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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 14 September 2021 |
| **Meeting venue:** | <https://mohnz.zoom.us/j/96507589841>  Meeting ID: 965 0758 9841 |

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| **Time** | **Item of business** |
| 10.00am | Welcome |
| 10.15am | Confirmation of minutes of meeting of 10 August 2021 |
| 10.30am | New applications |
| 10.30-10.55am  10.55-11.20am  11.20-11.45am  11.45am-12.10pm  12.10-12.25pm  12.25-12.50pm  12.50-1.15pm  1.15-1.40pm  1.40-2.05pm  2.05-2.20pm  2.20-2.45pm  2.45-3.10pm  3.10-3.35pm  3.35-4.05pm | i 21/STH/189Dominic /Paul  ii 21/STH/202 Sarah/Amy  iii 21/STH/212 Dominic/Mira  ~~iv 21/STH/219 Anthony/Devonie~~ Determined to be out of scope  *Break (15)*  v 21/STH/221 Sarah/Mira  vi 21/STH/222 Anthony/Paul  vii 21/STH/223 Sarah/Devonie  viii 21/STH/226 Dominic/Amy  *Break (15)*  ix 21/STH/228 Anthony/Mira  x 21/STH/230 Dominic/Amy  xi 21/STH/235 Sarah/Paul  xii 21/STH/236 Anthony/Devonie |
| 4.05pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |  |
| Dr Sarah Gunningham | Lay (other) | 05/07/2016 | 05/07/2019 | Present |  |
| Dr Devonie Waaka | Non-lay (intervention studies) | 18/07/2016 | 18/07/2019 | Present |  |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 28/06/2019 | 28/06/2020 | Present |  |
| Dr Paul Chin | Non-lay (intervention studies) | 27/10/2018 | 27/10/2021 | 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 |

## Welcome

The Chair opened the meeting at 10.00am and welcomed Committee members.

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 10 August 2021 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **21/STH/189** |  |
|  | Title: | A study of Odevixibat in patients with Alagille Syndrome |  |
|  | Principal Investigator: | Dr Helen Evans |  |
|  | Sponsor: | Syneos Health New Zealand Limited, a Syneos Health |  |
|  | Clock Start Date: | 29 July 2021 |  |

Helen Evans & Amy was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a Phase 3 double-blind, randomized, placebo-controlled study of the safety and efficacy of odevixibat (a4250) in patients with Alagille syndrome (ASSERT). This study includes a screening period of up to 56 days, followed by a 24-week treatment period, and a safety follow-up period. Participants who complete the Week 24 / end-of-treatment visit in this study will be invited to participate in an open-label extension study in which all participants will receive active treatment.

Summary of resolved ethical issues

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

1. The Committee raised a potential conflict in recruitment for patients with Alagille Syndrome. The researchers explained they are hiring a recruitment nurse to assist.
2. The Committee stated the importance during the recruitment period that the participants and parent/guardian gets to speak to one of the research team members who isn’t involved in their clinical care.
3. The Committee noted the guardian’s consent can be negated if the child / youth does not want to participate. The researchers have acknowledged this and stated it would result in a screening fail.

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 insurance cover and queried whether this was sufficient for children / adolescents. Please provide confirmation that the study’s insurance is sufficient to provide ACC-equivalent cover for all participants.
2. The Committee noted that in a study of this nature, notifying the participant’s GP of study enrolment should be mandatory. Please amend all relevant study documentation to show that notifying General Practitioners is mandatory for study participation, and that the participant and parent must consent to this in order to enrol in the study.
3. The Committee stated more information around data management is required than what is available in the Protocol and Participant Information Sheet, to satisfy the Committee that privacy and confidentiality is protected and that NEAC Standard 12.15a is met. Use of the HDEC template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/) is not mandatory but is encouraged to be adapted or used as a guide/starting point.

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

Children Patient Information Sheets(PIS):

1. Please change the age on the forms to “younger or older” to make it less specific; use of the forms should be based on comprehension rather than age.
2. Please refer to caregivers as “Parent or Guardian” as they are the only ones that can consent.
3. Please simplify the box at the top of page 1 to include lay title and study doctor name only.
4. Please add what is going to happen with the screening visits with children, explain the results of the tests, if they are in the study, to allow the children what to expect.

Parent/Guardian PIS:

1. Please amend duplication of text on page 2.

12 – 15 PIS:

1. On Page 1: Please explain the word “Cholestasis.”

Main PIS:

1. Please proofread for typos.
2. Please amend “ethnicity may be collected” to “will” be collected.
3. Please simplify blood collection tables to improve readability.
4. Please move information about PK samples to a bullet point under the blood tests subheading.
5. Where blood test abnormalities are included in the risk section, combine similar tests and explain what they may mean to participants (e.g. elevated LFTs and liver inflammation / injury).
6. Please separate allergic reactions from the ‘other risks’ paragraph.
7. The Information section mixes identifiable and de-identified data. Please amend the order so it is clear that auditors will view identifiable data.
8. Please ensure information is presented only once (e.g. data withdrawal, coding of data)
9. Please make “what happens after the study” open label extension clearer, explaining how long the extension is.

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 the suggestions made by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please supply a data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett & Dr Paul Chin.

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| **2** | **Ethics ref:** | **21/STH/202** |  |
|  | Title: | CaPTO study:Part 2 |  |
|  | Principal Investigator: | Dr. Ramya Nagarajan |  |
|  | Sponsor: | University of Auckland |  |
|  | Clock Start Date: | 29 July 2021 |  |

Dr. Ramya Nagarajan was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study is part 2 of the CaPTO observational study. Part 1 of the study reviewed records of men in the Northern cancer Region diagnosed with prostate cancer between 2008-2018, using the NZ Cancer registry, National Mortality collection, National Minimum Dataset, National Health Index and regional Radiotherapy databases along with Testsafe data. Part 2 of the study aims to approach a subset of this population and request they complete 3 questionnaires regarding quality of life, function, and outcomes.

Summary of resolved ethical issues

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

1. The Committee asked how the process of gaining consent from participants would occur. The researcher explained sending out the form as a written consent, not meeting in person.
2. The Committee asked why a potential participant with their own translator would still be excluded from the study. The researcher explained the 3 questionnaires are too difficult/long to translate.
3. The Committee noted the New Zealand population calculator and the New Zealand prostate cancer outcome predictor tool and asked if the researcher was making a predictor tool. The researcher confirmed this and stated the calculators might have commercial implications.

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 queried how recruitment would work for part 2 of the study. The researcher responded that recruitment involves sending a questionnaire to participants for Part 2. The Committee noted that recruitment needs to be an invitation and not a cold call/questionnaire.
2. The Committee noted that the letter to participants should be sent through the District Health Board or General Practitioners because of the way the first data set was acquired. It was also noted that the wording of the letter may create issues around how the researchers acquired the participants’ information, and would need to be carefully reviewed. The Committee noted that the invitation letter should include a contact number and email address so that the patient can decline to be contacted by the researcher regarding the study.
3. The Committee noted the lack of independent peer review. Please provide independent scientific peer review of the research. A template for use is available on the [HDEC website.](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance/) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
4. The Committee noted the protocol lacks information around exclusion criteria and the tele-consult. Please amend the protocol to provide more information and clarity around this *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

The Committee requested the following changes to the Participant Information Sheet (PIS) and Consent Form (CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please adjust the estimated time for questionnaires/survey completion from 13 minutes to 30-60 minutes.
2. Please proofread the Patient Information Sheet.
3. Please amend the wording around Māori, remove terms such as “being Māori”; reference to poor prognostic factors for Māori should be deleted.
4. Please review and amend for lay language.
5. Simplify 'the purpose of the study', which can be stated in a few sentences.
6. Ensure ‘How is the Study Designed’ to address Part 2 of the study only.
7. It is stated that not participating will 'not affect the care you receive from our service'. This is not applicable to many men as this is a national cohort study; amend accordingly.
8. Please remove the part for consent in part 1 – unless people are consenting for part 1; it currently reads that the participant is being asked whether the researcher is allowed to use already-collected data.
9. Please add more risks in the information sheet, and state how support will be offered in the event questionnaire completion results in distress or anxiety.
10. Simplify sections about access to information and delete reference to groups that are not applicable. The section regarding data-linking should not be included if this was already undertaken in Part 1.
11. Please remove the optional yes/no tick box for the General Practitioner being informed regarding significant abnormal findings during the study.

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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| **3** | **Ethics ref:** | **21/STH/212** |  |
|  | Title: | (duplicate) Parmacokinetics of Dexmedetomidine administered by Jet Injection- The DexJet Trial |  |
|  | Principal Investigator: | Dr Nicola Whittle |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 02 September 2021 |  |

Dr Nicola Whitle was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a healthy adult volunteer intervention study to look at the blood levels of a sedative pain relief medication, dexmedetomidine, achieved when administered by jet injection.

Summary of resolved ethical issues

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

1. The Committee noted the discharge of participants once they reached a criterion score of 12/14 asking if they are discharged to home or a ward. The researchers explained at that point they can go home however not allowed to drive.
2. The Committee noted the peer review section and optimization of the data and checked if points have changed. The researchers noted they haven’t changed anything in the study but may look to do this once basic data is acquired.
3. The Committee noted that any recruitment material for the study should be submitted for HDEC approval prior to use, and stated this can be done by submitting an amendment once the study is approved.

Summary of outstanding ethical issues

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

1. Please change the large font of the footers with the lay study title.
2. Please check typos and spacing in the reproductive risks section.
3. Please add a line separator between the text and the footer.
4. Please remove repeated information.
5. Please make it mandatory to inform the General Practitioner

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 suggestions made by the Committee.

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| **5** | **Ethics ref:** | **21/STH/221** |  |
|  | Title: | Combination T4/T3 trial for hypothyroidism |  |
|  | Principal Investigator: | Dr Mark Bolland |  |
|  | Sponsor: | The University of Auckland |  |
|  | Clock Start Date: | 24 August 2021 |  |

Dr Mark Bolland was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This intervention study describes a series of n-of-1 trials in 25 individuals with hypothyroidism taking thyroxine (T4) treatment who have been on a stable dose of T4 and have had normal thyroid function tests for at least 3 months but still have persistent symptoms potentially attributable to hypothyroidism. The duration of the trial for each individual is 52 weeks.

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 recruitment process from the endocrinology clinic, and stressed the importance of a separation between clinic and researcher rolls in inviting patients into the study. The researcher explained having an ad in the waiting room that will be circulated around clinics; if patients are interested, they can call the number on the ad and more information will be provided.
2. The Committee noted that the researcher had identified use of placebo as a potential ethical issue, but stated placebo use was appropriate given the study design.
3. The Committee noted that participants would have 18 blood tests over the study period of year, and agreed this was reasonable.
4. The Committee asked about the potential adverse effects of adding T3 into the treatment regime. The researcher explained that nothing to be related to T3 as it would be within the normal range – the main risk of combination therapy would be mild thyrotoxicosis.
5. The Committee noted there will be no future unspecified research for this 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 stated more information around data management is required than what is available in the Protocol and Participant Information Sheet to satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. Use of the HDEC template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/) is not mandatory but is encouraged to be adapted or used as a guide/starting point.
2. The Committee noted that question 1.3 in the questionnaire should read as “Dry Eyes”

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

1. Please explain the study design more clearly in lay language with the use of bullet points.
2. Please make it clear that a thyroid function test will be performed at screening, and if the results are outside the required range for study enrollment the patient would not be able to participate.
3. Please clearly lay out the risks/side effects of T4/T3 clearly for potential participants in lay language. This can be in a consumer information leaflet or similar if not included fully in the PIS.
4. Please add “There may be no benefit in you taking part in this study”
5. Please separate personal results and amalgamated study results as different sections.
6. Please amend “Northern A” HDEC to Southern HDEC.
7. The Committee requested the removal of the ‘yes / no’ tick boxes from the consent form unless it is for a clause that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study).

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 the suggestions made by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please supply a more detailed data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

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

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| **6** | **Ethics ref:** | **21/STH/222** |  |
|  | Title: | Comparison of two clozapine oral suspensions. |  |
|  | Principal Investigator: | Dr Noelyn Hung |  |
|  | Sponsor: | Douglas Pharmaceuticals Ltd |  |
|  | Clock Start Date: | 13 August 2021 |  |

Dr Noelyn Hung and Linda Folland were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a bioequivalence study comparing the blood levels of two clozapine oral suspensions from different manufacturers; test formulation (Versacloz)versus reference formulation (Denzapine) under fasting conditions. The clozapine suspension strength is 50 mg/mL and the dose is 0.25mL (equivalent to 12.5 mg clozapine). A single dose of the test suspension and a single dose of the reference suspension will be compared in this study.

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 satisfied that side-effects caused by long-term use of clozapine were not relevant to participants of this study as they are only receiving a single dose.

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 data management information covering how the study will address data/privacy breaches and named responsibility for data is not in the study documentation.

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

1. On page 2 please amend to state the Southern Health and Disability Ethics Committee is the approving HDEC.
2. On page 6, make it clear that participants stopping prescription drugs in order to participate in the study will only be permitted after researcher consultation with their doctor.
3. On page 6, state that non-prescription drugs include things like paracetamol and ibuprofen.
4. Page 9 states that an additional blood sample may be required. Please include that as an optional part to the schedule of procedures.
5. On page 10, please indicate how the study dosing compares to that of a therapeutic dose of clozapine.
6. On page 2 the study days has “-1 – 2”, please clarify this to state “-1 to 2”
7. Page 15 has a subsection about data collection under what happens after the study. Please place this in the “what happens to my data” section.
8. Please clarify that Covid and flu vaccines aren’t live organism vaccines. Please also state any restrictions to entry surrounding vaccine timeframes prior to participation/visits.

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 suggestions made by the Committee.

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| **7** | **Ethics ref:** | **21/STH/223** |  |
|  | Title: | Feasibility Study of a Group Intervention for Youths Impacted by the March 15th Attacks |  |
|  | Principal Investigator: | Dr Katherine Donovan |  |
|  | Sponsor: | University of Otago |  |
|  | Clock Start Date: | 16 August 2021 |  |

Dr Katherine Donovan and Dr Shaystah Dean were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The proposed study aims to assess the feasibility of an alternative treatment approach for Muslim teenagers affected by the shootings, incorporating well-evidenced transdiagnostic treatment principles as well as a faith-based element to address the local population’s need.

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 with the researcher that the impact of the attacks is kept broad as a criteria intentionally, and that there is for potential participants to self-determine if they are impacted. Recruitment is being done through agencies and youth groups who are working with teenagers that are having difficulties.
2. The Committee noted the faith-based approach and queried how this would work with those who do not share that faith. The researcher responded that they are predominately expecting participants from the wider Muslim community due to the recruitment pathways being contained to those working with the Muslim community affected by the attacks.
3. The Committee was satisfied there would be no undue influence on the teenager’s participation from the parent/caregiver as the approach is made by the agencies and youth groups referring them to the research team.
4. The Committee confirmed with the researchers that the questionnaires asking sensitive questions are reviewed immediately and are filled in on site.
5. The Committee confirmed with the researchers that proper consultation measures are in place for the presentation and dissemination of results to avoid stigmatization.

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 teenagers under 16 can provide their own informed consent if they are assessed to be competent to do so and should be given the option. Please develop and document procedures to be able to assess competency for under 16s to provide their own consent. Where teenagers have provided their own consent, it must be made clear to the parent that they are only consenting to their own participation, and not their child’s. Further, if a parent/guardian is consenting for a teenager who is not deemed competent to provide their own fully informed consent, please provide an assent form; a simplified version of the teenager’s participant information sheet (PIS) that is appropriate for their understanding level.
2. The Committee stated more information around data management is required than what is available in the Protocol and Participant Information Sheet, to satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. Use of the HDEC template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/) is not mandatory but is encouraged to be adapted or used as a guide/starting point. This can be done as a standalone document or incorporated across documentation.
3. The Committee noted that health data should be retained for 10 years following the participant turning 16.
4. The Committee requested that the heading on questionnaires that state “child form” be removed, as the target audience are teens.
5. The Committee noted the cards being given to the participants about their sessions, and clarified that participant-facing material should be submitted to the Committee for review prior to use.

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

1. Please provide a simple explanation of what the transdiagnostic approach is.
2. Please make the exact age range clearer and consistent.
3. Please include information about certain circumstances that the research team is obliged to report if the safety of participant or others are identified as at risk.
4. Please clarify that reimbursement is at the three main timepoints and that it is per family.
5. Please use the term “parents/guardians” to be more inclusive.
6. Please include that the teenager can say no even if their parent/guardian says yes. This must be in the assent form and PIS/CF for teens providing their own consent.
7. The study aims not clearly laid out, please outline these clearly in lay language. Further, the current study aims of referring people on to other care is a potential benefit, not an aim, and should be removed.
8. Please split the section regarding participation into the teenager assessment and parent assessment sub-headings, and for the teenager assessment section, separate information about questionnaires and session structures.
9. For weekly sessions please outline the basic structure of a session, how long they are, where they will be held, that they will have refreshments provided, and that they will be audio recorded . Outline expectations for maintaining confidentiality in group sessions.
10. State that questionnaires will be in a clinic setting and how long they may take to complete.Make it clear that questionnaires will ask about mental health and suicide risk.
11. More information is needed about confidentiality in data management, such as who has access to identifiable data (consent forms, contact list). If data is shared for future research, this needs to be made clear if this can be sent overseas, and whether this would be research related to transdiagnostic protocols or whether its unrelated. Please also address the risk of confidentiality breach; an appropriate paragraph is available in the HDEC PIS template.
12. The HDEC PIS template ACC statement around study related injury should be included if the researchers think that is at all possible for intervention being provided.
13. Please provide Muslim support contact(s).
14. Provide practical information about dress for the sessions that involve physical activity.
15. Please make it clear across all PIS and assent forms whether the parent/guardian participating has any bearing on the teenager’s participation, including what happens to the other’s data when withdrawing from the study, whether the other has access to their information they provide, etc.
16. Consent form clauses should only be included if the information in the clause has been provided in the body of the information sheet; please review and amend accordingly

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 provide an assent form for teenagers not able to provide their own fully informed consent.
3. 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).*
4. Please supply a data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

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

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| **8** | **Ethics ref:** | **21/STH/226** |  |
|  | Title: | UPPERCASE: Upper Limb Coordination After Stroke |  |
|  | Principal Investigator: | Professor Cathy Stinear |  |
|  | Sponsor: | University of Auckland |  |
|  | Clock Start Date: | 27 August 2021 |  |

Professor Cathy Stinear and Christi Essex were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This observational study will investigate the content of inpatient upper limb therapy following stroke and whether this is influenced by severity of impairment and handedness prior to stroke.

Summary of outstanding ethical issues

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

1. The Committee stated it was unclear whether the therapist would be present for the assessments either side of the observed session. Please make this clear in study documentation.
2. The Committee queried who at the Auckland District Health Board (ADHB) was doing the screening and whether this would burden their resources. The researcher responded that two stroke occupational therapists at ADHB will do the first approach and screening, then refer them to the research team for enrolment. Information they record for screening, even with a screen-failure is recorded and sent to the researchers. However, the Committee was assured this was de-identified with no identifiers attached, and the paper is destroyed. Please make sure it is outlined clearly in the Data Management Plan (DMP) in the study documentation.
3. The Committee noted that the location of the follow-up assessment is inconsistent across documentation. Please clarify the location and amend documents accordingly.
4. The Committee noted that the observer may witness interactions or aspects of the therapy session that raise concerns.Please amend the protocol to include a process for steps the observer should take, should they observe something about the therapy session or interaction with the participant that is cause for concern. Additionally, please include information in the therapist participant information sheet (PIS) about this process.
5. The Committee noted it is acceptable to be a little more technical and recognise the difference that this is a trained professional and their understanding is different to the patient-participant.
6. The Committee asked the researchers to consider if it is worth doing the therapist consent prior to approaching participants, as non-participation by a therapist will result in his or her patients not being eligible for study enrolment.
7. The Committee noted that home visits were a possibility. The researcher confirmed that a formal researcher safety plan would be adhered to. Please ensure the researcher safety plan for conducting home visits is documented in the protocol.
8. Please list the PhD student as a co-investigator in the protocol
9. The Committee noted that pregnancy is reason to withdraw someone from the study, but the study may have a therapist who is pregnant and still able to fulfil their duties. Please review and amend documentation accordingly.

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

Therapist PIS/CF

1. Please make it clear that the study is for a PhD
2. Data management information is deficient compared to patient PIS. Please review and amend to ensure the information presented is equivalent to the patient PIS.
3. On page 2, the reference to being over 18 is redundant. Please remove.
4. Outline whether the observer may note substandard therapy/conduct by the therapist and what the process is should this be observed.
5. Provide study rationale appropriate for this target population.
6. Clarify if therapists will be present for assessments.

Patient PIS/CFs

1. The Committee noted it was unclear if the second session was able to be broken up with breaks if needed. Please outline this if required in PIS.
2. Information on what happens when someone withdraws is not consistent with DMP; please review and amend accordingly.
3. For participants who chose to withdraw, please provide further information on how that would be handled in terms of what happens to their data, etc.
4. Second and third person is used inconsistently; please amend to use second person throughout.
5. Please review the document and delete repeated information.
6. If therapists are not being consented in advance, please make it clear that if their therapist doesn’t consent to take part, the patient cannot be enrolled in the study.
7. Please make it clear that the study is for a PhD
8. Explain what happens if the mental health questionnaire raises concerns, and what follow up will be done by the research team.
9. Please clarify the purpose of the handwriting being shared with the overseas company and state what information accompanies handwriting to the third party.
10. Please include the reasons for discontinuing participation.

Aphasia-friendly (AF) PIS

1. Page 3/8 states “within one week” while previous page states within 14 days.
2. Some information in the non-AF version is missing e.g. having whānau present during presentations.

Consent Forms

1. Remove yes/no tick-boxes for items that are not optional.

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 suggestions made by the Committee.

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| **9** | **Ethics ref:** | **21/STH/228** |  |
|  | Title: | A pilot study of contralesional motor cortex facilitation in chronic stroke |  |
|  | Principal Investigator: | Professor Cathy Stinear |  |
|  | Sponsor: | University of Auckland |  |
|  | Clock Start Date: | 02 September 2021 |  |

Professor Cathy Stinear and Afifa Safdar were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study aims to understand which type of non-invasive brain stimulation will be most effective to improve motor performance in severely impaired stroke patients. This study will compare the effects of facilitatory rTMS or facilitatory iTBS applied to the contralesional primary motor cortex to the effects of facilitatory rTMS or facilitatory iTBS applied at the dorsal premotor cortex (cPMd), and sham stimulation on handgrip performance.

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 satisfied that anyone who cannot provide their own informed consent is excluded, and there are a range of resources available to the researcher to help determine capacity.
2. The Committee was satisfied that there is sufficient clinical back-up in place in the event of seizures from the participants while participating in the research.
3. The Committee noted that this doesn’t appear to be a commercially directed study so participants would be eligible for ACC.

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 protocol table of contents doesn’t match the page numbers.
2. The researchers confirmed they have ongoing Māori consultation for their projects but not for this study specifically. The Committee asked that formal consultation for this specific study is undertaken, as a condition of HDEC approval. The researcher agreed to this.
3. The Committee noted that the difference between pre-screening activities and screening post-consent should be clarified across documentation.
4. The Committee stated more information around data management is required than what is available in the Protocol and Participant Information Sheet to satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. Use of the HDEC template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/) is not mandatory but is encouraged to be adapted or used as a guide/starting point.

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

1. Please ensure the title is lay-friendly.
2. Please explain how much touching of the head happens, if shaving needs to happen, etc.
3. Please outline in lay-language what the interventions involve.

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 a more detailed data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

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

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| **10** | **Ethics ref:** | **21/STH/230** |  |
|  | Title: | Real-World Evidence Study of the Impact of Esketamine (Spravato) on the Quality of Life of Patients Living with Treatment Resistant Depression in Australia and New Zealand |  |
|  | Principal Investigator: | Dr David Codyre |  |
|  | Sponsor: | Janssen -Cilag |  |
|  | Clock Start Date: | 02 September 2021 |  |

Dr Wayne Miles and Deborah Campbell were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This research project intends to understand the effectiveness of Spravato for participants with treatment-resistant Major Depressive Disorder (MDD) in the real-world setting. The primary objective is to assess the change in quality of life over the first 16 weeks of treatment.

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 satisfied after discussion that appropriate safety measures were in place in case any participant questionnaire responses raised concern for their wellbeing.
2. The Committee queried the statement about oversampling of Māori and Pasifika. The researcher clarified that this would happen due to the Early Access Program (EAP) is offered to more of this population, and because this study is about those already in the EAP, that statement was an error.

Summary of outstanding ethical issues

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

1. The Committee stated more information around data management is required than what is available in the Protocol and Participant Information Sheet to satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met, particular around the use of the app and third-party use of data. Use of the HDEC template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/) is not mandatory but is encouraged to be adapted or used as a guide/starting point.
2. The Committee noted that an expert independent peer review is required, as the review submitted is by an Australian investigator.
3. Because this is a commercially sponsored study run for the benefit of the manufacturer, this should still be covered by commercial insurance for injury, however unlikely, that can arise from the assessments. The Committee also noted that the trial cannot be stopped for commercial reasons.
4. Please confirm the data entered into the app is only available to the sponsor and not to the app owner.
5. The Committee required clarification on the recruitment process to be assured that there is potential for the participant to discuss their participation with someone who isn’t their usual doctor/care provider.
6. In the invitation letter, delete exclamation marks and promotional statements such as ‘Congratulations!’ Also delete ‘If you don’t download the application, we may no longer be able to guarantee your place in this study’.

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

1. Review and delete repeated information.
2. Make it very clear that participation in the study has no impact on starting / continuing esketamine.
3. State who the ‘study team member’ is that will be completing the HAM-D form. State whether this is done via review of records or at an appointment with the participant. State how many times this is completed during the study.
4. State who the participant should contact, should they become upset / distressed due to questionnaire completion. Options should include an appropriate member of the research team.
5. Clarify whether questionnaire responses will be reviewed at a local level, how quickly they will be reviewed, and what will happen if responses raise significant concerns about the participant’s health / safety. If responses could trigger reporting to a health care provider, this must be stated.
6. Provide information about risk of confidentiality / breach, sending data overseas, ownership rights, and future uses of data.
7. Participants are given the option of receiving overall study results in the consent form and should not have to contact the Investigator after the study to arrange this. Amend ‘What happens after the study finishes’ accordingly.
8. Please state what happens if a loaner phone is lost/destroyed/damaged.
9. Please make it clear what other information the app may be able to gather from the participants using it. The Committee noted that use of face recognition will no longer make the information entered de-identified.

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 current version of the study protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
4. Please supply a more detailed data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

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

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| **11** | **Ethics ref:** | **21/STH/235** |  |
|  | Title: | TRITONglaucoma or ocular hypertension |  |
|  | Principal Investigator: | Professor Anthony Wells |  |
|  | Sponsor: | Allergan Australia Pty Ltd |  |
|  | Clock Start Date: | 26 August 2021 |  |

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

Potential conflicts of interest

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

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

Summary of Study

1. The purpose of this intervention study is to obtain data on as-needed administration of Bimatoprost SR. The duration of the study for each participant is approximately 32 months, consisting of a screening period of up to 10 days before washout, washout period of up to 56 days before the initial Bimatoprost SR administration, 18-month PRN treatment period, plus at least 12 months of extended follow up.

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 a number of issues raised by the Committee could have been resolved with the researcher present but, in their absence, could not be addressed.

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 provide a clear justification for the washout period from a safety perspective for participants *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.1).*
2. Please provide justification for not using an independent data safety monitoring committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*
3. Please explain how potential participants are identified and contacted.
4. Please discuss how potential conflict of interest due to the existing doctor/patient relationship that may exist will be mitigated *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.23).*

The Committee requested the following changes to the Participant Information Sheet and Consent Form *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please simplify section regarding eye exams significantly.
2. Please further explain the risks of the study to potential participants.
3. Please explain what the video recordings are for, and who can access them.
4. Please provide more in-depth information on tissue collection and use. This should include information about where the samples are being sent to and stored, what they will be used for, and how long they will be retained for.
5. Please remove inverted commas from Māori words.
6. Please separate common and uncommon risks into separate paragraphs.
7. Reference to 'personal data' is confusing; refer instead to identifiable and de-identified / coded data respectively.
8. Provide a justification for requiring the results of genetic tests for the purposes of this study.
9. Access to safety and screening results should not be suspended during the study.
10. Collection of pregnancy follow-up data is subject to optional additional consent; make this clear in the PIS.
11. There is no information about the photographs in the body of the PIS; amend accordingly.

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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| **12** | **Ethics ref:** | **21/STH/236** |  |
|  | Title: | AML18 |  |
|  | Principal Investigator: | Dr Claire Hemmaway |  |
|  | Sponsor: | Cardiff University |  |
|  | Clock Start Date: | 21 August 2021 |  |

Dr Claire Hemmaway and Fadiya Al-Abuwsi were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The AML18 Trial will evaluate several relevant therapeutic questions in Acute Myeloid Leukaemia (AML), as defined by the WHO, and High Risk Myelodysplastic Syndrome. The trial is primarily designed for patients over 60 years considered fit for an intensive chemotherapeutic approach.

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 how recruitment would work for potential participants. The researcher responded that the vast majority are inpatients under a clinician attending the ward, and a research nurse can meet with the patients if they have any questions.
2. The Committee queried if the drug combinations are novel. The researcher stated that the combination of drugs is but not the individual drugs themselves.

Summary of outstanding ethical issues

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

1. The Committee stated more information around data management is required than what is available in the Protocol and Participant Information Sheet to satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. Use of the HDEC Data Management Plan (DMP) template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/) is not mandatory but is encouraged to be adapted or used as a guide/starting point. The Committee suggested a standalone DMP would be helpful for this study.

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

1. For ease of understanding, please provide a flowchart of how the overall study runs, showing the different parts of the trial.
2. Change “licensed” in New Zealand to “registered and not funded” or “not approved for this purpose” etc and explain what each drug’s status is in New Zealand.
3. Please review for formatting, grammar, line-spacing and readability.
4. Amend the consent form to indicate that the tissue will be sent overseas.
5. State in the body of the PIS that samples are going to Birmingham, and the purpose of the tests.
6. The Māori cultural statement should be moved to the section about tissue samples. Please also state whether a karakia is available at the time of destruction.
7. Please discuss under risks the frequency of serious liver injury during treatment.
8. The information section has grey boxes are at odds with other sections of text from the HDEC PIS template (i.e. named accountability of data management in NZ lies with the site, not the Sponsor). A lot of grey box text is repeated more clearly in the other sections of text. Please review and correct, ensuring each piece of information is presented only once.
9. The PIS states that the use of data for future research is optional but there is no optional part in the consent form; please delete the ‘if you agree’ phrase at the start of the paragraph about future research.
10. Clauses 4 and 8, and 7 and 11 of the Consent Form repeat the same information. Review and delete duplicates.
11. The Sponsor should not require access to identifiable info in event of a compensation claim, as injury is not covered by commercial insurance.
12. In the Future Research (FR) PIS, please make it clear that research will involve genetic analysis, and whether this will include whole genome analysis.
13. Please make it clear in the FR PIS that the research is exploratory, and therefore it is not intended to provide participants with results.

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 a more detailed data management plan to ensure the safety and integrity of participant data (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

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

## General business

1. The Committee noted the content of the “ noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 12 October 2021, 10:00 AM |
| **Meeting venue:** | ONLINE - Zoom Meeting |

The following members tendered apologies for this meeting.

* Dr Paul Chin

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 4.05pm