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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 13 November 2018 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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| **Time** | **Item of business** |
| 11:30am | Welcome |
| 11:35am | Confirmation of minutes of meeting of 09 October 2018 |
| 11:45am | New applications (see over for details) |
|  | i 18/STH/212  ii 18/STH/213  iii 18/STH/214  iv 18/STH/215  v 18/STH/217  vi 18/STH/218  vii 18/STH/219  viii 18/STH/220  ix 18/STH/221  x 18/STH/225  xi 18/STH/226  xii 18/STH/227 |
| 4:45pm | General business:  Noting section of agenda |
| 5:00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |  |
| Ms Raewyn Idoine | Lay (consumer/community perspectives) | 27/10/2015 | 27/10/2018 | Present |  |
| Dr Sarah Gunningham | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |  |
| Dr Nicola Swain | Non-lay (observational studies) | 27/10/2015 | 27/10/2018 | Present |  |
| Dr Devonie Waaka | Non-lay (intervention studies) | 13/05/2016 | 13/05/2019 | Present |  |
| Ms Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |  |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Apologies |  |
| Dr Cordelia Thomas | Lay (the law) |  |  | 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 | Apologies |  |

## Welcome

The Chair opened the meeting at 11:45am and welcomed Committee members, noting that apologies had been received from Prof Jean Hay-Smith.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Cordelia Thomas and Mrs Sandy Gill confirmed their eligibility, and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 9 October 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/STH/212** |
|  | Title: | ROCKet – Reduction Of Chronic Post-surgical Pain with Ketamine |
|  | Principal Investigator: | Dr Andrew Pitcher |
|  | Sponsor: | Auckland District Health Board |
|  | Clock Start Date: | 01 November 2018 |

Davina McAllister, Dr Tim Short and Leanne DeRichie 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

Ketamine is increasingly being used as a rescue drug to reduce surgical pain when opiates and other drugs are ineffective.

This study will look to define the place of ketamine in the peri-operative setting. The primary outcome variable is whether it will reduce chronic post-surgical pain. The study is simple in its concept and the protocols for the administration of Ketamine are those currently in use as a second line therapy. Ketamine is currently administered to 10-20% of patients intraoperatively in situations where opiates are inadequate to control pain, and in major surgery where regional blocks aren’t viable.

If chronic post-surgical pain can be reduced by 20-30%, healthcare savings could be in the ballpark of tens of millions of dollars.

Summary of ethical issues (resolved)

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

1. The Committee asked the Researchers to indicate how anaesthetists might feel about the administration of treatment or placebo in this study being blinded. The Researcher noted that intraoperatively there is not much difference. Current views about whether Ketamine is effective vary and the Researchers need to construct a study that can give a result.
2. The Committee sought assurance that Researchers would not collect and store any blood samples for future research in the absence of a protocol amendment and supplementary participant information sheet being submitted to HDEC for approval. Page 19 of the protocol discusses a genetic biobank, stating collection and long-term storage of refrigerated blood samples will be undertaken to create a genetic biorepository for subsequent bio genomic studies into underlying genetic risk factors. The Researchers confirmed that until there is a protocol amendment no samples will be taken for bio banking. Once a process is in place the Researchers will submit to the Committee for ethical review.
3. The Committee asked the Researchers for further clarification as to whether the two arms in this study are equally poised, as the response given in the application form did not discuss equipoise. The Researchers confirmed that the balance of risks and benefits for each groups was not yet known, and it could not be stated at this stage if one group may be better off.

Summary of ethical issues (outstanding)

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

1. The Researchers have stated that the desired outcome in this study is a 25% reduction in post-surgical chronic pain and, that currently 12% of people get this. The Committee sought clarification as to whether this means a 25% overall reduction, or a 25% reduction in the 12% of patients expected to experience CPSP (an absolute reduction of 3%), as this impacts on required sample size. The Researchers confirmed that the desired outcome is an absolute reduction of 3%.

The Committee noted that issues such as sample size would usually be addressed in the submitted peer review. The funding letter submitted as evidence of peer review does not provide any peer reviewer/s comments, making it difficult to assess any scientific critique of the trial. Please provide the Committee with the reviewer/s comments.

1. The Committee noted that the protocol specifies a wide range of events that will not be reported as adverse events or serious adverse events, with a bullet-pointed list that covers most of the major body systems. The Committee sought clarification as to why and how they will ensure that specific events in relation to Ketamine will be reported if they are not being reported as AEs and SAEs.

The Researchers noted that they don’t want recognised complications that they would flag as a matter of course reported as AEs or SAEs. The Committee noted that the protocol describes AEs and SAE reporting in detail, for example reporting windows for SAEs) but does not have the same level of detail around serious events that do not fall within the very narrow definitions of AEs and SAEs. The Researchers explained that SAEs will be forwarded to the trial co-ordinating centre but serious events that are happening that are primary such as sepsis would also be reported as well and an adjudication committee would decide whether it meets the study criteria for that event.

The protocol currently lacks detail around the reporting of severe or serious events excluded from AE/SAE reporting. The Committee asked that the Researchers go back to the steering committee to seek clarification and provide this to the Committee.

The Committee requested the following changes be made to the participant information sheets and consent forms.

1. Please remove the official names (e.g. WHODAS), for the three assessments that you will do
2. Page 2 under the heading “After surgery and discharge”, please state more clearly that the questionnaires participants will be asked to complete are the ones referred to above.
3. Page 6 of 7, the 4th bullet point states “I understand the contents of the information sheet *including but not limited to the following points*”. Please remove the italicised phrase.
4. The risks of Ketamine are not stated. The Committee noted that around 10% of people receive Ketamine as standard of care but 90% wouldn’t. As this is a research setting, the risks of the medication under trial are expected to be included.
5. The exclusion criteria on the pre-operative data case report form states that ‘yes’ must be answered on all questions for the patient to be eligible to enter the study. Please change this to ‘no’.

Decision

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

* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Provide details of the reporting guidelines for events excluded from AE/SAE reporting. *(Ethical Guidelines for Intervention Studies para 6.60).*
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This information will be reviewed, and a final decision made on the application, by Ms Raewyn Idoine and Dr Devonie Waaka.

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| **2** | **Ethics ref:** | **18/STH/213** |
|  | Title: | Feasibility of measuring PCT using existing blood samples |
|  | Principal Investigator: | Dr Jacqueline Hannam |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 01 November 2018 |

No member of the research team was present 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 ethical issues (outstanding)

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

1. The letter of funding acceptance for peer review could have provided more information about what aspects of the study were considered. The committee would like to see peer review comments from an expert who is independent of the study.

The Committee requested that the following changes to the participant information sheet and consent forms.

1. Please clarify what health information you intend to collect (e.g details about the baby’s birth, any antibiotics they have taken and any surgery they may have had)
2. Please outline what would happen should participants no longer want to be in the study, for example whether data and samples already collected and analysed would continue to form part of the study results.
3. Please remove the ACC statement as there is no risk of physical injury to participants in this study.
4. Please make it clear that the participant’s clinicians/caregivers will not be made aware of the biomarker results (and the reason for this).
5. Please remove the interpreter box.

Decision

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

* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This information will be reviewed, and a final decision made on the application, by Dr Devonie Waaka and Mrs Sandy Gill.

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| **3** | **Ethics ref:** | **18/STH/214** |
|  | Title: | QRK309: QPI-1002 Phase 3 for Prevention of MAKE in Subjects at High Risk for AKI Following Cardiac Surgery |
|  | Principal Investigator: | Dr Shay McGuinness |
|  | Sponsor: | Pharmaceutical Solutions Ltd |
|  | Clock Start Date: | 01 November 2018 |

Dr Shay McGuinness and Mr Charles Beasley 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.

Dr Devonie Waaka declared a potential conflict of interest, and the Committee decided that it was not substantial and that Dr Waaka could stay in the room and take part in the discussion and decision making for this application.

Summary of Study

1. Acute kidney injury after cardiac surgery is a significant problem that is increasing in frequency. Much observational data associating AKI independently with poor outcomes, such as mortality and morbidity exists and little progress has been made in finding interventions that work.
2. Using this investigative product researchers are looking to interrupt the cascade of cell death for a short period and they are hopeful that it will minimise the significant amount of kidney injury they see.

Summary of ethical issues (resolved)

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

1. Question r.5.4.1: the Committee asked the Researchers to the briefly describe how they intend to minimise and manage the potential conflict of interest between their research and clinical role and specifically, how they plan not to unduly influence patients under their clinical care to take part in the research. The researcher explained that as intensivists, patients don’t see them as having influence over their decision about whether or not to have surgery or to enter studies. They do have processes in place to minimise the risk of coercion - historically they put 300-500 cardiac surgery patients into studies into Auckland hospital with an acceptance rate of 60%. Their process is that they give patients opportunity and as much time as possible to decide about participating in the study.
2. The Committee noted its understanding that type II diabetes and heart disease are more prevalent in Maori than in other groups in the population and, for future applications, noted that this could have been more fully explained in the application at question p.4.1 and included any known statistics about prevalence rates in Maori.

Summary of ethical issues (outstanding)

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

1. Please provide evidence of medical indemnity for the co-ordinating investigator.

The Committee requested the following changes to the participant information sheets and consent forms.

1. Please include a short lay title.
2. In relation to how the drug works and the fact that it is an experimental treatment please state how many people have received the drug world-wide. Section b.1.2 in the application form provides this information which can be adapted for a lay audience and included in the information sheet.
3. The information under the heading ‘What will my participation involve?’ and what study procedures will be performed was difficult to follow logically. Placebo is noted at the start but not explained until a few paragraphs further down. The statement that the total amount of study drugs will be 3 tablespoons is unusual. Milligrams would be more useful. Further, the procedures are split throughout two sections. The Committee asked for the inclusion of a table that sets out the number and type of procedures that people in this study will have.
4. Page 6: The Researcher confirmed his understanding the future unspecified research is not planned. The Committee noted that the information sheet provides the statement that “Research done with your sample may help to develop products in the future” and that participants will not get paid for future findings. The Researcher confirmed there are no plans for this and in the event there were to be then they would come to HDEC and get permission to use again. Please revise this statement and amend so that it is clear that this is in relation to results from the study being used to develop products in the future.
5. The Committee noted the statement that test samples will be destroyed by incineration. Many laboratories no longer use incineration as a method of destruction. Please r confirm that this is the method being used. The Committee suggested that “by internationally accepted means” could be stated.
6. Please state that data/health information will be sent overseas and to where noting that other countries may not have same privacy protections in place as New Zealand.
7. The instructions in the study protocol in relation to contraceptive advice seem to be more stringent than those suggested in the information sheet. The Committee suggested that the researchers use the contraception advice in the HDEC pro forma instead: <https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates>

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide evidence of medical indemnity for the coordinating investigator.

This information will be reviewed, and a final decision made on the application, by Dr Sarah Gunningham and Dr Cordelia Thomas.

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| **4** | **Ethics ref:** | **18/STH/215** |
|  | Title: | A first in human study of DCR-HBVS in Healthy Volunteers and Patients with Chronic Hepatitis B |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Novotech (New Zealand) Limited |
|  | Clock Start Date: | 01 November 2018 |

Dr Paul Hamilton and Miss Shuruthi Balachandran 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

This study is a Phase I trial for a new Hepatitis B treatment compound. The study design is in three parts: Part A in healthy volunteers with ascending dose cohorts. Parts B and C will be conducted in patients with chronic Hepatitis B who are treatment naive. Part C will be in patients already being treated with commercially available Hep B suppression therapy who will receive multiple doses. A Safety review by committee is planned in between each of the ascending dose cohorts before proceeding to the next dose level.

Summary of ethical issues (outstanding)

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

1. The Committee sought clarification in relation to the active and placebo numbers for cohorts. The protocol states that for each cohort, 2 sentinels will be dosed 1:1, then the remainder of the cohort will be dosed in a 2:1 randomisation. This is written as a blanket treatment allocation, with no differences noted between Parts A, B and C. As written, the numbers provided per cohort in the protocol do not result in treatment allocation ‘blocks’ for Parts B or C, which is a significant design issue.

The application form does not match what is outlined in the protocol, and is also different from the information provided in the Participant Information Sheets.

The Committee asked that the Researchers review the issue and amend the protocol and/or information sheets accordingly.

Summary of ethical issues (resolved)

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

1. The study protocol states that a maximum extended stay due to clinical concerns cannot be defined as the extension will be as long as is necessary to ensure the safety of the participants. In the event that is extended on a whole group basis the Committee asked whether the participant payment will be adjusted to reflect that. The Committee acknowledged that this question does not apply to individual participants required to stay longer as a result of an adverse event. The Researchers explained that if a group (or groups) of participants were required to extend the inpatient stay, adjustment of payment would be considered and HDEC notified accordingly.
2. Information related to payment for the study is at variance. The information sheet state that 100 dollars will be paid for travel while the application states 75 dollars will be paid for travel. The Researchers explained that 75 dollars will be for healthy volunteers and 100 dollars will be for patients. Healthy volunteers are recruited within the Auckland region but patients may live further away, hence the difference in reimbursement for travel costs. The patients will still get a payment as this is a non-therapeutic study and the Committee asked that this information needs to be included in the application form for future reference.

The Committee requested the following changes be made to the participant information sheets and consent forms.

1. Please clearly state which cohort each of the three participant information sheets relate to.
2. The fact that this is a first in human study needs to be in bold up front on all three information sheets under the short title/location information on the first page. The Committee suggested that this information be entered in a box as a way of further emphasising this point.
3. ‘What is the purpose of the study?’ contains statements that are not related to the purpose of the study. Please revisit this section and move any statements that are not relevant.
4. The section ‘What are my rights?’ lists a number of things that participants must not do while they are in the study, and information about data management and study withdrawal. Information about what happens to test samples is confused and has information about data as well as samples. Please revise these sections and include only information relevant to each section.
5. Please include Hepatitis C in the discussion about diseases notifiable to the MOH.
6. Page 3: the Committee noted the statement that people will attend clinic until the amount of hepatitis virus is a certain amount below the amount they had on day one. Please remove “certain amount” and be more specific about what the amount is.
7. In the application form sample storage duration after the study is completed is stated as “xxx”. The Researchers believe the blood samples will be destroyed at the end of the study and they will follow up on the storage and come back to the Committee.
8. The Pregnant Partner form is lacking in information. Please include information about the right to withdraw, who to contact, what will happen to data already collected and how long data will be kept for. Please review and provide an updated copy for the Committee. The Committee noted ACS has used a number of Pregnant Partner forms in previous studies, and these could be used as a reference for the type of material to be included.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide clarification in relationto the active and placebo numbers for cohorts provided in the application as the information sheet and application don’t match. (*Ethical Guidelines for Intervention Studies* *para 5.7*).

This information will be reviewed, and a final decision made on the application, by Dr Devonie Waaka and Mrs Sandy Gill.

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| **5** | **Ethics ref:** | **18/STH/217** |
|  | Title: | A study of the safety and efficacy of intravenous CR845 in hemodialysis patients with moderate to severe itching |
|  | Principal Investigator: | Dr Kannaiyan Rabindranath |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 November 2018 |

Dr Rabindranath and Ms Jen Coetze 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 double-blind, placebo-controlled intervention study will trial a new medicine looking at moderate to severe itching experienced by 30-40% of haemodialysis patients, to see whether it might reduce the intensity of the itching. The drug will be given at the end of dialysis sessions. Part 2 of the study is a roll-over open label study for up to one year.

Summary of ethical issues (resolved)

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

1. The Researchers had stated in the application that consultation with Maori is not needed. The Committee expects that consultation with Maori will happen and asked that this be done before the study starts. For future reference the Committee would like to see the prevalence of the condition and any known statistics in relation to Maori discussed at question p.4.1 in the application form.
2. The Committee can only approve documents submitted in English and is not approving the documents submitted in Chinese language as part of this application.

Summary of ethical issues (outstanding)

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

1. The Committee asked whether the drug will be available at the end of the study if it is shown to work. The Researcher noted that they don’t have confirmation of this yet and would need to put this question to the sponsor. The Committee noted that people going into this study would likely want to know this and that it would be preferable that the Researchers put this to the potential participants as part of the informed consent process.

The Committee requested the following changes be made to the participant information sheet and consent forms.

1. The possibility of extra clinic visits was mentioned in the application but it was not clear in the information sheets how many visits there are likely to be in part one of the study.. The Researcher explained extra clinic visits will not be required. Please make sure this is clear in the participant information sheet.
2. Page 6: “you should be careful when operating heavy machinery or driving if you are dizzy or sleepy”. Please replace the words “should be careful when operating” with “must not operate”.
3. Page 11: people can withdraw their data from the study if they wish. In the section under ‘collection of follow up data’ please say that information can be collected with your consent or permission rather than stating that it is an absolute requirement.
4. Under the heading ‘number of subjects and duration of the study’ please state this is world-wide and there will be 15 participants in New Zealand.
5. Please replace the word “subjects” with “participants” throughout the document.
6. The Committee asked whether the information collected for the study will be in a separate folder from the patient’s usual clinical notes. The researcher confirmed that it wouldn’t be in the clinical notes and that they have separate folders for the research participants. Please remove the statement that the information for the study will be in patient clinical notes.
7. Page 11: while the information sheet states that samples will be labelled with a code the application states that samples will also be labelled with date of birth, gender and child bearing potential which is potentially identifiable information. If that is the case, then please make clear in the information sheet that all those identifiers will be used on the labelling of samples.

Decision

This application was *approved* by consensus with non-standard conditions.

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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| **6** | **Ethics ref:** | **18/STH/218** |
|  | Title: | Study of VTS-270 (2-hydroxypropyl-β-cyclodextrin) to Treat Niemann-Pick Type C1 (NPC1) Disease |
|  | Principal Investigator: | Dr Kelly Byrne |
|  | Sponsor: | Pharmaceutical Solutions Ltd |
|  | Clock Start Date: | 01 November 2018 |

Mr Charles Beasley and Mr Naetko 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.

Dr Devonie Waaka declared a potential conflict of interest in relation to this application but the Committee decided that the conflict of interest was not significant and that Dr Waaka could stay in the room for the discussion and decision-making for this application.

Summary of study

1. The potential participant in this trial is from New Zealand and has NP1 disease. He is currently 18 years old. He entered Part B of the Australian study conducted at Monash medical centre in 2017 as a blinded participant. He entered Part C of the study 30 weeks ago and is on open label administration which requires travel to Australia and he travels every two weeks, which is a burden to him and his parents who travel with him.

Summary of ethical issues (outstanding)

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

1. The Committee asked the Researchers for an indication of the patient’s cognitive ability to understand what participation in the trial involves and to consent/assent to participating. A letter from the patient’s treating neurologist in Australia has been submitted with this application. The Committee explained that the law in New Zealand provides that parents cannot consent on behalf of adult participants (18 years or older) for participation in research.
2. In New Zealand the legal position is governed by Code of Rights. Right 7 distinguishes between people who have diminished competence but are able to express a view for themselves and those who are incompetent. The Committee asked to what extent the patient is able to express views about his participation in research. The Researchers explained that the patient is not in a position to provide informed consent.
3. As the Committee understands it what is now being proposed is that the patient will have fortnightly lumbar punctures for the purposes of this research and that there are arguments made that this is in his best interests because he is being helped by this particular treatment and he would otherwise have to travel to Australia every fortnight.
4. The Committee explained that the legal test in New Zealand is whether the *provider* believes participation in the study is in the participant’s best interests. The “provider” is not the Australian researchers – it is the clinician in New Zealand who will administer the lumbar punctures and medication. In this case the clinician involved in New Zealand must decide that it is in the patient’s best interests and that the participant would be better off having this treatment than not. If the provider decides that this is the case, they must take reasonable steps to ascertain the young person’s views. If the young person is not able to make choices then the provider must consult others who are interested in the welfare of this person and are available to advise the provider.
5. The Committee would like more information about whether staying on in this trial is in the best interests of the patient and this needs to be provided by an expert in New Zealand. At the time of submission the proposed adviser, Dr Byrne, has had to rely on information from the Australian PI and he has not met the patient himself to assess whether participation would be in his best interests. Dr Byrne would need to assess information from an expert physician in New Zealand before making the decision about whether participation is in the patient’s best interests and then make the decision about whether he will provide the treatment in New Zealand.

The Committee requested the following changes to the participant information sheet and consent forms.

1. The Committee advised that the research team need to rethink the forms to fit the New Zealand context. The forms have to indicate that the clinician thinks it is in the patient’s best interests, that the family have been consulted for their views but that they are not providing consent on the patient’s behalf. The forms need to be adapted to reflect this situation in New Zealand.

Decision

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

* The Committee stated that it is not possible for HDECs to approve an application unless it is consistent with New Zealand law, including the right not to be subjected to medical or scientific experimentation without that person's consent (section 10 of the New Zealand Bill of Rights Act 1990). Research involving participants who are not competent to consent is inconsistent with the Bill of Rights unless it is undertaken in accordance with Right 7 (4) of the of the Code of Health and Disability Services Consumers’ Rights. In addition to requirements regarding ascertaining the views of the consumer and other suitable persons (forms consistent with this aspect are currently included in this application), Right 7(4) of the Code requires that any health services provided without the informed consent of the consumer must be in the best interests of the consumer. This means that there must be some benefit, or potential benefit, to the participant beyond what they would receive if they were not participating in the research.
* The Committee notes that proxy consent by a welfare guardian or EPOA to participation in a “medical experiment” is only legally acceptable in cases where the purpose of the medical experiment is to save the person’s life or prevent serious damage to the person’s health.
* Therefore the information documents should only be used to gauge views of relatives/ friends/welfare guardian/EPOA of potential participants involved who are unable to consent for themselves. This means that the forms should not involve language whereby the relative/friend consents on behalf of someone else. As an alternative, the language should reflect that the document seeks the friend/relative’s view that the non-consenting person would be agreeable to participate. This is in line with Right 7(4)cii: If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider. Once reasonable steps have been taken the clinician can enrol provided enrolment is in the participant’s best interests.

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| **7** | **Ethics ref:** | **18/STH/219** |
|  | Title: | A study of Zanubrutinib Compared with Ibrutinib in patients with Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma |
|  | Principal Investigator: | Dr Robert Weinkove |
|  | Sponsor: | PPD |
|  | Clock Start Date: | 01 November 2018 |

No member of the research team was present 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 ethical issues (resolved)

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

1. The Committee agreed that there were not significant ethical issues of concern in relation to this application and, that the application was well completed.
2. Question p.4.1 on the application form. For future reference please note that the Treaty of Waitangi doesn’t give Maori the right to be involved in research and reference to the Treaty is not needed here. What would be useful is any known statistics about prevalence rates in Maori to help the Committee know whether and how Maori are affected by the condition.

The Committee requested the following changes be made to the participant information sheets and consent forms.

1. In the future unspecified research consent form it is not clear whether genetic sampling is planned. If genetic sampling is planned please make this clear and also specifically state what type of genetic sampling will be done.
2. Please remove the statement “If you are unable to provide interpreters please clearly state this” from the interpreter box in the consent forms.

Decision

This application was *approved* by consensus with non-standard conditions.

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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| **8** | **Ethics ref:** | **18/STH/220** |
|  | Title: | A study of the influenza drug Boloxavir Maroboxil in combination with standard care in hospitalised patients with severe influenza |
|  | Principal Investigator: | Dr DIANE HANFELT-­GOADE |
|  | Sponsor: | PPD |
|  | Clock Start Date: | 01 November 2018 |

Dr Diane Hanfelt Goade and Ms Margaret Ross 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 being conducted to see whether this new drug combined with Tamiflu will improve outcomes in patients who have moderate to severe influenza. This is a Phase III trial and the new drug has been given in combination with Tamiflu and looks to be synergistic with Tamiflu.
2. The particular dose and treatment period being given and the fact that it is happening in New Zealand first is to make sure that all sites are ready for the ‘flu season in advance.

Summary of ethical issues (resolved)

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

1. The Committee noted that the Researchers state in section b.4.2 of the application form that there will be no restrictions on publications of results. The researcher explained that the company will not withhold any information and it will not pick and choose not to publish any information; the results will be published in entirety.
2. The answer given at section a.1.6 in the application form could be applied to any research study. The Committee noted that the main ethical issue is that acutely unwell patients will be enrolled in the clinical trial and there are issues in relation to this in terms of the informed consent process at a time when potential participants are acutely unwell. The Committee asked the Researchers how they intend to manage this issue and whether they are confident that all people will be able to wade through the full information sheet/consent forms and the time that they are being asked to consent. The Committee also asked whether the Researchers had given any thought to a briefer information sheet being given initially and then re-consent on a full information sheet once the patient is less acutely unwell.
3. The Researchers explained that they would want to go through the full consent process even though these are time limited studies. The Researcher explained the approach they usually take in such studies is to meet with the patient and their family/whanau. The information sheet and consent forms are then left with them for 30 minutes up to 3 hours depending on the situation. There is a team approach to this process so that any questions raised by the participant can be addressed as they come up.
4. It is stated in the application form that Maori consultation is not needed but this was an error. The Researchers confirmed that they have consulted with Maori. For future reference statistics showing incidence rates in Maori would be helpful for the Committee to see at section p.4.1 in the application form.

Summary of ethical issues (outstanding)

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

1. A practicing certificate has been uploaded as evidence of medical indemnity. Please provide a copy of your MPS certificate or equivalent.

The Committee requested that the following changes be made to the participant information sheet and consent form.

1. Please replace the long title on the information sheets with the short title.
2. Page 9: Please expand on the statement that the medication has had limited testing in New Zealand to state that there are limited numbers worldwide and indicate how many people have had the drug.
3. As there are no children in this study and participants will be adults who can consent for themselves, please remove reference to “legally authorised representative” throughout the document.
4. Page 10: under the heading ‘Who pays for the study’ there is a paragraph that references the American system. Please amend this paragraph to reflect the New Zealand system.
5. Page 10: Please state that placebo looks like the active study drug but does not have any medicine in it.
6. In the table of events please remove reference to the CXR and CT scan as the Researcher has confirmed that imaging is part of standard of care and is a study-specific assessment.
7. RIDT PIS on page 2: please remove duplication of the following – “if you decide not to participate in this study the results from this test will not be collected”.
8. On the Pregnant Partner form there is reference to “authorisation on behalf” of that person. In New Zealand the person themselves must consent. Please revisit this section and amend to so that it is compliant with New Zealand law. Please also amend the statement that says if participants want to withdraw from the study they must do so in writing as this is not a legal requirement in New Zealand.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide a copy of your MPS certificate or equivalent

This following information will be reviewed, and a final decision made on the application, by Ms Raewyn Idoine and Dr Sarah Gunningham.

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| **9** | **Ethics ref:** | **18/STH/221** |
|  | Title: | Taking MARS Spectral CT to Human Imaging |
|  | Principal Investigator: | Prof Anthony Butler |
|  | Sponsor: | University of Canterbury |
|  | Clock Start Date: | 01 November 2018 |

Dr Ben Bamford, Mr Joe Healy and A/Prof Stephen Gieseg were present in person 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 Researchers have developed a CT scanner for use in humans that uses the MARS technology. MARS is new type of advanced CT technology based on a type of censor developed at CERN in Switzerland and which turns black and white CT imaging to colour imaging. The colour imaging process can differentiate tissues much more precisely than a conventional CT scanner.
2. There are two legs to this study, one of which is to use the scanner to look at the extremities in imaging and validate the design and the second leg will look at particular areas of medicine predominately arthritis and bone and vascular disease and extending onto cancer imaging and infectious diseases.

The Committee requested that the following changes be made to the participant information sheet and consent form.

1. Please provide a statement in bold upfront saying that this is the first time this scanner will be used in human trials.
2. The Committee asked that the healthy control group be separated from the clinical group by having separate information sheets for each of the groups: Part 1 (healthy controls) and Part 2 (clinical group).
3. In relation to the healthy control group the Committee asked whether the Researchers have chosen a peripheral area. The Researcher explained it is a random decision at this stage that they want to develop a catalogue of upper/lower extremity imaging at different points to validate the protocol for each part as different information will be useful for different physicians. Please state on the healthy control group information sheet something along the lines of they will be chosen to have a scan of a particular body part such as hand or elbow as it is currently hard to get a sense of what will happen. For the clinical control group something along the lines of we will scan the area of interest – if they have vascular issues we’ll focus on that or, where the arthritis is.
4. Please include a photo of the prototype scanner.
5. The Researchers explained that the radiation dose that participants will receive from the four scans in this study is essentially equivalent to a few extra hours in the sunlight. The Committee asked that the Researchers state that the scans are the same amount of radiation as if you were exposed to 2-3 hours of sunlight in a normal day.
6. The details about scanning for each cohort are a little vague in the study protocol and information sheets. The Researchers clarified that participants will have one to two scans and about half will have the conventional scan. Please flesh this information out in both the protocol and the participant information sheet so that people can be more fully informed about what they are receiving.
7. Under the heading ‘What are my rights?’ please separate out the information in the first paragraph as it currently reads as participants can only access information about themselves if they decide to withdraw from the study as this is not correct. People can access information about themselves even if they remain in the study.
8. Under the heading ‘What happens after the study or if I change my mind?’ The Researchers are planning future research once the consultants have looked at data from the preliminary research. The future research will be related to this study and data will be de-identified. Please reword the first paragraph to make these points clear.
9. Under the heading ‘Possible benefits and risks of this study’ please rephrase the statement “we believe the MARS scanner will produce significant health benefits in the future” to read more neutrally. For example “we hope” or “we are investigating to see whether the MARS scanner will produce…”
10. The Committee noted that the information given in section a.1.5 on the application form about giving scores to images is helpful for understanding and this information could be included in lay language in the information sheet.
11. Under the heading ‘possible risks and benefits of this study’ although the risk to pregnant participants is negligible please quantify the risk as public perception is that x-rays are teratogenic. Think about whether you are prepared to take the risk of accepting someone’s word that they are not pregnant in the event that they later come back and claim that being in the study was detrimental to their baby.
12. This study appears to be a commercial enterprise with shareholders and as such participants are unlikely to be covered by compensation by ACC. If this study is held primarily for benefit of the eventual manufacturer then ACC won’t cover for compensation if there are any injuries and sponsor insurance is needed. The Researchers explained that the grant has been made through the University of Canterbury. If the grant is made through the commercial arm of the university then equivalent cover is needed. Please provide evidence of sponsor insurance and replace the ACC statement in the information sheet with the following statement:

*As this research study is for the principal benefit of its commercial sponsor [insert name], if you are injured as a result of taking part in this study you* ***won’t*** *be eligible for compensation from ACC.*

*However, [insert name] has satisfied the [ insert name] Health and Disability Ethics Committee that approved this study that it has up-to-date insurance for providing participants with compensation if they are injured as a result of taking part in this study.*

*New Zealand ethical guidelines for intervention studies require compensation for injury to be at least ACC equivalent. Compensation should be appropriate to the nature, severity and persistence of your injury and should be no less than would be awarded for similar injuries by New Zealand’s ACC scheme.   
Some sponsors voluntarily commit to providing compensation in accordance with guidelines that they have agreed between themselves, called the Medicines New Zealand Guidelines (Industry Guidelines).These are often referred to for information on compensation for commercial clinical trials. There are some important points to know about the Industry Guidelines:*

* *On their own they are not legally enforceable, and may not provide ACC equivalent compensation.*
* *There are limitations on when compensation is available, for example compensation may be available for more serious, enduring injuries, and not for temporary pain or discomfort or less serious or curable complaints.*
* *Unlike ACC, the guidelines do not provide compensation on a no-fault basis:*
* *The Sponsor may not accept the compensation claim if:*
* *Your injury was caused by the investigators, or;*
* *There was a deviation from the proposed research plan, or;*
* *Your injury was caused solely by you.*
* *The injury was caused by <<NAME OF COMPARATOR DRUG>> (include only if holds true for specific study)*

*An initial decision whether to compensate you would be made the by the sponsor and/or its insurers.*

*If they decide not to compensate you, you may be able to take action through the Courts for compensation, but it could be expensive and lengthy, and you might require legal representation. You would need to be able to show that your injury was caused by participation in the trial.*

*You are strongly advised to read the Industry Guidelines and ask questions if you are unsure about what they mean for you.  
If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.*

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide evidence of Sponsor indemnity.

This information will be reviewed, and a final decision made on the application, by Dr Nicola Swain and Dr Cordelia Thomas.

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| **10** | **Ethics ref:** | **18/STH/225** |
|  | Title: | A Phase 1/2 Study of Durvalumab and Monalizumab in Adult Subjects with Select Advanced Solid Tumours |
|  | Principal Investigator: | Dr Sanjeev Deva |
|  | Sponsor: | Covance New Zealand |
|  | Clock Start Date: | 01 November 2018 |

Dr Sanjeev Deva and Ms Aya Cervantes 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 is a study in patients with advanced solid tumours, mainly those with advanced metastatic colorectal cancer. A combination of known immunotherapy and a newly developed immunotherapy will be used in various combinations of treatment which are standard for patients with metastatic bowel cancer, to determine if these new immunotherapies can improve patient survival and can be delivered without undue toxicity.

Summary of ethical issues (resolved)

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

1. The Committee queried whether any of the lead investigators will be on the internal data safety committee. Currently the protocol indicates sponsors only. The Researcher noted that much of the initial part of the study would have had lead investigators on it but most of the dose escalations have been completed in the USA and that this research team is getting involved in the dose expansion component of the study. It will be their obligation to report any serious adverse events to the committee to notify that there may be other toxicities not aware of in the in dose escalation component of the study.
2. In relation to question r.1.6 in the application form the Committee noted that in New Zealand a study cannot be stopped purely for commercial reasons and especially if it is a therapeutic study. An example of “commercial reasons” could be in the situation when some other drug comes onto the market that affects the company’s market share so they want to stop the study.
3. Question r.3.4 about where archival tissue is going to be obtained from was not answered. The Researcher confirmed that this will be from the local pathology departments. The Researcher explained that the amount of tissue sent will depend on what the amount of tissue in store. The sponsor has confirmed that sending tissue is optional and if there is not enough tissue or the patient decides that they don’t want to send their tissue then they can still participate in the study.
4. Question p.3.1. The Committee noted that the initial approach to participants should come from the patient care team and that the message conveyed could be something as brief as that there is a clinical trial happening looking at some investigative medicine to treat their condition and would they be interested in hearing some more about it so that patients don’t feel like they are being cold called by a researcher and that their details have been given out without their knowledge. The Researchers confirmed that this is the approach that they take in the oncology department.
5. For future reference p.4.2 on page 27 of the application form asks researchers to identify possible cultural issues for Maori. It would be helpful for the researchers to note their understanding that bloods/tissue are tapu to Maori here. In section p.4.1 it would also be helpful to the Committee to see any known statistics of prevalence in Maori.

The Committee requested the following changes be made to the participant information sheets and consent forms.

1. Please state the length of time that participants will be expected to commit to this study for. The Committee’s understanding is that this is up to three years.
2. The Committee asked that the Researchers amend the opening statement “You are invited to take part in a research study on solid tumours for a specific cohort for patients with colorectal cancer” so that it is more accessible to a lay audience. . For example “specific cohort” is meaningless to many lay people.
3. The Flesch reading score noted as 82 suggests a simple and readable document. This doesn’t seem to be the case, and, the length of the document is around 18,000 words. The information sheet should have a lay title regardless of what is in the protocol such as “A study of a combination of drugs for colorectal cancer”. The opening sentence needs to reflect this in a more gentle way.
4. Pregnant Partner form: please allow space for participants to give consent for their neonate’s data to be collected that the parent signs after the child is born.
5. Pregnant Partner form, page 3: Please replace the word “abortion” with miscarriage or loss of your pregnancy as this is a more sensitive way to express that in the sentence that reads “We’d like to contact your study doctor should you decide to terminate your pregnancy for any reason or if you suffer and unexpected abortion”.
6. Addendum about continuing treatment: please give a brief explanation of a couple of sentences about why you want to continue with treatment despite apparent worsening of disease.

Decision

This application was *approved* by consensus, with non-standard conditions.

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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| **11** | **Ethics ref:** | **18/STH/226** |
|  | Title: | Assessment of the trial drug AG-B1512 in adults with growth hormone deficiency. |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: | Pharmaceutical Solutions |
|  | Clock Start Date: | 01 November 2018 |

No member of the research team was present for discussion of this application.

Potential conflicts of interest

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

Dr Devonie Waaka declared a potential conflict of interest, and the Committee decided that Dr Waaka could stay in the room but not take part in the discussion or decision making for this application.

Summary of ethical issues (outstanding)

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

1. The Committee requested that the researchers provide documentation confirming that they will have sentinel dosing in this study.

The Committee requested the following changes to the participant information sheets and consent forms.

1. Page 3: please clarify what “strenuous exercise” is as different people have different views to what they think this is.
2. The Committee suggested that the researchers refer to the HDEC pro forma that sets out guidelines for reproductive risks and consider including the suggested statements in the information sheet. <https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates>

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide documentation confirming that you will use sentinel dosing in this study.

This information will be reviewed, and a final decision made on the application, by Dr Nicola Swain and Dr Cordelia Thomas.

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| **12** | **Ethics ref:** | **18/STH/227** |
|  | Title: | The C\*STEROID Feasibility Study: Corticosteroids before planned caesarean section from 35+0 to 39+6 weeks |
|  | Principal Investigator: | Associate Professor Katie Groom |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 01 November 2018 |

A/Prof Katie Groom 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. Babies born by caesarean section have a slightly increased risk of respiratory morbidity in the short term. Steroids given to mothers prior to early birth have been shown to reduce risk of babies having breathing problems and also the risk of death. None of the current national guidelines give any advice about whether steroids given to mothers before planned caesarean section are beneficial for babies or not. That is because there is evidence both for and against.
2. The Researchers ultimately would like to plan and run a trial that is sufficiently powered to look at breathing problems as well as the potential problem of low sugars in babies. Because two and a half thousand babies would be needed the Researchers want to know that they will target the right women in the right ways and make sure that outcomes they collect and any follow up they do is acceptable to women and their families.
3. The study before the Committee is a feasibility study that would have two sites in New Zealand. The Researchers plan to ask women whether they would be interested in participating in the larger trial and for those that do take part also complete questionnaires about what was good about being in the study and what level of follow up they would be happy with. For those who decline to be in the study the Researchers would like to find out their reasons to help inform the design of the larger study.
4. A one year study is planned which would be a randomised placebo controlled trial where mothers receive two doses of the steroid within a week before delivery. The Primary outcome would be to record respiratory morbidity and whether there is any effect in the drop in blood sugar levels of babies who receive the steroids. Follow up with the mothers will be by a short questionnaire at six weeks and then a questionnaire that asks whether they would be willing to take part in later studies for longer term follow up.

Summary of ethical issues (outstanding)

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

1. The Committee asked the Researcher whether she had considered consenting all of the women to the study and then offering them a separate choice about whether they would also consent to being in the steroid administration part of the study (with the acknowledgement that they won’t all get the steroid as it is a randomised trial). This approach would allow women the choice to be involved in the questionnaire part of the study or to be in the randomised trial, or both. It would also allow them the right to choose not to be involved in any aspect of the study.
2. The Researcher explained that she thought this is the approach they had taken. The Committee noted that the way it appears in the information sheets for potential participants is that if they decline to take part in the study they will be asked to complete a study specific questionnaire. The Committee noted that when a person declines to take part in the study that this should mean that they don’t take part in either aspect. The Committee suggested that the Researcher include the questionnaire as part of the whole study so that when patients decline to take part that this decision would mean they do not have to take part in the whole study. The Researcher agreed that she could take that approach and would reword the information sheet to reflect that participants could choose to take part in this study and if they say no, then they have the choice to consider a second part of the study (randomised controlled trial) to participate in.
3. The Committee sought clarification in relation to parental consent for further studies that was noted under the heading ‘Follow up until 6-7 years of age’ on page 5 of the participant information sheet. The Researcher explained that what they are asking for now is for consent to be able to maintain contact with parents so that they can contact them later. The Committee noted its concern about the sentence “You would not need to provide additional consent at a later stage” as parents do not know at this stage what they are consenting to as their child has not been born yet and, the potential separate studies that the researchers might do if they get funding have not been designed or ethically approved. The Committee is happy for the Researchers to say that parents provide consent to the researchers maintaining contact with them but they must also state that if there are future studies then the Researchers will approach them for consent.
4. The Committee noted that the peer review document submitted with this application states that Researchers have received funding for the study. The Committee would like to see further comment that shows the peer reviewer has considered the in the peer review that the reviewer has looked at the power analysis for example and that they have done a scientific review of the study protocol. There is a template on the HDEC website that the peer reviewer could complete that covers off the points that the Committee needs to check.

The Committee requested the following changes to the participant information sheet and consent forms.

1. Page 7 under the heading ‘Will my taking part in the study be kept confidential?’ Please remove reference to the “age of majority” as the legal definition of this can differ. Instead please state that information will be kept for a minimum of 10 years.
2. Please include provision for the mother to consent to information about her baby being released after the baby is born. This can be included as an additional section on the information sheet. The Committee notes that the reason this is needed is that the mother is giving consent for her child to be part of the research pursuant to section 36 of the Care of Children Act. A child is not a ‘person’ until born live and therefore the mother cannot give consent for the child until after the birth. Suggested wording is a title that says ‘Consent to be signed after the baby is born’ followed by statements that say:
3. “I have had the reasons explained to me as to why data with regard to my child has been requested.”
4. I have had an opportunity to discuss with the study doctor and I have had my questions answered to my satisfaction.”
5. I consent to data about my child being released to [person/organisation] and I understand that I will receive a signed copy of this consent for my records.”
6. The Committee noted the statement that the mother cannot find out whether she is on placebo or active treatment until the trial is complete. The Committee asked whether mothers can find out sooner than that if there is a medical reason. The Researcher explained that there is the option for 24/7 breaking of the code for example if there is a medical emergency. Please state that in exceptional circumstances it is possible to find out before the trial is complete.
7. Edinburgh postnatal depression score: The Committee asked whether there is any mechanism in place to check the questionnaires and, to act appropriately if someone scores highly in terms of suicidality on the form. The Researchers confirmed that they have a process in place do a screening test and notify the participant’s health care provider if there are any concerns about safety. Please include “mental health concerns” in the information sheet so that both mental and physical health are covered.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).

This information will be reviewed, and a final decision made on the application, by Ms Raewyn Idoine and Dr Nicola Swain.

## 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 December 2018, 11:45 AM |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

No members tendered apologies for this meeting.

The meeting closed at 4.00pm.