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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 10 December 2019 |
| **Meeting venue:** | Christchurch Clinical Studies Trust Limited |

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| **Time** | **Item of business** |
| 11:15am | Welcome |
| 11:30am | Confirmation of minutes of meeting of 12 November 2019 |
| 11:45am | New applications (see over for details) |
|  | i 19/STH/217  ii 19/STH/215  iii 19/STH/208  iv 19/STH/209  v 19/STH/210  vi 19/STH/211  vii 19/STH/212  viii 19/STH/213  ix 19/STH/214  x 19/STH/216  xi 19/STH/218  xii 19/STH/219 |
| 4:45pm | General business:  Noting section of agenda |
| 5:00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Sarah Gunningham | Lay (other) | 05/07/2019 | 05/07/2022 | 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 |
| Professor Jean Hay-Smith | Non-lay (health/disability service provision) | 31/10/2018 | 31/10/2021 | Present |
| Mr Dominic Fitchett | Lay (the law) | 05/07/2019 | 05/07/2022 | Present |
| Dr Pauline Boyles | Lay (consumer/community perspectives) | 05/07/2019 | 05/07/2022 | Present |

## Welcome

The Chair opened the meeting at 11:15am 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 12 November 2019 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **19/STH/217** |  |
|  | Title: | A Phase 1/2 Study of DCR-A1AT in Healthy Adult Volunteers and Patients with A1ATD-Associated Liver Disease |  |
|  | Principal Investigator: | Professor Edward Gane |  |
|  | Sponsor: | Dicerna Pharmaceuticals, Inc. |  |
|  | Clock Start Date: | 28 November 2019 |  |

Prof Edward Gane was present by teleconference 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 first-in-human, 2-part, parallel-group treatment study to compare the effects of DCR-A1AT with placebo to find out of DCR-A1AT is safe and effective for participants with Alpha-1 Antitrypsin Deficiency (A1ATD) associated liver disease.
2. In part 1, up to 36 healthy volunteers will be given DCR-A1AT or placebo (sterile normal saline for injection). This part helps to determine the dose of the study drug. In part 2, up to 24 participants with A1ATD will be recruited.
3. The participants will receive either the study drug or placebo. It is anticipated that the participant will attend approximately 11 visits over approximately 9 months.

Summary of resolved ethical issues

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

1. The Committee queried whether just the described single-ascending study was being reviewed at this time. The Researcher confirmed that this was the case, as separating the Participant Information Sheets would made it easier for participants to read and would also allow for modifications between the present study and a multiple ascending study, which would be submitted as a separate application.
2. The Committee queried whether only men are being recruited to this study. The Researcher stated that due to reproductive risks, women of reproductive age will be excluded from the study, therefore most participants (but not necessarily all) will be male.
3. The intended number of participants for Part A of this study was confirmed as 36

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 clarify what potentially identifiable information will be attached to study samples sent overseas, noting that the Committee’s preference is study number only, although year of birth is acceptable if necessary).

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

1. The Committee requested that the Participant Information Sheet and Consent Forms be amended to include a lay-friendly title, rather than the current title.
2. The Committee stated that the first section of the PIS describes background information, but should be amended to also address the question posed by the research title.
3. The Committee requested that the PIS is amended to include an explanation using lay-language of what the study drug does.
4. The Committee stated that the table on page 17 of the study protocol should be converted into lay-friendly language and added to an appropriate part of the PIS.
5. Requirements for the inpatient stay should be clearly stated in the PIS, including the duration and timing of the stay (e.g. Day 1 – Day X). Please ensure that it is included in the table described in Point 9 (above).
6. Please include the in-patient study in the table described in Point 9 (above).
7. The Committee stated that method of drug administration (e.g. oral, intravenous, etc.) should be included in lay-language in the PIS.
8. The Committee stated that the beginning of the PIS should be amended to include a textbox that states this trial is first-in-humans; this box should be placed underneath the title and the header should be reduced to accommodate this.
9. Please amend the statements on study aims/goals/purposes throughout the PIS, so that the study aims are described only once in one section of the PIS and related to Part A of the study.
10. Please move the study risk described at the bottom of Section 4 of the PIS to the Risks Section of the PIS.
11. Please amend the section titled “early termination” to a title using lay-language.
12. Please amend the PIS to include total volume of blood given by volunteers for this trial.
13. Please remove the statement in the PIS stating HIV is commonly known as the AIDS virus, as the Committee considers HIV lay-knowledge.
14. Please add a heading for Participant Responsibilities, to separate this section from the Section of the PIS on what could happen if giving samples.
15. Please include information in the PIS on whether complete loss of antitrypsin and loss/reduction of lung functioning is always reversable. If it is not reversible, please describe the potential health implications for an affected individual.
16. Please amend the PIS section on sperm collections to explain why they are necessary for the study. If the risk of reduced sperm motility described in the Investigator’s Brochure is relevant, please include this.
17. Please amend the PIS section on data to separate data into identifiable and coded subsections, making it clear what data is coded versus what is identifiable, and in each subsection stating: which parties will have access to each type of data; the reasons parties will have access to each type of data; and where each type of data may be transferred. If data is to remain on-site when accessed (e.g. source data or health records) this should also be stated.
18. The Committee stated that the Reproductive risk statement in the PIS pertains to fathering a baby and should also include women, as some women may not be aware that they are still of child-bearing age when they consent to participating in this study.
19. Please check all participant-facing documents for headings on different pages to their relevant sections once editing has been completed (i.e. “orphaned” headings).
20. Please include a statement in the PIS that states that the Partner PIS must be re-signed once the baby is born.
21. Please realign section on withdrawal from study and use of data on page 11 of the PIS with the Consent Form.
22. Please review the spacing and text size of headers and footers in participant-facing documents, so that they are more clearly separated from the main body of text.

Decision

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

* Please confirm the intended number of participants for this study.
* Please clarify what potentially identifiable information will be attached to study samples sent overseas, noting that the Committee’s preference is study number only, although year of birth is acceptable if necessary).
* Please amend the information sheets and consent forms, taking into account the suggestions made by the Committee (above)

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

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| **2** | **Ethics ref:** | **19/STH/215** |  |
|  | Title: | Kōwhai Study |  |
|  | Principal Investigator: | Prof Alexandra McCarthy |  |
|  | Sponsor: | University of Auckland |  |
|  | Clock Start Date: | 20 November 2019 |  |

Sandie McCarthy & Sarah Benge were present by teleconference 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. Younger women (50 years of age or younger) treated for cancer represent a growing population in New Zealand. While the treatment outcomes of this cohort have improved, their likelihood of developing treatment-related chronic disease such as diabetes and obesity is considerable, and could pose a significant public health issue in the future.
2. The Younger Women’s Wellness after Cancer Program (YWWACP) is a whole-of-lifestyle intervention that enables younger women to self-manage their chronic disease risk. It promotes physical activity, optimal diet, smoking cessation, alcohol reduction, plus strategies for sleep, stress, sexual wellbeing and menopausal symptom management based on the latest evidence.
3. Developed and piloted in Australia, the Australian YWWACP intervention has been adapted to meet the expressed needs of Māori and New Zealand European women.
4. The Kōwhai Study will test the adapted YWWACP intervention and proposed trial design for feasibility in a representative sample of younger New Zealand women (50 years of age or younger) after treatment for breast cancer.
5. This feasibility research will include the conduct of two studies:
   * 1-Kōwhai Randomised Controlled Trial (RCT), and
   * 2-Kōwhai Māori Sub-study (which will follow a non-randomised, single arm, trial design using Kaupapa Māori methodology.

Summary of resolved ethical issues

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

1. The Committee queried whether the focus groups were part of the feasibility study. The Researcher stated that three focus groups form part of the Kaupapa approach for the Māori subgroup.
2. The Committee queried how the small risk of emotional distress would be managed, The Researcher stated that study nurses are trained in distress management; additionally, there is a protocol for referring participants on to cancer counselling, and participants will be given the option to opt out of the only questionnaire that has historically been distressing.
3. The Committee queried whether weight and waist measurements as an outcome measure will result in distress or feelings of failure among some participants. The Researcher stated that other outcomes will also be reported to mitigate this.
4. The Committee queried whether there is a safety plan in place for participants completing the SF-36 Questionnaire. The Researcher stated that standard procedure is for study nurses to assess risk and refer on as necessary.
5. The Committee queried whether the statement in the PIS about participant-facing documents being translated into other languages was feasible. The Researchers stated that they would provide translations as needed.

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 copy of the independent scientific peer review that has been done for this study. If this is not available, please use the HDEC template for peer review.
2. Please provide confirmation of who will have access to identifiable study data (e.g. data safety monitoring committee, data monitors from NZC).

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

1. Please review the PIS and amend jargon with lay-language where possible.
2. After initial description of the Younger Women’s Wellness After Cancer Program, please refer to as “the program” rather than by its full name or acronym.
3. Please use lay-language to explain randomisation as it pertains to this study.
4. Please amend the Consent Form for Younger Māori women, where the word “intervention” has been used in place of “interview”.
5. Please amend the section of the PIS that describes how participants can use their computer or tablets, to also state that they can use their smart phones.
6. Please amend the section of the PIS on Risks to include what a participant should do if they become distressed by the questions they are answering.
7. Please amend the PIS for the Māori sub-study to include information on who will be present at focus groups, how focus groups will be recorded and where and how data will be stored.
8. Please review page numbering for both the main and Māori sub-study PIS for accuracy.
9. Please include a brief description of the questionnaires in the PIS so that potential participants know in advance the kind of questions they will be asked, namely that questions include topics such as body image and sexual functioning.
10. Please include a text box in the table of the PIS to show that the control group will receive a hard copy of the program at the end of the study.
11. The Committee stated that the Consent Forms for the main study and the Māori sub-study both state that information collected up until the point of withdrawal from the study will be retained, but the PIS states that this is optional. Please reconcile these, noting that it is not a requirement to give participants the option to remove data collected prior to withdrawal from the study.
12. Please remove sections of PIS for main study on focus groups, if there are to be no focus groups outside of the Māori sub-study.

Decision

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

* Please provide a copy of the independent scientific peer review that has been done for this study. If this is not available, please use the HDEC template for peer review.
* Please provide confirmation of who will have access to identifiable study data (e.g. data safety monitoring committee or those perofmring source data verification as noted elsewhere in the application).
* Please amend the information sheets and consent forms, taking into account the suggestions made by the Committee (above)

After receipt of the information requested by the Committee, a final decision on the application will be made by Assc Prof Mira Harrison-Woolrych and Dr Pauline Boyles.

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| **3** | **Ethics ref:** | **19/STH/208** |  |
|  | Title: | Pēpi Splint Project |  |
|  | Principal Investigator: | Dr Deborah Harris |  |
|  | Sponsor: | Victoria University of Wellington |  |
|  | Clock Start Date: | 28 November 2019 |  |

Dr Deborah Harris was present by teleconference 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. Iatrogenic skin injury in hospitalised babies is common. The majority of babies admitted to a Newborn Intensive Care Unit require a peripheral intravenous catheter (PIVC) for fluids, medication and nutrition.
2. PIVCs (drips) are the most commonly used device in unwell babies, with many babies requiring multiple drips. PIVCs are secured to the baby’s limb using splints and adhesive dressings. Removing the adhesive dressing (elastoplast) frequently tears the fragile skin, causing pain, increasing the risk of infection and lasting skin damage.
3. Following a traumatic evident to a newborn, the researchers sought to design a product which was more suitable for babies. The Pēpi Splint is made from medical silicone. It will secure the drip to the baby without the need for adhesive dressings to be applied to the baby’s skin.
4. The Researchers propose a proof-of-concept pilot study to determine the effectiveness and acceptability of the Pēpi Splint in 30 hospitalised newborn babies at Wellington Newborn Intensive Care Unit.
5. If the Pēpi Splint is found to be effective, the researchers intend to proceed to a randomised controlled trial. It is possible that the we will be able to considerably reduce the incidence of skin injuries in medically fragile babies.
6. The first phase is a prospective observational proof-of-concept pilot study to determine the effectiveness and acceptability of the Pēpi Split. Researchers will recruit 30 newborn babies > 1000g who will require a drip as part of routine treatment in the Wellington Regional Newborn Intensive Care Unit. Babies enrolled in the study will be cared for in the same way as those not in the study, with the addition of the Pēpi Splint.

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 parents of potential participants will be approached for recruitment into the study. The Researcher stated that Bedside nurses will approach appropriate parents, and there will also be advertising placed in the wards. Recruitment will not be done in emergency departments to avoid distress and give families enough time to consider their options.
2. The Committee queried the peer review comment on the possibility of a comparison group. The Researcher stated that as this is an exploratory pilot study a comparison group is not required.

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 response to question 1.7.1 had been answered incorrectly, resulting in several questions regarding compensation in the event of study-related injury not being addressed.
2. Information about who is primarily receiving benefit from this device trial is required. Please ensure that appropriate insurance cover (e.g. ACC or private ACC-equivalent) is in place.
3. The Committee stated that the potential conflict of interest for one of the Co-Investigators (who is also the device designer and patent-holder) should have been declared in the study application for. Details of how this potential conflict will be managed are required.
4. The Committee stated that differences between interacting with Māori and non-Māori families should be considered (with appropriate consultation) by the Researchers, and that this information should be included in the cultural section of the application form.
5. Please amend the study protocol to include information on how effectiveness and acceptability of the study device will be measured, and how the chosen measures will answer any other potential study questions (e.g. safety).
6. Please include a broader description of possible adverse events; skin damage can be a possible event of special interest but is unlikely to be the only possible adverse event.
7. Please amend the questionnaire to include more balanced and open questions (e.g., “what did you not like about the splint?” in addition to “what did you like about the splint?”).

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

1. Please use the HDEC template PIS as a guide where possible.
2. Please state that photographs of the participants with the splints in situ will be taken as part of data collection, and clarify what will e visible in the photograph (namely will participants be identifiable).
3. Please amend the PIS for parents to include information on whether data collected for this study will be used for future research.
4. Please reconcile the protocol and PIS, so that they both either include or exclude focus groups as part of participation.
5. Please include the photograph of the Pēpi Splint found on study advertising materials in the PIS.

Decision

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

* Please amend the information sheet, consent forms and protocol, taking into account the suggestions made by the committee (Ethical Guidelines for Intervention Studies (2012), para 6.13 & 5.4)
* Research involving Maori participants should be developed in consultation with a Maori representative (Ethical Guidelines for Intervention Studies (2012), para 4.9)
* Please ensure that adequate ACC or other compensation for injury is available to participants (Ethical Guidelines for Intervention Studies (2012), para 8.5)

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| **4** | **Ethics ref:** | **19/STH/209** |  |
|  | Title: | Group A streptococcus PCR for throat swabs |  |
|  | Principal Investigator: | Dr Amanda Taylor |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 28 November 2019 |  |

Dr Amanda Taylor & Susan Taylor was present by teleconference 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. Group A streptococcal (GAS) pharyngitis or ‘Strep throat’ is common in New Zealand and is responsible for significant post-infectious complications such as acute rheumatic fever (ARF) and post-streptococcal glomerulonephritis. Although ARF has been almost eradicated in many developed countries, Aotearoa NZ has unacceptably high rates of ARF, a condition that almost exclusively affects Māori and Pacific children.
2. The current gold standard for diagnosis of Strep throat is throat culture, this can take up to 48 hours to provide a result. The Xpert® Xpress Strep A molecular test is a rapid polymerase chain reaction (PCR) test that can diagnose Strep throat within one hour. It was recently evaluated in a Northern Territory (Australia) population and found to be highly sensitive when compared to culture.
3. In the Middlemore Hospital laboratory, the Researchers aim to assess 200 throat swabs, comparing the performance of the current gold standard, throat culture, to the Xpert® Xpress Strep A molecular test.
4. Secondary aims are to:
   * a) evaluate the cost-effectiveness of the Xpert® Xpress Strep A molecular test in comparison to throat culture.
   * b) to consider whether a rapid GAS molecular test could improve antimicrobial prescribing for pharyngitis in a population at high risk of post-streptococcal non-infectious sequelae.
5. The Researchers hypothesise that the Xpert® Xpress Strep A test will offer a sensitive and rapid result which will improve the management of pharyngitis and will contribute towards efforts to reduce the inequitable burden of GAS related disease in our population.

Summary of resolved ethical issues

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

1. The Committee noted that the justification for a waiver of consent provided by the Researcher was satisfactory.
2. The Committee queried at what point samples and data will be deidentified. The Researcher stated that while in the lab samples are identifiable, and the study spreadsheet is potentially re-identifiable. After this point all datapoints are deidentified. Some linkage data will be retained for descriptive reasons; however, these links will then be removed.
3. The Committee queried how withholding demographic data would affect the chances of the study being published. The Researcher stated that they will manage this with Journals as they need to ensure data is sufficiently de-identified.
4. The Committee queried whether the second PCR has been selected. The Researcher stated that it has, although it is a more time-consuming process.
5. The Committee queried whether the second PCR had been validated. The Researcher stated that it had, but not in their laboratory, therefore the results of both PCRs are considered exploratory.
6. The Committee queried whether the peer reviewer’s query about a tighter age range had been considered. The Researcher stated that they wished to keep the age range wide to ensure a full range of hospital patients are sampled.
7. The Committee queried how many swabs will need to be collected in order to obtain enough swabs suitable for the study. The Researcher stated that they have a limited exclusion criteria, and will lose about 20% of swabs due to timing of sample collection and staffing.

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 further information on which assays take priority in analysis; for The Committee stated that a biostatistician should be utilised to determine whether current sample size is sufficient to answer study questions.

The Committee requested the following changes to the Protocol:

1. Please amend the statement in the protocol on retention of health data for ten years, to state that data will be retained for ten years after the youngest participant had turned 16 years old.
2. The Committee requested that the protocol is amended to include how data is identified at each stage of its life cycle in this study.
3. The Committee requested that the protocol is amended to include information on the second PCR.

Decision

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

* Please provide evidence that a statistician has analysed the proposed study to ensure that the sample size is sufficient to answer the research question.
* Please amend the Protocol, taking into account feedback from the Committee (above).

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

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| **5** | **Ethics ref:** | **19/STH/210** |  |
|  | Title: | Bronchiolitis in Infants Placebo versus Epinephrine Dexamethasone - BIPED |  |
|  | Principal Investigator: | Prof Stuart Dalziel |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 28 November 2019 |  |

Prof Stuart Dalziel & Dr Megan Bonisch were present by teleconference 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. Bronchiolitis is the most common reason for infants to be admitted to hospital throughout the developed world. In New Zealand, 1 in every 13 infants in their first year of life are admitted to hospital (length of stay >3 hours) with bronchiolitis, with those living in the most deprived socioeconomic areas, Māori and Pacific infants having increased rates. Currently, national and international guidelines recommend only supportive care (oxygen or fluids) for the management of infants with bronchiolitis.
2. However, previous studies by the research team suggest that combined therapy with steroids and epinephrine (adrenaline) may reduce admissions to hospital. While these results are exploratory, they are supported by other clinical and basic science evidence.
3. Guidelines have cited the need for further evidence to confirm whether combined treatment with steroids and epinephrine reduces admission to hospital for bronchiolitis.
4. The proposed project will enrol 1,616 infants with bronchiolitis in a randomised controlled trial of corticosteroids and epinephrine at hospitals in Canada, New Zealand, and Australia.

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 potential participants will be recruited into the study. The researcher stated that parents of potential participants will be identified at triage in the hospital Emergency Department, then approached by a member of the clinical team for consent. The decision to approach for consent will be based primarily on the parents’ emotional state at the time.
2. The Committee queried whether the follow-up with the hospital would be conducted using the NHI number. The Researcher confirmed that this was the case, as follow-up for some participants could be up to six years away and what is available at that time is uncertain.
3. The Committee queried who will have access to NHI-linked data. The Researcher stated that NHI will only be stored on a password protected computer at locality, on which NHI will be stored with associated study number.
4. The Committee queried whether a study-specific peer review could be provided. The researcher stated that this study is currently being reviewed by SCOTT.
5. The Committee noted that CRF documents are excess to the requirements of the HDEC ethics review process and thus were not reviewed during the approval process. Submission of these documents is unnecessary for future applications.

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

1. The Committee requested that the PIS is revised with a focus on brevity where possible.
2. The Committee requested that a lay-title be used for the PIS.
3. Please remove rare adverse reactions from page five of the PIS, if they only pertain to babies who would have met the exclusion criteria for participation (and therefore would not be in the study anyway).
4. Please review the formatting for header on printed versions of the PIS, do ensure that they do not merge with the main body of text.
5. Please review the PIS for jargon and replace with lay-language where possible.
6. Please highlight in bold text that the child should not be given a home dose of steroid if they have been prescribed other steroids. Additionally, add this to study discharge instructions.
7. Please remove the optional tick box on the Consent Form for informing the participant’s GP, as the GP should always be informed.
8. Please remove the optional tick box on the Consent Form for removal of collected data up to the point at which a participant may withdraw, as this data should be kept to ensure the scientific validity of the study is upheld.

Decision

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

* Please amend the information sheets and consent forms, taking into account the suggestions made by the Committee (above)

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| **6** | **Ethics ref:** | **19/STH/211** |  |
|  | Title: | Comparison of the blood levels of two forms of tretinoin under fasting conditions. |  |
|  | Principal Investigator: | Dr Noelyn Hung |  |
|  | Sponsor: | Douglas Pharmaceuticals Ltd |  |
|  | Clock Start Date: | 28 November 2019 |  |

Dr Noelyn Hung & Linda Folland were present by teleconference 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 is designed to evaluate the relative bioavailability of 1 x 20 mg Tretinoin extended release tablet (Douglas, NZ) administered as a single dose and 2 x 10 mg Tretinoin® immediate release capsules (Glenmark, USA) administered as two equal doses of 10 mg (1 x 10 mg) given 12 hours apart in healthy male participants under fasting conditions. Tretinoin is a known teratogen so only males are participating in this study.
2. Subjects will stay at the Zenith Clinical Site from 12 hours before dosing until the last PK blood sample of each period (24 hours after dosing).
3. During each treatment period, each of the enrolled and randomised healthy male subjects will receive either a single dose of 1 x 20 mg Tretinoin extended release tablet or a split dose of two (2) equal doses of 1 x 10 mg Tretinoin® immediate release capsules administered 12 hours apart.
4. Subjects will receive each formulation in one period under fasting conditions. There will be at least 2 weeks washout (14 days) between each dosing period.
5. Blood samples will be collected at baseline (pre-dose) and at specified times up to 24 hours. The plasma will be assayed for tretinoin using a fully validated LC MS/MS method.
6. To assure the good health of subjects, pre-study physical examinations, ECG and clinical laboratory tests will be performed.
7. Post-study laboratory tests, vital signs and safety assessments will also be carried out and subjects will be monitored for AE’s throughout the 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 queried whether the project timeline is feasible. The Researcher stated that it is, as the commencement date is when recruitment starts.
2. The Committee queried how identifiable information will be stored following study completion. The Researcher stated that data will be stored in a secure records room.

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 evidence of trial-specific insurance.
2. The Committee stated that any compensation received by peer reviewers must be declared by either the peer reviewer or the Researcher in the application.

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

1. Please review the PIS/CF for jargon, replacing with lay-language where possible, including the participant-facing study title (e.g., “without food”, rather than “fasting”).
2. Please amend the wording of the exclusion criteria in the PIS, for example “drugs that affect the liver” is sufficient as greater detail can be elucidated through conversation with potential participants.
3. Please amend the PIS section on Adverse Effects to distinguish which effects are relatively common and which are rare, providing a list of effects.
4. Please clarify the wording in the PIS about eating a big meal before participants attend, as it only needs to be conveyed that they feel full.
5. Please amend the section of the Consent Form on use of participant information after withdrawal from the study, as it currently refers to the incorrect page number.

Decision

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

* Please provide evidence of trial-specific insurance.
* Please provide confirmation of any compensation received by any scientific peer reviewer of this study, including the amount of compensation that was received by the reviewer for reviewing this application.
* Please make the requested changes to the Participant Information Sheets and Consent Forms, taking into account feedback provided by the Committee (above)

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| **7** | **Ethics ref:** | **19/STH/212** |  |
|  | Title: | Comparison of the blood levels of two forms of tretinoin under fed conditions. |  |
|  | Principal Investigator: | Dr Noelyn Hung |  |
|  | Sponsor: | Douglas Pharmaceuticals Ltd |  |
|  | Clock Start Date: | 28 November 2019 |  |

Dr Noelyn Hung & Linda Folland were present by teleconference 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 is designed to evaluate the relative bioavailability of 1 x 20 mg Tretinoin extended release tablet (Douglas, NZ) administered as a single dose and 2 x 10 mg Tretinoin® immediate release capsules (Glenmark, USA) administered as two equal doses of 10 mg (1 x 10 mg) given 12 hours apart in healthy male participants under fed conditions. Tretinoin is a known teratogen so only males are participating in this study.
2. Subjects will stay at the Zenith Clinical Site from 12 hours before dosing until the last PK blood sample of each period (24 hours after dosing).
3. During each treatment period, at Time -0.5 hours prior to dose administration, each of the enrolled and randomised healthy male subjects will be served a high-fat, high caloric meal which they are required to consume within 30 minutes or less.
4. They will receive either a single dose of 1 x 20 mg Tretinoin extended release tablet or a split dose of two (2) equal doses of 1 x 10 mg Tretinoin® immediate release capsules administered 12 hours apart.
5. Subjects will receive each formulation in one period under fed conditions. There will be at least 2 weeks washout (14 days) between each dosing period.
6. Blood samples will be collected at baseline (pre-dose) and at specified times up to 24 hours. The plasma will be assayed for tretinoin using a fully validated LC MS/MS method.
7. To assure the good health of subjects, pre-study physical examinations, ECG and clinical laboratory tests will be performed.
8. Post-study laboratory tests, vital signs and safety assessments will also be carried out and subjects will be monitored for AE’s throughout the 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 queried whether the project timeline is feasible. The Researcher stated that it is, as the commencement date is when recruitment starts.
2. The Committee queried how identifiable information will be stored following study completion. The Researcher stated that data will be stored in a secure records room.
3. The Committee stated that any compensation received by peer reviewers must be declared by either the peer reviewer or the Researcher in the application.

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 evidence of trial-specific insurance.
2. The Committee stated that any compensation received by peer reviewers must be declared by either the peer reviewer or the Researcher in the application.

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

1. Please review the PIS/CF for jargon, replacing with lay-language where possible, including the participant-facing study title (e.g., “with food”, rather than “fed”).
2. Please amend the wording of the exclusion criteria in the PIS, for example “drugs that affect the liver” is sufficient as greater detail can be elucidated through conversation with potential participants.
3. Please amend the PIS section on Adverse Effects so distinguish which effects are relatively common and which are rare.
4. Please amend the section of the Consent Form on use of participant information after withdrawal from the study, as it currently refers to the incorrect page number.

Decision

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

* Please provide evidence of trial-specific insurance.
* Please provide confirmation of any compensation received by any scientific peer reviewer of this study, including the amount of compensation that was received by the reviewer for reviewing this application.
* Please make the requested changes to the Participant Information Sheets and Consent Forms, taking into account feedback provided by the Committee (above)

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| **8** | **Ethics ref:** | **19/STH/213** |  |
|  | Title: | “Transcranial electrical stimulation for early Alzheimer's disease.” |  |
|  | Principal Investigator: | Dr Divya Adhia |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 28 November 2019 |  |

Dr Divya Adhia was present by teleconference 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 study is to explore the effect of a non-invasive external brain stimulation technique [Transcranial electrical stimulation (TES)] on cognition (e.g. memory, attention), function, and quality of life in individuals with early Alzheimer's disease.
2. The activity in the brain region [posterior cingulate cortex (PCC)] targeted in the current study have been demonstrated to be altered in the very early stages of AD and are associated with cognitive dysfunctions.
3. The TES technique has considerable potential as a treatment for AD due to its relatively low cost, safety, portability, and ease of use compared with other brain stimulation methods.
4. The Researchers propose to explore a novel TES technique [high definition transcranial infraslow pink noise stimulation (HD-tIPNS)] targeting the PCC. The HD-tIPNS technique has been specifically developed in our Otago Brai3n laboratory to modulate the infraslow electrical activity (0-0.1 Hz) in the brain.
5. The infraslow electrical activity, a fundamental frequency range of the brain, re-organises neurons, regulate oscillatory patterns in the brain during awake and sleep cycles, and improves the electrical connectivity of the brain-wide functional networks; and thereby may improve cognitive functioning.
6. The evidence obtained from this study may help develop novel interventions to improve the health outcomes (cognition and function) in individuals with early AD.

Summary of resolved ethical issues

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

1. The Committee queried whether the CI was a clinician. The CI responded that they are not, however a neurosurgeon and neurologist are involved in the study.
2. The Committee queried whether the two clinicians will provide clinical oversight of any adverse events. The researcher confirmed that they would.
3. The Committee queried how the patients will be assessed as able to consent to participate in the study. The Researcher stated that this would be assessed by the patient’s clinician.

Summary of outstanding ethical issues

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

1. The Committee requested that the peer review conducted as part of the research grant application is provided.
2. The Committee stated that the role of the participant’s carer implies that they are necessarily present at the same time as the participant. Additionally, using the carer for informant data collection means that they are a participant, and will require their own PIS and Consent Form (current PIS for Support Persons is insufficient as it stands).
3. The Committee stated that the protocol needs to be amended to include information on whether carer attendance is mandatory or if there is a process by which the necessity of their attendance is assessed, what the process is if a participant does not have a carer, does the carer need to attend every session with the participant and if so, does the carer need to be the same person every time.
4. The Committee stated that more information needs to be provided on the qualitative post-intervention interviews, including safety and security protocols for how data is managed once it is collected.
5. Please submit the intended questions for the qualitative part of this study for HDEC review.
6. The Committee requested that the clinicians involved in the study clarify how potential conflicts arising from recruiting their own patients for a study will be managed.
7. The Committee stated that, if home visits are to occur, the protocol needs to be amended to include a safety plan for researchers; a safety plan for participants (including the management of any acute adverse events and appropriate clinical support). The Committee also noted that the researcher conducting the visits should be trained and appropriately experiences in home visits of this nature.
8. The Committee stated that the study documentation needs to be amended to state that documented history of hypertension is an exclusion criterion, and that medical records will be reviewed for screening, in addition to other listed methods of screening.
9. Please amend the protocol and other relevant study documentation to include a plan for how incidental findings (in particular as a result of MRI) will be managed and communicated with participants.
10. The Committee stated that the protocol should be amended to include a plan for collecting evidence of each patient’s competence assessment.

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

1. The Committee requested that the Participant Information Sheet be simplified where possible, including using lay-language over jargon.
2. The Committee stated that, as this trial has been described as a feasibility trial, any implications of benefits should be removed from participant-facing documents (including study hypotheses as necessary).
3. Please amend the PIS to state that there may be no benefits to participants for joining this study, and there are some risks.
4. The Committee requested that, if possible, a diagram of the intervention should be added to the PIS.
5. Please amend the PIS to describe what a participant can and cannot do post-intervention, including driving, whether they will need a support person post-intervention, and for how long any effects from the intervention are expected to last post-intervention.
6. Please confirm in the PIS that participants’ GPs will be informed of participation and incidental findings.
7. Please amend the PIS and protocol to specify what part(s) of the body are being scanned for the MRI.
8. Please amend the PIS to bullet-point the possible risks for clarity.
9. Please use personal pronouns (you, we) consistently throughout the PIS and Consent Form for clarity.
10. Please replace acronyms and abbreviations with full names where practical.
11. Please remove the section that states that forms can be provided in a potential participant’s first language (other than English) unless provision of translations are possible.
12. Please amend the PIS so that information in the appendix pertaining to participation for Māori is first fully described in the main body of the PIS and can stand alone (i.e. read without referring to the appendix).

Decision

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

* Please amend the information sheet, consent forms and protocol, taking into account the suggestions made by the committee (Ethical Guidelines for Intervention Studies (2012), para 6.13 & 5.4)
* Please provide the peer review that was undertaken as part of the grant application for this study (Ethical Guidelines for Intervention Studies (2012), para 5.11)

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| **9** | **Ethics ref:** | **19/STH/214** |  |
|  | Title: | The New Zealand-China Berry Lung Health (EDIBLE) study |  |
|  | Principal Investigator: | Dr. Olivier Gasser |  |
|  | Sponsor: | Malaghan Institute of Medical Research |  |
|  | Clock Start Date: | 28 November 2019 |  |

Dr Olivier Gasser & Dr Jeffry Tang were present by teleconference 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. In China, long-term exposure of individuals living in various urban areas to ambient airborne particulate matter (PM), has been identified as a major contributing factor for elevated susceptibility to respiratory diseases. Airborne PM can compromise the lung health of individuals, as these fine particles can cause the walls of the air sacs in the lungs to become thick, stiff and scarred from inflammation. This results in the lungs being less able to inflate easily, like healthy lungs should.
2. This study is aimed at investigating whether daily intake, as part of the habitual daily diet, for 4 weeks, of a New Zealand berry fruit product, made from natural boysenberries and apples, with biologically-active natural ingredients previously shown to benefit lung health in animal models of lung inflammation, can improve an aspect of lung health in adults living in an urban area in China (Nanjing, Jiangsu).
3. Lung health will be assessed using spirometry.
4. To better understand how the intervention product mediates the effects on lung health, information will be collected from the participants through a number of questionnaires, as well as biological samples in the form of blood and faeces. This is to determine if improvements in lung health may be linked to changes in the state of the participants’ blood immunological system, and/or changes in the gut bacteria composition, which may influence immune activation, inflammation and lung health.
5. A non-invasive scanning device, which can be directly applied to the skin, will also be used to determine changes in a number of dermatological parameters (the pH of skin, skin elasticity, and the amount of water released from the skin), which have been associated with the human immune response to PM.

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 the section that stated all electronic data will be deleted at the end of the study. The Researcher clarified that data monitoring will take place in New Zealand and the deleted data described here refers to data held in China.
2. The Committee queried the path and life cycle of the tissue samples being sent to New Zealand. The Researcher stated that samples will be stored and processed in New Zealand; the DNA extracted in New Zealand will be sent to the University of Cork in Ireland for analysis, as New Zealand does not have capability for this.

Summary of outstanding ethical issues

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

1. The Committee stated that their approval of this study would only pertain to the safety and security of data and samples held in New Zealand and would be provisional on receipt of an official English-language translation of the Ethics Approval letter given to the Researchers by the Committee’s counterpart in China, which will be reviewed by the Committee Chair and the HDEC Manager.

Decision

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

* Please provide an official English-language translation of the Ethics Approval given to the Researcher by the appropriate Chinese Ethics Committee (see point 8 above).

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

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| **10** | **Ethics ref:** | **19/STH/216** |  |
|  | Title: | RMHA gain adjustment for amblyaudia |  |
|  | Principal Investigator: | Dr Joan Leung |  |
|  | Sponsor: | University of Auckland |  |
|  | Clock Start Date: | 28 November 2019 |  |

Dr Joan Leung was present by teleconference 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. About half the children diagnosed with auditory processing disorder (APD) have amblyaudia alone or among a number of auditory processing disorders. Amblyaudia is similar to the vision disorder amblyopia (lazy eye) in that one ear dominates, suppressing input from the non-dominant side.
2. Of the thousands of children with amblyaudia in New Zealand, the Researchers believe that only the 300 or so cases treated so far at SoundSkills have received treatment. Amblyaudia can be rapidly corrected using the ARIA (Auditory Rehabilitation for Interaural Asymmetry) method, however this requires attendance at a clinic for at least four auditory training sessions.
3. This study aims to investigate if amblyaudia could be treated by varying the gain (the difference between loudness levels coming into each ear) of remote microphone hearing aids (RMHAs).
4. A hearing aid-based treatment for amblyaudia would improve treatment efficiency and reduce treatment costs for children who need both amblyaudia therapy and hearing aids for their APD.

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 what data might be shared, and whether it is deidentified or anonymous. The Researcher stated that they will obtain consent for first test results when participants were diagnosed, and age (not date of birth) will be recorded. Researchers will deidentify all other data.
2. The Committee queried whether data will be shared. The Researcher stated that only de-identified data will be shared in aggregate dataset form only.
3. The Committee queried who is forming the described data monitoring committee. The researcher stated that this was written in error and that no data monitoring committee was intended.
4. The Committee queried how potential participants will be approached for recruitment. The Researcher stated that an administrator will search the database of those who have previously expressed interest in participating in research and meet the diagnosis criteria, and will then send them advertising materials. It is then up to the potential participant to contact the researcher (who is not their normal health provider)
5. The Committee queried whether this study is of benefit to Māori. The Researcher stated that this study investigates a relatively new diagnosis that is different from unilateral hearing loss, of which Māori are disproportionately represented.

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 either a copy of the funder’s peer review document, or evidence of peer review using the HDEC template document.
2. The Committee asked for further information about how potential cultural issues will be addressed (e.g. potentially tapu interactions with participants, such as touching the head).
3. Please provide evidence of consultation with Māori.
4. Please refer to the HDEC template for all sections that should be included in the study protocol (e.g., the Research Agreement with the University document contains information that should be in the Protocol).

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

1. Please ensure that age ranges for participant recruitment are consistent across study documents.
2. Please amend the younger children’s assent form to be no more than one page, with the inclusion of pictures and simplified, age-appropriate wording.
3. The Committee stated that the PIS should be amended to include a section that states that if there is a benefit from receiving this intervention, it may not persist beyond the study period.
4. Please amend the PIS to describe randomisation in lay-language.
5. Please remove the section of the Consent Form that states that forms can be provided in a potential participant’s first language (other than English) unless provision of translations are possible.

Decision

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

* Please provide evidence of independent scientific peer review
* Please provide evidence of how cultural safety will be adhered to
* Please provide evidence of consultation with Māori
* Please review the study protocol to ensure all appropriate information is contained within, using the HDEC template as a guide
* Please amend the Participant Information Sheets and Consent/Assent Forms, taking into account feedback from the Committee (above)

After receipt of the information requested by the Committee, a final decision on the application will be made by Professor Jean Hay-Smith and Mr Dominic Fitchett.

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| **11** | **Ethics ref:** | **19/STH/218** |  |
|  | Title: | A Phase 3 study of Viltolarsen in boys with Duchenne Muscular Dystrophy (DMD) |  |
|  | Principal Investigator: | Dr Gina O'Grady |  |
|  | Sponsor: | Clinical and Regulatory Services (CARSL) Consultin |  |
|  | Clock Start Date: | 28 November 2019 |  |

Dr Gina O’Grady was present [in person/by teleconference] 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. Duchenne Muscular Dystrophy (DMD) is a disorder of progressive weakness leading to severe disability and ultimately death caused by a deficiency of the dystrophin protein. Dystrophin is a functional protein in striated muscle tissue that is essential for healthy muscle function and muscle fibre integrity.
2. In DMD patients, dystrophin is not produced because of a deletion of one or more exons from the dystrophin gene. DMD symptoms are usually first noticed from 3 - 5 years of age. There is currently no cure for DMD.
3. This study aims to analyse the efficacy of new investigational product "Viltolarsen", which is designed to interact with dystrophin RNA by exon skipping.
4. In this study, 74 participants with DMD will be split evenly and randomly into two groups. Those groups will be treated with (1) Viltolarsen or (2) inactive placebo.
5. The safety, efficacy and tolerability of this treatment will be assessed and compared to inactive placebo.
6. Participants will be treated with Viltolarsen or placebo via intravenous injection for 48 weeks.
7. This study hypothesizes that treatment with Viltolarsen will improve muscle function due to an increase in muscle tissue dystrophin expression.

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 the use of a placebo arm, due to the process involved for participants. The Researcher stated that the placebo arm is an FDA requirement for the study to be scientifically valid. Additionally, there is no comparator drug to use instead of a placebo as this is the only current treatment option.
2. The Committee queried the advertising materials used for the study. The Researcher stated that these were provided by the company, however they will not be used as only one person in New Zealand meets inclusion criteria for participation.

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 review the protocol to ensure that health information is stored for ten years after the youngest participant has turned sixteen years old.
2. Please clarify who is the local Sponsor for the study, i.e. who has overall local responsibility for the trial.
3. Please amend study insurance policy to ensure that the New Zealand sponsors are covered by the policy.
4. Please clarify that the described reward materials are not brought into play until after informed consent has been obtained.
5. Please provide confirmation that the travel policy will reimburse for unscheduled clinic visits in the same manner as scheduled visits.

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

1. Please amend the PIS to make it clear to parents that there is a 50% chance their child will receive placebo, i.e., half of all participants will be receiving placebo.
2. Please amend the PIS to state that both treatment and placebo arms have the option to enrol in the open-label extension study, in which all participants will receive active study drug.
3. Please create an assent form for children aged four to eight years old.
4. Please change the current consent forms so that it is not implied that parents can overrule their child’s decision not to participate and vice-versa (e.g. a sentence that reads ‘even you your parents say yes, you can still say no”).
5. Please amend sentence in PIS/CF that read that the child’s participation will help their family in the future, as it can be coercive to the child.
6. Please amend the child’s PIS to have a simplified header and title, and remove the Sponsor and Ethics Committee information.
7. Please amend the PIS to clarify that a physiotherapist is not a medical doctor.
8. Please amend the PIS for parents, to clarify whether adverse effects are minor feelings of discomfort or significant illness, what the expected frequencies of these effects are, and whether the effects pertain only to the drug infusion via IV, or if they are longer lasting than this.
9. Please amend the PIS for parents so that the statement regarding “if the patient is not truthful with the study doctor” is reworded or removed.
10. Please amend the privacy section of the PIS for parents to refer to “your child” instead of “you”.
11. Please amend page two of the PIS to state the correct number of pages for the entire document.
12. Please replace text on page four of the PIS, regarding what happens and when, with a table to improve clarity about what is happening to the participant, when things are happening, and how often they are happening.

Decision

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

* Please review the protocol to ensure that health information is stored for ten years after the youngest participant has turned sixteen years old.
* Please clarify which entity has local responsibility for the study.
* Please amend study insurance policy to ensure that the New Zealand sponsors are covered by the policy.
* Please clarify that the described reward materials are not brought into play until after informed consent has been obtained.
* Please provide confirmation that the travel policy will reimburse on unscheduled clinic visits in the same manner as scheduled visits.
* Please amend the Participant Information Sheets and Consent/Assent Forms, taking into account feedback from the Committee (above).

After receipt of the information requested by the Committee, a final decision on the application will be made by Assc Prof Mira Harrison-Woolrych and Mr Dominic Fitchett.

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| **12** | **Ethics ref:** | **19/STH/219** |  |
|  | Title: | Detecting changes in habits in rapid eye movement sleep behaviour disorder (RBD): a pilot study. |  |
|  | Principal Investigator: | Professor John Reynolds |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 28 November 2019 |  |

Prof John Reynolds & Dr Mariana Leriche Vazquez were present by teleconference 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. One of the early signs of Parkinson’s disease (PD) is the loss of habitual movements, however it is unclear if this loss is also present in disorders associated with PD.
2. The Researchers have developed a simple computational tool by which to detect habit loss and will test a sample of people with a condition called rapid eye movement sleep behaviour disorder (RBD), which has been associated with the subsequent development of PD.
3. Comparison between results obtained from RBD and healthy participants with the researchers’ ongoing PD study, will allow them researchers to determine the specificity of their tool for PD and the ability to detect habit loss in a population with some association with PD.

Summary of resolved ethical issues

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

1. The Committee queried whether participants at the sleep clinic will have already been told about the association between RBD and Parkinson’s Disease. The Researcher stated that they will be told, and that researchers will look through records for possible RBD symptoms.
2. The Committee queried where the healthy volunteers for the control group will be recruited from. The Researcher stated that healthy age-matched control volunteers will be recruited from public advertising and not from the sleep clinic, due to the likelihood of an existing sleep condition.

Summary of outstanding ethical issues

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

1. The Committee stated that, with regards to participants potentially being informed of a diagnosis that currently has no treatment, the PIS/CFshould be amended so that participants can indicate whether they wish to be informed of a diagnosis, with both the benefits and costs of being informed described to them. Upon completion of their participation, participants should be approached to either confirm or change their decision on whether they wish to be told about any diagnosis that arises from their participation in the study.
2. The Committee stated that healthy volunteer advertising should include the inclusion criteria about not having an existing sleep condition.
3. Please provide peer reviewer’s comments and the Researcher’s rebuttals if possible, otherwise please provide independent scientific peer review using the HDEC template.

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

1. The Committee stated that the PIS/CF should include a statement that there is an association between RBD and Parkinson’s, but that receiving one diagnosis does not necessarily mean an individual will receive the other.
2. Please discuss what receiving a diagnosis of probably prodromal PD would mean; the treatment options available for PD (or lack thereof); and the options regarding the return of this result.
3. Please amend point 10 of the Consent Form, as consent to use participant information after they have withdrawn from the study does not need to be optional.
4. Please amend point 11 of the Consent Form as the participant’s GP should be informed of findings of potential clinical significance (except f the participant wishes not to be informed of a diagnosis of prodromal PD, as noted above).
5. Please review the PIS and replace jargon and technical language with lay-language where possible.
6. Please add a Māori contact person to the bottom of the PIS.
7. Please include a statement in the PIS that there may be no benefit to participants.

Decision

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

* Please amend the PIS/CF so that participants can consent to being informed about possible diagnoses resulting from this study before they agree to participate, including the chance to reconsent once their participation in the study is complete (see points 6 and 10 above for details).
* Please amend advertising materials for healthy volunteers in accordance with point 7.
* Please provide peer review comments and rebuttals, or new peer review using the HDEC template.
* Please amend Participant Information Sheets and Consent Forms, taking into account feedback from the Committee (above).

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

## 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:** | 11 February 2020 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

1. **Problem with Last Minutes**

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

The meeting closed at 5:00pm.