoom details:** | 96507589841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11:30am-12:00pm | 2024 FULL 20002 | 1490-0004 | A study to test whether BI 1839100 improves cough in people with idiopathic pulmonary fibrosis or progressive pulmonary fibrosis | Dr. Catherina Chang | Kate O’Connor & Devonie Waaka |
| 12:00pm-12:30pm | 2024 FULL 19941 | A Randomized, Double-Blind, Placebo-Controlled, Phase 2b Study Evaluating the Safety and Efficacy of Pirfenidone Solution for Inhalation (AP01) in Subjects with Progressive Pulmonary Fibrosis (PPF) | Dr Michael Epton | Alice McCarthy & Devonie Waaka |
| 12:30pm-1:00pm | 2024 FULL 20084 | A single-centre, double-blind, randomized, placebo-controlled, 2-arm study to evaluate safety and efficacy of intermittent Rapamycin on muscle strength and endurance in older adults following a 13-week exercise program. | Dr Joanna Wojciechowska | Kate O’Connor & Devonie Waaka |
| 1:00pm-1:30pm | 2024 FULL 19478 | The RECONNECT study | Dr Andrew Marshall | Maakere Marr & Barry Taylor |
|  |  | **BREAK 30 MINUTES** |  |  |
| 2:00pm-2:30pm | 2024 FULL 19541 | Selatogrel Outcome Study in suspected Acute Myocardial Infarction (SOS-AMI) (HDEC submission) | Dr Madhav Menon | Kate O’Connor & Amber Parry-Strong |
| 2:30pm-3:00pm | 2024 FULL 19766 | A comparison of x-ray imaging and low-dose computed tomography (CT) scans for ankle imaging following surgery (total ankle replacements -TARs). | Dr Sibusiso Mdletshe | Alice McCarthy & Leesa Russell |
| 3:00pm-3:30pm | 2024 EXP 19970 | AI in Diabetic Retinopathy Screening | Dr Cheng Kai Jin | Kate O’Connor & Amber Parry-Strong |
| 3:30pm-4:00pm | 2024 FULL 20097 | 1462-0004 | A study to test whether BI 1819479 improves lung function in people with idiopathic pulmonary fibrosis (IPF) | Dr. Catherina Chang | Maakere Marr & Barry Taylor |
|  |  | **BREAK 10 MINUTES** |  |  |
| 4:10pm-4:40pm | 2024 FULL 20102 | Enhancing swallowing skills in children with cerebral palsy | Dr Ksenia Bykova | Alice McCarthy & Leesa Russell |
| 4:40pm-5:10pm | 2024 FULL 20112 | PRECISION-TBI - A multi-centre observational cohort study of patients with traumatic brain injury | Dr Jonathon Taylor | Maakere Marr & Barry Taylor |

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| **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 | Present |
| 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 | Apologies |
| Dr Amber Parry-Strong | Non-Lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Mr Ewe Leong Lim | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Apologies |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Dr Devonie Waaka | Non-lay (Intervention studies) | 18/07/2016 | 12/08/2022 | Present |

## Welcome

The Chair opened the meeting at 11am and welcomed Committee members, noting that apologies had been received from Ms Joan Petit and Mr Ewe Leong Lim.  
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Devonie Waaka confirmed their eligibility and were co-opted by the Chair as a member 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 02 April 2024 meeting were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2024 FULL 20002** |
|  | Title: | A Phase IIa/IIb, randomised, double blind, placebo-controlled, parallel-group dose-finding study to examine the efficacy and safety of BI 1839100 administered orally over a 12 week treatment period in patients with idiopathic pulmonary fibrosis or progressive pulmonary fibrosis with clinically meaningful cough. |
|  | Principal Investigator: | Dr. Catherina Chang |
|  | Sponsor: | Boehringer Ingelheim Singapore Pte. Ltd. |
|  | Clock Start Date: | 26 April 2024 |

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

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. If necessary, good quality ethnicity data relevant to the New Zealand population may need to be collected in addition to CRF-specified race/ethnicity fields. Please ensure this is accounted for.
2. The Committee requested amendment section E12 of the injury compensation section. It currently states that compensation will not cover specific entitlements available through ACC compensation. The study cannot be improved in New Zealand unless it is confirmed that compensation is at least ACC-equivalent. Please provide confirmation from the Sponsor that compensation will be available for all entitlements listed in E12.
3. The Committee noted the following about the Data and Tissue Management Plan (DTMP):
   1. Please include institutional data governance policies applicable to clinical research in Section 2
   2. Please amend Section 7.5 to state that data will be used for future research, as noted in the participant information sheet.
   3. Section 7.5 states tissue may be used for future unrelated research; this appears to be distinct from samples entered in the risk/benefit ratio (RBR), which are discussed in Section 7.8. Please clarify what is intended; future unrelated research should apply to RBR samples only.
   4. Please include the New Zealand legal situation regarding the return of genome sequencing data. As section 11.2.2 states these results will be provided 'as permitted by local law' which is not particularly informative for participants.

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

Main PIS/CF:

1. Please delete references to tablespoons of blood and use millilitres.
2. Please delete repeated information about optional bio banking.
3. Please state approximately how many people have taken the study drug in previous clinical trials.
4. On page 7 “Do not participate in another research study" please change to clinical trial.
5. On page 22 please explain what 'cardiovascular risk' means in lay language.
6. On page 23 please note that additional consent is required to collect neonatal / infant health information.
7. Please include the risk of privacy breach.
8. Please Include an optional YES/NO tick box for consent clause regarding a lay summary of study results in the consent form.
9. Please include a photo of the cough monitor.
10. Please review the application throughout for spelling mistakes especially Māori words needing a Tohu Toa (macron).
11. Please include a statement that explains if participants are allowed to join another clinical study whilst being a part of this current study depending on the inclusion/exclusion criteria of future studies.

Optional Biobanking PIS/CF:

1. Please delete references to teaspoons of blood.

Optional Caregivers PIS/CF:

1. Please clarify whether the caregiver would be eligible to apply for ACC cover in the event of a travel-related injury.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the data and tissue management plan, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms. Kate O'Connor and Dr Amber Parry Strong.

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| **2** | **Ethics ref:** | **2024 FULL 19941** |
|  | Title: | A Randomized, Double-Blind, Placebo-Controlled, Phase 2b Study Evaluating the Safety and Efficacy of Pirfenidone Solution for Inhalation (AP01) in Subjects with Progressive Pulmonary Fibrosis (PPF) |
|  | Principal Investigator: | Dr Michael Epton |
|  | Sponsor: | Avalyn Pharma Inc. |
|  | Clock Start Date: | 26 April 2024 |

Dr Michael Epton 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 asked about the context surrounding IPF patients in New Zealand and what the patients’ options are when joining these types of studies. The Researcher explained that there are two parallel processes occurring and that there is change in the way that researchers and clinicians are thinking and classifying disease. Patients are being recognized with slightly different interstitial lung diseases such as progressive pulmonary fibrosis that do not fit the rigid criteria of idiopathic pulmonary fibrosis. These patients have significant disease and unmet needs and have yet to receive medication that has been specifically trialled on their group.
2. The Committee asked if Pirfenidone is funded for this group of participants. The Researcher explained that it is not.
3. The Committee asked about inhaled version of the approved drug and the possibility of rolling over into an open label extension and when this would likely to happen. The Researcher explained that it is dependent on the company and how quickly the recruitment occurs globally, and that a definite timeline has not been provided. However, the Researcher confirmed these is an expectation to be able to roll New Zealand participants over into an open label extension study.
4. The Committee asked if there is any risk in combining everyday medications with the study medication. The Researcher explained that participants who are on prohibited concomitant medications will not be able to partake in 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 requested removal of the 'age-appropriate' information as all participants will be 18+ years of age, so references to this is unnecessary.
2. For the ethnicity data, please ensure local sites collect good quality ethnicity data relevant to the New Zealand population. If necessary, this may need to be collected in addition to CRF-specified race/ethnicity fields.
3. The Committee raised the following about the Data Management Plan (DMP):
   1. Please amend section 2 by inserting the contact details for Syneos Health.
   2. Please delete the second and third paragraphs from Section 12.1; they are not applicable to the current study.
4. The Committee requested amendment of the GP letter by including a list of the adverse events of special interest (AESIs) for the study (bronchospasm, cough, rash, photosensitivity).

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

1. Please amend the survival status section by explaining the options if a participant wants no further information collected on withdrawal from the study, including survival status.
2. Please note that page 17 states that 'If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you'. Please amend to line up with the previous point.
3. On page 2 please replace 'efficacy' with effectiveness.
4. On page 3 please amend restrictions regarding medical marijuana to address New Zealand regulations specifically.
5. In the risks section please amend to provided lay-language descriptions of risk frequencies.
6. On pages 9 and 19 please review and delete repeated statements regarding financial benefit.
7. On page 22 please use the lay title at the top of the consent form.
8. On page 23 please delete the optional tick box for GP notification in the consent form.
9. On page 15 please include the stipend amount.
10. The Committee suggest including a visual representation of how the placebo and doses are allocated as referring to the ratio might be confusing for participants.

**Decision**

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

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

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| **3** | **Ethics ref:** | **2024 FULL 20084** |
|  | Title: | A single-centre, double-blind, randomized, placebo-controlled, 2-arm study to evaluate safety and efficacy of intermittent Rapamycin on muscle strength and endurance in older adults following a 13-week exercise program. |
|  | Principal Investigator: | Dr Joanna Wojciechowska |
|  | Sponsor: |  |
|  | Clock Start Date: | 26 April 2024 |

Dr Joanna Wojciechowska, Julie Jones, Ruth Lucas, Dr Brad Stanfield 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 Sponsor, Researcher and CRO are as follows.

1. The Committee asked if the study drug will become an over the counter medication and what happens next with this study/study drug. The Sponsor explained that they are waiting for the human research to come through, which is currently lacking. The Sponsor stated that the study drug is already showing great results in the mice research space. The Sponsor also explained that the study drug will remain a prescription medicine but could possibly change with more human research.
2. The Committee asked about the sourcing of the study medication. The Sponsor explained that Pfizer is the source for the study drug, which is an approved medicine being used off-label in this instance.
3. The Committee asked about the commercial aspects of the study. The Committee queried whether the study might have commercial aspects even though it is submitted as investigator lead research. The Sponsor explained that the intention of the study is to fully publish the protocol and all research, there will be no protected IP/patent, and no viable commercial outcome from the study.
4. The Committee asked why the Sponsor is listed as the co-investigator on the ANZCTR registry. The CRO explained that this is a mistake and have already applied for it to be updated on the registry.
5. The Committee asked about the crowd funding and raised the Sponsor may have to approach a clinical insurance company. The Sponsor explained the crowd funding has been secured and the funding target has been reached of which took around 3 years and per National Ethical Standards, the trial is not being conducted principally for the benefit of the manufacturer or distributor of medicine, making note that Dr Brad Stanfield is not the manufacturer or distributor of the study drug.
6. The Committee asked if there are any plans on making the study drug available via Dr Brad Stanfield’s website by prescription or any other means. The Sponsor explained that there is no plan for this and does not want to interfere with the patient and clinician. Furthermore, the Sponsor made it clear there is no stake in this trial working or not and ensures there is no money to be made if the trial is successful.

Summary of outstanding ethical issues

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

1. The Committee asked for clarification on why individuals taking medicines that interact with rapamycin are not excluded from study participation and why these are not listed as prohibited medications for the duration of the study. The Sponsor explained that the study drug is a very low dose (6mg) and is administered once a week to keep with what is happening in the United States off label that is currently how the medication is prescribed. The Committee reminded the researcher that participant safety was paramount in clinical research and asked whether it had been proven that there were no drug-drug interactions at the dose to be used in the current study.
2. Please amend the protocol eligibility criteria to exclude participants taking any medications known to interact with rapamycin.
3. Please amend the protocol to state that medications known to interact with rapamycin are prohibited for the duration of the study (prohibited concomitant medications).
4. The Committee queried the lack of any safety monitoring during the 13-week treatment period. Please amend the protocol to include a set of safety assessments, and another set of safety bloods to be taken, including safety laboratory tests, at an appropriate interval after commencing rapamycin.
5. The Committee asked why only 'adverse events that impact exercise ability or dosing or serious adverse events' will be used to assess safety, per protocol, and commented that this could result in several drug-related adverse events not being recorded. The Sponsor stated that they had limited which adverse events were collected as the study population was elderly and would likely report several changes in health. The Committee stated that all adverse events should be reported, with an assessment made by the Investigator or designee as to the severity and relatedness of the event. Please amend the protocol to ensure collection of adverse event data is in line with standard practice.
6. The Committee asked why no data safety monitoring is planned for a drug with known side effects and variable PK in an elderly population. The Researcher explained that the risk of anything going wrong after 3 doses of once a week dosing is extremely unlikely hence the reasoning for the lack of safety monitoring plan at 3 – 6 weeks. Please provide the evidence that has led to the Researchers deciding that there is no requirement to monitor safety while participants are on treatment.
7. The Committee noted the protocol statement that the sample size selected was 'primarily to satisfy logistic constraints of this feasibility study' and asked whether the Sponsor believed the study is sufficiently powered to detect an effect. The Sponsor confirmed that the study was unlikely to be powered to show any effect but may give an early signal. The Committee requested that this be made very clear in all participant-facing documents.
8. Please supply detailed information about prohibited concomitant medications that is reflected in the eligibility criteria.
9. The Committee requires scientific expert and independent peer review to affirm that the protocols is scientifically valid. This should be done after amendments to protocol have been made. The Committee recommended use of the [template available](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance/) on the HDEC website.
10. The Committee raised the following about the advertisements:
    1. Please amend the recruitment material to tone down the overly promotional language and adopt an appropriately objective tone.
    2. Please amend the advertising by changing to less certain words “may” “might”.
11. Please include in the data management plan if there will be karakia available at blood disposal or not.
12. Please provide confirmation that Dr Brad Stanfield has been removed as Co-Investigator in the ANZCTR database for this study.
13. Please ensure the CRO authorises the application form as local Sponsor.

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

1. The statement that rapamycin dose in immunosuppressive Rx is 'a daily dose over 6x higher than the proposed weekly dose used for this study' is misleading. Usual starting dose is 2mg daily; study dose is 6 mg weekly. The PIS/CF quotes max daily dose of 40 mg which is rarely used, please amend.
2. Please include whether the sponsor is involved in study conduct.
3. Please amend the typos in study title and elsewhere.
4. Please include a comparison when describing capsule size and how big the capsule is.
5. Please remove the section explaining metformin as an alternative. It is not a true alternative to this study and is not approved either for this use.
6. Please amend the exclusion criteria by specifying abnormal blood results and include anaemia, low white blood cell or platelet count.
7. Please include the potential for adverse events with low dose rapamycin into the PIS/CF and how the adverse events would be followed up by the study team.
8. Please review for typos.
9. Please remove references to "treatment'.
10. Please describe that this study is placebo controlled.

**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 supply an independent peer review for the updated version of the study protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.25-9.32).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Devonie Waaka, Dr Amber Parry Strong and Ms Kate O’Connor.

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| **4** | **Ethics ref:** | **2024 FULL 19478** |
|  | Title: | A Randomized, Double-Blind, Placebo-Controlled Multiple-Center, Efficacy and Safety Study of ZYN002 Administered as a  Transdermal Gel to Children, Adolescents, and Young Adults with Fragile X Syndrome - RECONNECT |
|  | Principal Investigator: | Dr Andrew Marshall |
|  | Sponsor: | Zynerba Pharmaceuticals Pty, Ltd |
|  | Clock Start Date: | 26 April 2024 |

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 asked about the participant families and the behavioural symptoms. The Researcher explained that the participants are families with children that have fragile-x syndrome which gives the children intelligential disabilities, the syndrome normally comes from the mother of the child. The study is effectively part 2 of a study that the Researcher has been running for 6 years, with this study being a new opportunity for a new cohort. Furthermore, the Researcher confirmed that the mothers will have capacity to consent.
2. The Committee asked about the possibility of continued care for participants through a compassionate program with the sponsor. The Researcher explained that all participants that wanted to continue will move to a long-term follow up study, however there is no stop date for that follow-up study, the Researcher explains to the participants that there is a risk that care might cease, as it is up to the company to continue to offer long-term trial care.
3. The Committee asked about the screening visits. The Researcher confirmed that the screening visits will occur in the morning after an 8 hour fast.
4. The Committee noted that common risks associated with the study drug, and any potentially serious risks, should be summarised in E1 of the application form, and asked that the researcher bear this in mind for future submissions.

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 local sites collect good quality ethnicity data relevant to the New Zealand population. If necessary, this may need to be collected in addition to CRF-specified race / ethnicity fields.
2. The Committee noted that therapeutic trials in New Zealand cannot be terminated solely due to 'decisions made in the business or commercial interests of the Sponsor' Please ensure this is clear across study documentation.
3. Please amend the Sponsor Certificate of Insurance to name New Zealand as the territory.
4. Please provide a current MPS Certificate of Membership or equivalent as proof of CI indemnity.
5. The Committee noted the following about the data and tissue management plan (DTMP):
   1. Please amend Section 4 to reflect that consent will be obtained from the participant's parent/guardian.
   2. Please state how identifiable data such as tattoos on the shoulder will be managed when photos of participants are being taken.
   3. Please remove reference to tissue from Section 7.3 as no future research will be undertaken on samples.
6. The Committee recognised this as a commercially sponsored study, authorisation must be obtained from a representative of the commercial sponsor. Please amend the authorisations page of the submission form and obtain authorisation prior to submitting the response to provisional approval.
7. Regarding continued care for participants on study completion, the Committee explained that in cases where the sponsor needs encouragement to allow for continued care the Researchers can refer the sponsor to the current National Ethical standards (para 10.15-10.17) which state ongoing access should be made available to those receiving therapeutic benefit in a clinical trial upon its completion, or sufficient justification provided if not. It is the Committee and wider HDEC’s expectation that there will be some form of ongoing access where participants are receiving clinical benefit.

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

1. On page 3, please clarify that New Zealand will only enrol participants aged less than 18 years.
2. On page 3, please delete repetition in second bullet point under study duration.
3. On pages 4 and 5, please delete significant repetition about study design.
4. Please delete the sentence regarding parents or guardians for children who are not capable of giving consent, as the Researcher has ensured the parents or guardians would not be enrolled if this is the case.
5. Please simplify weight-based sachet dosing (it is the same for placebo and active).
6. Please delete significant repetition about study procedures. It is strongly suggested that procedures are explained once and the visit schedule is provided in the body of the PIS as a simplified schedule of assessment table. The table at the end of the PIS looks to have been cut and pasted directly from the protocol and is not fit for purpose.
7. Please provide lay descriptions of questionnaires.
8. Please delete references to sedation.
9. Please note that GP notification of study participation should be a mandatory component of study participation, particularly given the potential for drug-drug interactions. Please amend the bullet point on page 17 accordingly and remove the optional tick box from the applicable consent clause in the CF.
10. On pages 19 and 21 please delete repeated information about financial benefit / ownership rights.
11. For child participants who have a milder condition, please submit an assent form using the HDEC template if needed, this template can be found on the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates). Please ensure the assent form includes pictures, and easy to read sentences and is not aged tiered, supply the most appropriate assent form for the participant.
12. If 'the study drug has been shown to work and does not need further testing', please explain whether the study drug will be made available to participants receiving therapeutic benefit under a compassionate access or alternative program.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the data and tissue management plan, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

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

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| **5** | **Ethics ref:** | **2024 FULL 19541** |
|  | Title: | Multi-center, double-blind, randomized, placebo-controlled, parallel-group study to evaluate the efficacy and safety of selfadministered subcutaneous selatogrel for prevention of all-cause death and treatment of acute myocardial infarction in subjects with a recent history of acute myocardial infarction. |
|  | Principal Investigator: | Dr Madhav Menon |
|  | Sponsor: | Idorsia Pharmaceuticals Ltd |
|  | Clock Start Date: | 26 April 2024 |

Dr Madhav Menon, Zoia Gubskaw, Liz Low and Malia Rogers 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 asked what would the risks be to participant who mistake other symptoms for a heart attack and administer the study drug. The Researcher explained that based on the phase 1 and 2 studies the risk of adverse effects is minimal as the study drug has a short half-life and is out of the participant’s system within 24 hours. The main concern is a bleeding risk from a participant utilizing the study drug.
2. The Committee asked how the ambulance drivers will be notified that a participant has used the study drug. The Researcher explained that the participant will tell the ambulance staff that the participant has used the injection and the ambulance staff will have alerts on the screen on the clinical workstation and that they will also notify ambulance staff the participant is a part of the study. A standard of care document will be uploaded for participants who are part of the trial while ambulance staff check for any risks including the bleeding risk.
3. The Committee asked about National Health Index (NHI) linking for participants involved in the trial. The Researchers confirmed there will be NHI linking for participants.

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 amendment of section C.4 of the application form to include what is known about the burden of disease in Māori, especially, rural Māori who do not have access to emergency care.
2. The Committee raised the following about the Data and Tissue Management Plan (DTMP):
   1. If the study is being done at just the one site (Waikato), please identify the local data governance policies instead of "Data governance will be in accordance with each sites current policies and SOPs”.
   2. Please remove reference to participants under the age of 16.
3. Regarding ethnicity data, if necessary, good quality ethnicity data relevant to the New Zealand population may need to be collected in addition to CRF-specified race/ethnicity fields.
4. The Committee requested the researcher notify St Johns of the the trial and study drug/injector, highlighting that ambulance staff will not need to do anything different when treating a participant in the trial. Please ensure the three emergency departments involved and ambulance services are aware of the study.

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

1. In the main PIS, please amend the instructions to ring for help and show the ambulance the injector by making the font bolder, to easier stand out.
2. Please include if participants who live alone may join the study, considering that the information for support persons may not be used.
3. Please include the risks of injecting if the situation is a false alarm for participants.
4. Please further clarify and include the role and duties of ambulance staff and the treating doctor. Furthermore, include how the treating staff will know the patient is a participant of the study.
5. On page 9 please amend the compensation section adjusting it to a New Zealand context. Please customise aspects such as loss of earnings, costs of ambulance ride, and specify reimbursements related to travel costs of extra study visits etc.
6. On page 10, 11 and 12, please review the information section. It currently appears as a hybrid of the HDEC template sections with other formats, and mixes in pseudo-anonymised with coded, personal with un-coded. The access to data section is different to those parties identified in the data management plan. Please review and amend this section.
7. On page 11, please use the correct Ethics approval statement as per the [HDEC templates](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/). This should not be added it as a bullet point to the information about the locator company.
8. Please remove reference to legally designated representatives in the CF.
9. Please include whether selatogrel has any additive bleeding risk when used in combination with standard of care treatment for acute myocardial infarction.
10. Please amend the reimbursement section and check for grammatical errors and typos.
11. Please include that whether someone is a participant in the trial or not, once in hospital the exact same care will be provided with standardised care.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the data and tissue management plan, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms. Kate O'Connor and Dr Amber Parry Strong.

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| **6** | **Ethics ref:** | **2024 FULL 19766** |
|  | Title: | A quantitative study comparing ankle x-ray imaging and low-dose computed tomography (CT) scans for post-operative evaluation of  total ankle replacements (TARs). |
|  | Principal Investigator: | Dr Sibusiso Mdletshe |
|  | Sponsor: |  |
|  | Clock Start Date: | 26 April 2024 |

Dr Sibusiso Mdletshe and Ashleigh Hammer 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 queried that this project might be a too large undertaking for a master’s project and asked for the supervisor’s thoughts about such a large project. The Supervisor agreed that the project is large and has tried to contain as much as possible to make it achievable and intends moving aspects of the master’s to the Doctorate level. The Committee made note that this study is too big for a Master’s study, highlighting that even the procedural aspects and 3 applications for Locality Authorisation will take much longer than what a Master’s student will have time for. The Committee suggested a conversation between student and supervisor and make the study scope smaller with only the feasibility aspect of the studies with intention of converting the Master’s study into a Doctorate.
2. The Committee asked if there are plans to access participants’ health information. The Researcher explained that the only participant health information used will be the participant age and possibly the factors that led to the ankle placement such as a history of arthritis for comparison.

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 several questions in application form were answered incorrectly: compensation, data safety monitoring. Please review and amend these in the resubmission.
2. Please describe how the main research question regarding economic viability will be answered. Furthermore, confirm whether outcome data, including complications, further medical/surgical intervention and/or ongoing disability are being assessed. If so, collection of this data should be clearly described in the protocol, data management plan and participant information sheet and consent form.
3. As per National Ethical Standard 9.20, all researchers conducting health research in New Zealand must collect good-quality ethnicity data. Ethnicity data will be required for submission to HDEC with the final study report unless sufficient justification is provided for not doing so.
4. The issue of data sovereignty should be considered when Māori data is included in research; please bear this in mind for future submissions.
5. For recruitment material, please ensure all material is uploaded and the planned patient information leaflet is submitted for approval prior to use.
6. The Committee raised the following about the Data Management Plan (DMP):
   1. Please include the protocol title (cover page).
   2. Section 2 lists Mercy Hospital as the lead site; the application form lists Te Whatu Ora Southern. Please amend for consistency.
   3. Please include the Sponsor of the study; the University of Auckland is referenced in places, PRG is referenced in others.
   4. Please ensure Pacific Radiology Dunedin gives locality authorisation for the study, in addition to Te Whatu Ora.
7. The Committee raised the following about the study protocol:
   1. The Committee explained that the 3 month follow up from surgery may offer some richer data that would be valuable for the study, this will require acquiring consent from participants and should be considered now before the trial begins.
   2. The application form explains earlier diagnosis of complications and better outcomes resulting in reduced overall costs and outweighing extra radiation however there is no collection of complications or outcome data despite the protocol stating that the 'analysis will consider the costs of imaging, subsequent medical interventions based on imaging findings, and the quality-adjusted life years (QALYs) gained from accurate and timely diagnosis of complications'. Please adjust the researcher aims accordingly.
   3. Please include intended sample size.
8. Please ensure the institution awarding the qualification provides their Authorisation as study Sponsor.

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

1. The participant information sheet could be shortened significantly; please review the document and delete repeated information.
2. On page 1 of the consent form please delete the template statements intended for researchers.
3. Please include that in addition to routine care, the participants will also be consenting to the CT scans.
4. The PIS has confused study funders with study sponsors. Please replace with the University of Auckland or PRG, as stated in the application form.
5. Please include the option to withdraw by verbally informing the research team; withdrawal does not have to be in writing.
6. Please give a lay example of the amount of additional radiation participants will be exposed to.
7. Please delete all but the final paragraph of text under 'What if something goes wrong'.
8. Identifiable data includes imaging, which will be retained indefinitely. Please amend the text under 'security and storage of your information' accordingly.
9. Please delete the second paragraph under 'rights to access your information'.
10. Please delete the optional YES/NO tick box from the GP notification clause of the consent form as this should be mandatory.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the data management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
4. 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 Mrs Leesa Russell and Ms Alice McCarthy.

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| **7** | **Ethics ref:** | **2024 EXP 19970** |
|  | Title: | AI in Diabetic Retinopathy Screening |
|  | Principal Investigator: | Dr Cheng Kai Jin |
|  | Sponsor: | Te Whatu Ora |
|  | Clock Start Date: | 26 April 2024 |

Dr Cheng Kai Jin 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 agree that the waiver of consent for the secondary use of health information from participants 7 and older is justified and accepted.
2. The Committee asked about the safety of the AI tool being used and what decisions it has during the trial. The Researcher explained the AI tool will be making no clinical decision and part of the images will be collected from a model of care trial being conducted at Counties Manukau of which are put into the grading system that is conducted by human research staff and will be doubled checked along-side the AI.
3. The Committee asked why the AI is being used and what problem it is trying to solve for the research team. The Researcher explained that using this AI program will increase the number of locations the service can be delivered, would help with the grading capacity and further down the line will be used to better, differentiate normal verses abnormal cases.
4. As the AI review document consists of informal notes the Committee asked to supply approved documentation regarding the AI applications being used for the study. However, the Researcher processes the approval letters for the AI applications therefore is a conflict of interest and will not be available.
5. The Committee requested the Researcher road-test the new HDEC AI application form and made it clear this is not going to affect the decision making of the application and will be sent to the Researcher as correspondence and attached to the HDEC decision letter.

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 response regarding the engagement process in C5 and C6 of the application form regarding Māori consultation does not clearly state whether formal consultation will be undertaken. This is required for the current study, please ensure it is undertaken prior to collecting data. Please identify the parties required for approval.
2. As the AI review document consists of informal notes, please supply approved documentation regarding the AI applications being used for the study.
3. The Committee noted the authorisation in the application form has not been done correctly. Under Sponsor Authorisation, the answer should be “Yes, but authorisation will be obtained during the locality process (e.g. Te Whatu Ora locality).
4. The Committee raised the following about the Protocol:
   1. Regarding the analysis plan in the protocol, please supply more information on the free text analysis for secondary eye diseases and how this analysis will be conducted and utilized.
   2. Please include the goal of using the AI in the trial and the problems the programme will try to fix.

**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. Kate O'Connor and Dr Amber Parry Strong.

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| **8** | **Ethics ref:** | **2024 FULL 20097** |
|  | Title: | A randomised, double-blind, placebo-controlled, dose-finding study evaluating efficacy, safety, and tolerability of different oral doses of BI 1819479 over at least 24 weeks in patients with idiopathic pulmonary fibrosis (IPF) |
|  | Principal Investigator: | Dr. Catherina Chang |
|  | Sponsor: | Boehringer Ingelheim Pty Ltd |
|  | Clock Start Date: | 07 May 2024 |

Christine Tuffery and Leeann Shaw 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 asked if the previously reviewed study (2024 FULL 20002) will be competing for participants with this study as the studies are similar and commencing at the same time. The Researchers explained that the previous study is specifically targeting participants with IPF that have a cough whereas this study is targeting participants from another pool. The Researchers believe the recruitment pools across both studies will not be an issue.

Summary of outstanding ethical issues

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

1. Regarding ongoing access, per National Ethical Standard 10.15, participants who benefit from a study intervention during a clinical trial should have ongoing access to the study intervention for as long as it is clinically beneficial. Please supply a response as to why this is not planned for the current study and provide an ethical justification.
2. Regarding recruitment as noted in B21.1 of the application form, patients may feel pressure to participate when a treating physician is also recruiting patients. Please ensure a member of the research team not involved in the patient's clinical care conducts at least part of the recruitment process, to give the patient an opportunity to decline away from the doctor, patient relationship.
3. If necessary, good quality ethnicity data relevant to the New Zealand population may need to be collected in addition to CRF-specified race / ethnicity fields.
4. Please quantify the additional risk of radiation to participants who agree to enrol in the optional high-resolution computed tomography component of the study.
5. Regarding the injury compensation section E12, the application form states that compensation will not cover specific entitlements available through ACC compensation. The study cannot be approved in New Zealand unless it is confirmed that compensation is at least ACC-equivalent. Please provide confirmation from the Sponsor that compensation will be available for all entitlements listed in E12.
6. The Committee raised the following regarding the Data and Tissue Management Plan (DTMP):
   1. Please include institutional data governance policies applicable to clinical research in Section 2.
   2. Please amend Section 7.2 as data will not be collected anonymously.
   3. Please amend Section 7.5 to state that data will be used for future research, as noted in the participant information sheet.
   4. Section 7.5 states tissue may be used for future unrelated research, which appears distinct from samples entered in the risk/benefit ratio. Please clarify and amend what is intended; future unrelated research should apply to risk/benefit ratio samples only.
   5. Please clarify the New Zealand legal situation regarding the return of genome sequencing data; Section 11.2.2 states these results will be provided 'as permitted by local law'.
7. Please review the application throughout for spelling mistakes, especially Māori words needing a Tohu Toa (macron).

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

Main PIS/CF:

1. Please clarify and amend that participants assigned to 0.3 mg weekly will receive a combination of active and placebo tablets, as the text on page 7 states all participants will take 2 tablets daily, a picture would help.
2. Please delete references to tablespoons of blood.
3. Please delete repeated information about optional bio banking.
4. On page 23 please note that additional consent is required to collect neonatal/infant health information.
5. Please include the risk of privacy breach.
6. Include an optional YES/NO tick box for consent clause regarding a lay summary of study results.
7. Please use gender neutral language where possible.
8. Please review the main participant information sheets for repetitive information especially regarding the pregnancy section.
9. Please include a statement that explains if participants are allowed to join another clinical study whilst being a part of this current study depending on the inclusion/exclusion criteria of future studies.

HRCT PIS/CF:

1. Please amend the optional HRCT PISCF and replace 'samples' with 'images' in the heading 'use of samples for this optional HRCT scan(s)'.
2. Please quantify the amount of additional radiation participants are exposed to (for example 'the amount of radiation from one HRCT is about the same as 2 years of natural background radiation that we are all exposed to as part of our daily living'.)
3. Please limit discussion of costs to those related to the HRCT visits only.
4. HDEC suggest referring participant to main PISCF for compensation statement.
5. Please delete reference to biological samples from the consent form.

Optional biobanking PIS/CF:

1. Please delete references to teaspoons of blood and use millilitres instead.

Optional caregivers PIS/CF:

1. Please clarify whether the caregiver would be eligible to apply for ACC cover in the event of a travel-related injury.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the data and tissue management plan, taking into account the feedback provided by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Barry Taylor Ms Maakere Marr.

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| **9** | **Ethics ref:** | **2024 FULL 20102** |
|  | Title: | Feasibility and effectiveness of a home-based training protocol to enhance swallowing skills in children with cerebral palsy: A pilot project. |
|  | Principal Investigator: | Dr Ksenia Bykova |
|  | Sponsor: |  |
|  | Clock Start Date: | 07 May 2024 |

Dr Ksenia Bykova 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 asked about the separate phases of the study and future participants’ inclusion. The Researcher explained that the second study planned will have a bigger roll out and the participants in this study will have the option to join the bigger roll out. There is also 1 home treatment session using the 3 clinical assessment tools.
2. The Committee asked about the device software and data storage. The Researcher explained that whoever is conducting the study in lab has access to data storage through the cloud and only accessible by the researcher with no-one else having access, the data will not be going back to the device company.

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 identify for the HDECs the local sponsor as someone within the Researcher’s institution needs to take responsibility for this study. Ideally, this should be the Research Office of Canterbury University, or in the absence of a university centre body, a Faculty Dean will suffice.
2. Please reference the University’s research data polices in the data management plan.
3. Please provide content to illustrate the differences between study 1 (dysphagia evaluation) and 2 (feasibility of treatment delivered in home setting) and please include a timeframe and explain the differences. The Committee recommend using a flow chart or another infographic.
4. Please amend the brief home safety plan mentioned in the response letter. Please ensure that this is documented so that staff know where to find it and attach the University home safety plan policy onto the study safety plan.
5. The response to D11 in the application form states the group referred to as 'children 16-18 years who are not able to write to sign the consent form'. Please note this is not the same as lacking capacity to consent; usually in this setting consent can be obtained verbally, for example.
6. Please amend the wording found throughout the application forms referring to ‘treatment’, this is not medical treatment and the study is non-therapeutic.
7. The Committee noted that certain health information must be retained for at least 10 years after a participant turns 16. Please check this applies to the swallowing data generated in the current study and amend data management plan retention timeframes if required.
8. For the study device, please include information regarding the one month free trial by including if there is a requirement for participants to supply personal information and/or credit card details to enable this trial, and who supplies the device for participants.
9. Please provide the terms and conditions of the application (SwalTech Ltd) if participants are required to sign up to it themselves and include if any results or information will be provided to this company. This needs to be transparently portrayed in study documentation, and the information flow and potential future use of data by the company needs to be included.
10. The Committee noted that the study needs to be registered on clinical trials registry as it is an intervention.

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

Assent Forms:

1. Assent forms should be provided to individual participants based on comprehension rather than age. Please remove specific age ranges from the forms.
2. Please provide an assent form for very, young children. Using pictures/graphs/faces easy to read for young children.
3. Please amend the assent form that is aimed at the lowest level of comprehension, it could simply just include a picture of the device and some simple instructions.

All:

1. Please limit discussion on page 1 around testing the reliability of 3 swallowing tests in young people with cerebral palsy.

**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 Mrs Leesa Russell and Ms Alice McCarthy.

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| **10** | **Ethics ref:** | **2024 FULL 20112** |
|  | Title: | PRECISION-TBI - A multi-centre observational cohort study of patients with traumatic brain injury |
|  | Principal Investigator: | Dr Jonathon Taylor |
|  | Sponsor: | Monash University |
|  | Clock Start Date: | 26 April 2024 |

Dr Jonathon Taylor and Colin McArthur 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 accepts the justifications of the waiver of consent for the secondary use of health information for inclusion in the study, given that the patients lack capacity and are not being randomised to any intervention.

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 local CI cannot nominate himself as the local sponsor, authorising the study from the perspective of the Hospital. Please approach the Research Office and change the “my study has received authorisation” tick box in the application form.
2. Please review the data management plan and delete statements not applicable to the current application (e.g. GP notification, CROs, safety and screening results etc).
3. Please amend Māori language used throughout the application, the use of tohu toa (macron) is missing throughout the application with the words Māori and whānau.

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

1. Regarding opt in/out consent for continuing use of data by participants who regain capacity, the Committee recommend changing the consent forms into opt in as opposed to opt out. The Committee explained the participants who recover enough to receive information about the study will be in hospital for a while and will have an opportunity to give written consent for continuing use of their data.
2. Please amend the consent form for continuing use of information by adding another oral consent protocol for the telephone call. The Committee recommend separating these and using a tick box to exercise options with respect to both the continued use of data and the follow-up telephone call.
3. Please move 'The purpose of the Study' section. The Committee recommend it would be better placed in the next column 'How is the Study Designed' as it introduces the study being an international one.
4. Please include how many participants in New Zealand. 40 per year, instead of "hundreds".

**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 Barry Taylor and Ms Maakere Marr.

## General business

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

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| **Meeting date:** | 04 June 2024 |
| **Zoom details:** | https://mohnz.zoom.us/j/96507589841 |

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.