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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 27 March 2018 |
| **Meeting venue:** | Room GN.6, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 27 February 2018 |
| 12:15pm | General business:   * Noting section of agenda |
| 12:30pm | New applications (see over for details) |
|  | 1. 18/CEN/41 2. 18/CEN/36 3. 18/CEN/37 4. 18/CEN/38 5. 18/CEN/10 6. 18/CEN/43 7. 18/CEN/46 8. 18/CEN/47 9. 18/CEN/48 10. 18/CEN/49 11. 18/CEN/52 |
| 4:30pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 30/07/2015 | 30/07/2018 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Present |
| Dr Melissa Cragg | Non-lay (observational studies) | 30/07/2015 | 30/07/2018 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Apologies |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Dr Peter Gallagher

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting

The Committee welcomed observers to the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 27 February 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/CEN/41** |
|  | Title: | Community use of strong opiate following total hip and knee joint replacements |
|  | Principal Investigator: | Dr David Lees |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 March 2018 |

Dr David Lees 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 project will use existing national datasets (the National Minimum Data Set and the Pharmaceutical Information Database) to review opiate prescriptions following discharge after primary total hip or knee joint replacement in New Zealand over the last five years.
2. It will explore regional variations in practice, quantify the duration strong opiates started in hospital are continued to be prescribed and review variations between age, sex, ethnicity and comorbidities.
3. It will look for any association of these variables with length of hospital stay, co-morbidities and readmission.

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 if the data used for the study will be fully anonymised once linked through the participant NHI number and data from the National Minimum Dataset and the Pharmaceutical Information Database. The Researcher confirmed that all data would be fully anonymised.
2. The Committee queried whether the main purpose of the study is to look at the use of strong opiates or the prescription of strong opiates. The Researcher clarified that the primary aim of the study is to look at dispensing prescriptions. The Researcher noted that in terms of opiate dispensing the most that can be dispensed from a hospital is a month’s long prescription at one time. The intention of the study is to assess whether clinicians are creating a dependency by determining the amount of repeat prescriptions, rather than looking at actual use of opiates.
3. The Committee noted that the peer review had suggested the Researcher may wish to consider, in their analysis of data, identification of where responsibility for prescribing opiates lies and the level of prescribing authority (such as junior doctor, consultant, etc.). The Committee queried whether it would be possible to see this in the data accessed for the study. The Researcher advised that it would not be possible to see this level of detail in the data analysis.
4. The Committee noted that the study is going to explore possible differences in prescribing between different ethnicities and queried whether there are any statistics / data in regard to Māori and prescribing of opiates. The Researcher advised that available data was limited in terms of the orthopaedic field. The Researcher commented that from their own personal experience of Māori patients seen in orthopaedics is that they tend to be more stoic, take less pain relief and wait the longest for their surgery. The Committee noted that it would be worth exploring in this study if Māori are systematically under treated, or treated differently in terms of opiate prescribing.
5. This study involves accessing health information about patients without consent. The Committee noted that they can approve access to identifiable health information without consent for research in certain circumstances. The Ethical Guidelines for Observational Studies states at Paragraph 6.43:

* Access to identifiable or potentially identifiable data for research without the consent of the people the data identifies or makes potentially identifiable may be justifiable when:

a) the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; and

b) there would be no disadvantage to the participants or their relatives or to any collectives involved; and

c) the public interest in the study outweighs the public interest in privacy.

The Committee confirmed they were satisfied to approve this study involving access to health information without consent as these requirements are met as all the data sets will be completely anonymised before analysis.

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 Committee noted that the answer to question r.2.5 (page 13) of the application form states that “Data will be stored for 5 years from the completion of the study”. Please ensure data will be stored for a minimum of 10 years after completion of the study, in accordance with New Zealand law.

Decision

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

* Please ensure data will be stored for a minimum of 10 years after completion of the study, in accordance with New Zealand law.

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| **2** | **Ethics ref:** | **18/CEN/36** |
|  | Title: | (Duplicate 1) Visualisation rate of duodenal ampulla with versus without a capped gastroscope – Prospective study |
|  | Principal Investigator: | Dr Wayne Bai |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 March 2018 |

Dr Wayne Bai and Dr Frank Weilert 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. A standard gastroscopy uses an uncapped gastroscope to examine structures to the duodenum (start of small bowel). The duodenal ampulla is at the start of the small bowel, but seeing this structure is not part of a standard examination, as it is difficult to see due to its tangential location from the bowel lumen.
2. Patients are commonly referred to specifically examine the ampulla due to clinical concerns suggestive of biliary obstruction such as dilated ducts on imaging. The standard procedure is to use a special side-viewing scope (duodenoscope), but these scopes are limited in numbers and need special skills to use.
3. Using a tiny plastic cap fitted at the end of the scope is thought to improve the visualization rate of ampulla, as it helps flatten the bowel folds to allow tangential structures to be seen.
4. Patients referred specifically to examine the ampulla are excluded, as the test we are offering (capped gastroscope or without) is not currently the gold standard test for this purpose.
5. If the ampulla is not seen, patients are not referred for a second test with the side viewing scope.

Summary of ethical issues (resolved)

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

1. The Committee thanked the Researcher for their cover letter which provided very systematically answers to the issues raised by the Southern HDEC in the previous decline.
2. The Committee queried the response to question p.2.1 in the application form which explains the process that potential participants in the study will be provided with information on the study. The Committee queried if calling up the participants about 1 week after they received the Participant Information Sheet and invitation letter appeared too pushy. The Researcher confirmed that this was intended to try and reduce the rate of non-attendance at clinic procedures. The Committee queried if a member of the Researcher team would go through the Participant Information Sheet with potential participants. The Researcher confirmed that the Research team would ensure participants in the study are fully informed and have the opportunity to ask questions.
3. For future applications please note there is no “s” in the Māori language, and the term ‘Māoris’ should not be used.
4. For future applications when answering the question on “cultural issues that may arise for Māori who may participate in your study”. Please note the head is regarded as tapu.

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 Committee noted that the cover letter for the application states that the study will recruit equal numbers of Māori and non-Māori. The Committee queried if this is correct as this seems unsuitable for this study. Maori and non-Maori have the same anatomy and thus whether or not the ampulla can be visualised with the cap is not ethnicity dependent. Participants should be recruited on a first come first served basis. The Researcher agreed to remove the reference to recruiting equal numbers of Māori and non-Māori.

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

1. Please replace ‘totally safe’ with something less definite regarding safety.
2. In the Participant Information Sheet under the section ‘what will my participation in the study involve?” in the 4th paragraph please amend the sentence to read “you will be assigned to eithercap or no cap”.
3. Please add page numbers to the Participation Information Sheet.
4. Please be cautious when using the word ‘safe’ under the risks section of the Participant Information Sheet. Please consider using a different word.
5. The Committee noted the sentence under Risks “It does not make the main reason why you are referred for this test any harder” does not make sense. The Researcher confirmed they would remove this sentence form the Participant Information Sheet.
6. The Committee noted the sentence under ‘Who pays for the study” where it says, “You will not receive any charge” is confusing. The Committee noted that this does not answer who pays for study. Please re-word this sentence. The Committee suggested stating that there is no funding / no sponsor for the study to be clear.
7. The Committee noted that the reference to data being anonymous under the section “what are my rights” conflicts with the statement in the next section “what happens if I change my mind” stating any data collected will be destroyed. The Committee suggested using a statement such as ‘data will be de-identified and securely stored.”
8. The Committee noted that there is reference to compensation from ACC under the section “What are my rights?” The Committee noted that there is also reference to ACC under “What if something goes wrong?” To avoid duplicating information please make reference to ACC only under the section “What if something goes wrong?”
9. Page 1 of the Participant Information Sheet - the point which says “you can pull out at any time” needs clarifying as this is not possible after they have had the surgery. Please clarify by adding a statement such as “up to the point of the procedure”.

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*).
* Remove the reference to recruiting equal numbers of Māori and non-Māori.

This following information will be reviewed, and a final decision made on the application, by the secretariat.

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| **3** | **Ethics ref:** | **18/CEN/37** |
|  | Title: | The VITAMINS Trial |
|  | Principal Investigator: | Dr Paul Young |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 March 2018 |

Dr Paul Young and Dr Daniel Frei 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 study investigates Hydrocortisone compared to Hydrocortisone and intravenous vitamin C and thiamine for patients with septic shock.
2. One large stage III clinical trial has shown a clinical benefit from Hydrocortisone in this patient group with respect to a shorter stay in ICU. Although it is not routinely used as standard care by all clinicians, the Researcher explained that in their view this is primarily because the evidence supporting it is quite recent and standard care has not yet caught up.
3. Some small studies have found potential benefits from intravenous vitamin C and thiamine, this study hopes to add support to their use in this clinical setting.
4. Most participants in this study will be unable to provide informed consent, those who are able will be supported to provide their own consent, for participants unable to provide informed consent the Researcher propose to enrol participants under Right 7(4) of the HDC Code of Health and Disability Services Consumers’ Rights.

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 Committee queried the expected benefits from this study participation for individual participants. The Researcher explained that recent evidence shows that Hydrocortisone can speed up recovery from septic shock, reduce length of stay in ICU, and reduced likelihood of needing a blood transfusion. The Committee asked what is the standard care. The researcher said use of hydrocortisone is gold standard so the research is in the best interests of all participants as they all will receive hydrocortisone
2. The Committee explained that as a mix of lay and non-lay members they require the expected benefits and risks of study participation to be clearly explained and quantified, especially for studies that involve participants unable to provide consent as in this case study participation must be in the best interests of each individual participant.
3. The Committee requested justification for the dosages chosen for this study, and clarification of the expected safety of the chosen dosage.
4. The Researcher explained that patients are usually very keen to be in studies involving vitamin C. The Committee agreed this is interesting but not relevant to considerations of best interests when enrolling participants unable to provide informed consent.
5. The Committee discussed the proposed provisions for obtaining the views of participant’s friends and family or other suitable persons available to be consulted, noting that these views should be obtained for participants unable to provide informed consent regarding whether they believe the participant would want to be in the study if they were able to provide informed consent.
6. The Committee questioned who would determine whether study participation is in the best interests of each individual participant, and whether the clinician making this determination will be independent from the study. The Researcher explained that most enrolling clinicians in the ICU are not directly involved in the study, except for the CI, and that the CI could easily be excluded from making best interests determinations on individual patients if the Committee feels the potential conflict of interest in this situation is significant. The Committee requested that the protocol is updated to require that a clinician independent from the study makes the determination regarding whether study participation is in the best interests of each individual participant.
7. The Committee discussed the provisions for obtaining consent from participants who regain capacity, and for participants to withdraw from the study, noting that this is not retrospective consent and that participants do not need to withdraw from the study in writing. The Researcher fully agreed with this, nothing that the primary reason for the withdrawal of consent form is for people to have something to sign if they want to, as some participants like to have this recorded in writing.
8. The Committee stated that it is not possible for HDECs to approve an application unless it is consistent with New Zealand law and noted that the researchers had submitted a set of scenarios that appear to demonstrate a lack of understanding of the law. Researchers and sponsors are responsible for ensuring that their health and disability research is conducted lawfully. HDECs need to be satisfied that any research approved by the Committee is consistent with NZ law. An HDEC may not approve an application that is inconsistent with NZ law, even if that application is consistent with ethical guidelines.
9. Research involving participants who are not competent to consent must be undertaken in accordance with Right 7(4) of the Code of Health and Disability Services Consumers’ Rights. In addition to requirements regarding ascertaining the views of the consumer or other suitable persons, 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 to the participant beyond what they would receive if they were not participating in the research.
10. The Committee noted that they had not been provided with sufficient information on the expected benefits of study participation, and statements in the Participant Information Sheet stating that benefits of the study are uncertain have contributed to the Committee being unsatisfied that the best interests test would be able to be met for each participant. The Committee asked how it could be in the best interests of participants to be in either arm of the research. It noted that the PIS sets out risks; and the benefits of hydrocortisone plus vitamin C and thiamine are as yet speculative.
11. The Committee questioned the ANZICS paper about High Dose Intravenous Vitamin C Treatment in Critically Ill Patients in New Zealand, which states that the ANZICS does not support the use of high dose intravenous vitamin C treatment in any critically ill patient in New Zealand. The Committee requested a formal response to this from the Researcher, including whether or not this advice applies to patients in this study. The researcher noted that the dose they intend to use is much lower than that in the ANZICS paper (6g compared to 50-100g).
12. The Committee explained that they are not satisfied that the research proposal is lawful, and as per their Standard Operating Procedures they advise the Researcher to seek formal legal advice. The Researcher stated that they were prepared to seek legal advice, noting that they had done so for a number of other studies and were confident that the legality of this study would also be supported in legal advice.

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

1. Please clarify in participant facing documents that the ICU is ‘undertaking’ not ‘participating in’ the study, as individuals participate in a study, not the site.
2. Please clarify in the family/friends’ information sheet that no one gets paid for study participation.
3. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. 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*).
* It is the investigator’s responsibility to ensure that all applicable legal standards are met (Ethical Guidelines for Intervention Studies paragraph 6.26).
* HDECs need to be satisfied that any research approved by the Committee is consistent with NZ law (HDEC Standard Operating Procedures paragraph 15).

This following information will be reviewed, and a final decision made on the application, by the whole Committee.

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| **4** | **Ethics ref:** | **18/CEN/38** |
|  | Title: | A study of Selonsertib, GS-0976, GS-9674 and combinations in Non-alcoholic Steatohepatitis (NASH) patients |
|  | Principal Investigator: | Dr David Orr |
|  | Sponsor: | Gilead Sciences Pty Ltd |
|  | Clock Start Date: | 15 March 2018 |

Sarah Coates, Julianne Brewer and a representative from the study sponsor 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. The study is a phase 2 study is a new treatment for Non-alcoholic Steatohepatitis (NASH). Up to 5 participants are expected to be recruited in New Zealand.

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 why such a large number of questionnaires are required to be completed by participants. The Researcher explained that quality of life is an important outcome measure for this study and they feel the questionnaires will not be overly burdensome on participants. The Committee accepted that they can be used, but suggested that they should be reduced if possible.
2. The Committee queried whether any data is available on the rates of NASH in Māori, or any other ethnicities. The Researcher explained that they do not have any specific data on this. The Committee requested that this kind of information is included in future applications.

Summary of ethical issues (outstanding)

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

1. Please provide details of payments to participants. All payments, reimbursements and health services provided to study participants must be disclosed to an ethics Committee (Ethical Guidelines for Intervention Studies paragraph 6.36).

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

1. Please remove any mention of tests that will not be done in New Zealand from the Participant Information Sheet, this includes liver stiffness tests if they will not be conducted.
2. Please move the contact details to the end of the Participant Information Sheet to make this easier for participants to find.
3. The Participant Information Sheet indicates that NASH is a more severe form of fatty liver disease, please clarify what fatty liver disease is and in what way NASH is more severe.
4. Please revise the Participant Information Sheet to state that participants ‘must not’ breast feed, rather than ‘may not’.
5. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured as a result of treatment given as part of this study, which is unlikely, you* ***won’t*** *be eligible for compensation from ACC. However, compensation would be available from the study’s sponsor, [x], in line with industry guidelines. We can give you a copy of these guidelines if you wish. You would be able to take action through the courts if you disagreed with the amount of compensation provided.*

*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.”*

1. Please revise the Participant Information Sheet to state that the study will be explained to participant, not that the study will be reviewed with participants.
2. Please adjust the pregnant partner Participant Information Sheet to include a provision to obtain parental consent to the inclusion of information about the baby after they are born, consent cannot be obtained from the mother before the baby is born.

Decision

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

* All payments, reimbursements and health services provided to study participants must be disclosed to an ethics Committee (Ethical Guidelines for Intervention Studies paragraph 6.36).

This following information will be reviewed, and a final decision made on the application, by Dr Patries Herst.

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| 5 | **Ethics ref:** | **18/CEN/10** |
|  | Title: | Bu4Day-PK-2016 |
|  | Principal Investigator: | Dr Lochie Teague |
|  | Sponsor: | ANZCHOG |
|  | Clock Start Date: | 15 February 2018 |

Dr Lochie Teague and Emily Grant 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 multi-centre, prospective, clinical study for patients undergoing haematopoietic stem cell transplant (HSCT) with busulfan as part of their conditioning regimen.
2. The target group of participants are patient’s ≤18 years of age, with an underlying disease with a recognised HSCT indication, who are receiving once daily IV busulfan as a component of their HSCT conditioning regimen and have adequate central venous access for blood sampling.
3. The studies primary aims are to describe cumulative busulfan exposure following consecutive once daily intravenous dosing in paediatric patients undergoing haematopoietic stem cell transplantation (HSCT) and to describe the pharmacokinetics of intravenous once daily busulfan in paediatrics over four consecutive doses.

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 planned commencement date stated in the application for is 01 February 2018. Please ensure this is current in future applications.

Summary of ethical issues (outstanding)

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

1. The Committee noted the statement in the Participant Information Sheet (for parents / guardians) on page 2 “Information on whether your child experiences any toxicity related to their transplant and your child’s bone marrow transplant engraftment will be assessed at day +30, +100 and +365 post-transplant”. The Committee queried how this information will be obtained. The Researcher confirmed that it will be taken from medical records. The Researcher agreed to clarify in the Participant Information Sheet that information will be taken from medical records.

Decision

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

* 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/CEN/43** |
|  | Title: | CA224-047 |
|  | Principal Investigator: | Dr Richard North |
|  | Sponsor: | Bristol-Myers Squibb |
|  | Clock Start Date: | 15 March 2018 |

Dr Richard North, Lesley Goodman and Charlie Stratton 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 Phase 2/3, double blind, randomized study of BMS-986213 (the fixed-dose combination of the investigational drug relatlimab and nivolumab), compared to nivolumab alone, in participants with unresectable or previously untreated metastatic melanoma.
2. This study aims to demonstrate that treatment with BMS-986213 shows improved Overall Response Rate (Phase 2) and increased Progression Free Survival (Phase 3) compared with nivolumab alone. Additional objectives of the study include characterisation of safety and tolerability, pharmacokinetics, potential predictive biomarkers, and changes in patient-reported outcomes for quality-of-life assessments.
3. The study population includes adults and adolescents ≥ 12 years of age, however, the New Zealand site will not enrol participants <16 years of age. Participants will sign a consent form and attend study visits as outlined in the informed consent document.
4. About 700 patients are expected to participate globally, and if enrolled they will be treated with a fixed dose via an intravenous infusion once every 4 weeks until cancer progression or if stopped for other reasons, and followed for up to 5-7 years to monitor for potential benefits or side effects.

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 the age of the participants to be recruited to the study. The Researcher confirmed that all participants would be over the age of 16. The Committee noted a number of consent forms for minors were submitted with the application but were not applicable.
2. The Committee queried the response to question r.2.5 in the application form which states that health information will be retained for 2 years post marketing. The Committee noted that health data derived from the study must be stored for a minimum of 10 years in accordance with New Zealand law. The Researcher clarified that health records would be retained for 15 years at the Bay of Plenty Clinical Trials Unit and the 2 years may be from the Sponsors’ point of view who are obliged to hold health records for 2 years after they have marketed the drug.
3. The Committee queried the response to response to question r.1.6 in the application form which states “The study may be terminated in part or in its entirety, in consultation with the Sponsor, if, in the opinion of the investigator, the clinical observations suggest that it may be unwise to continue (i.e. due to safety concerns or lack of efficacy). The Sponsor may stop this study at any time”. The Research confirmed that the standard treatment (nivolumab) is available in New Zealand so patients could access standard treatment if the study was stopped.

Summary of ethical issues (outstanding)

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

1. The Committee queried the meaning in of “terminated” on page 1 of the in the Event of Pregnancy of a Research Project Participant or their Partner Information Sheet. Is this referring to abortion or terminated for any reason such as miscarriage? The Researcher confirmed that this could be for any reason. The Committee suggested replacing ‘terminated’ with the phrase “the pregnancy ends”.
2. Optional consent form for additional research – the Committee noted that there are a number of yes/no tick boxes on the form and asked for clarification these statements are genuinely optional. Please remove the yes/no tick boxes from the Consent Form for all statements that are not truly optional, meaning that a participant could respond ‘no’ and still participate in the study. The Researcher confirmed that consenting to these statements are truly optional.
3. The Committee noted that the pregnant partner consent form currently provides for the pregnant woman to provide consent on behalf of her child before they are born. The Committee noted that in New Zealand it is not possible for a parent to provide consent on their child’s behalf before they are born. Please rephrase this Participant Information Sheet and Consent Form to reflect that the pregnant woman is providing consent to her participation, and consent to being contacted after the birth to provide consent for her child’s enrolment in the study. Please provide a revised consent form with two areas for signing; one where the mother can provide consent for you to track the pregnancy and a different section to sign after the child is born where the mother can provide consent for the research team to track the child’s health records.
4. Please provide contact details for the Māori advisory/support person, HDEC and the research team contact details on all Participant Information Sheets. The Researcher noted that all current Participant Information Sheet are New Zealand master sheets and would be made site specific with local details.
5. Please add “Future Unspecified Research” to the title of the ‘Optional consent form for additional research” form to ensure consistent with New Zealand terminology.
6. Page 4 of the Optional Participant Information Sheet for Additional Research says, “You should be aware that BMS Researcher may not be able to destroy samples or information collected from you when the study doctor no longer has the de-identifier master list”. The Committee requested clarification around this statement. The Researcher present was unsure what this statement meant and agreed to seek clarification from the Sponsor and provide more information to the Committee.
7. Please amend the typo “porgression” in the treatment beyond progression Participant Information Sheet.
8. The Committee queried what would happen to the research participants if the tumour progresses. The Researcher confirmed that the study would continue in the current form including the current follow-up, schedule of scans etc. The Committee requested that it is made explicit in the Participant Information Sheet that for those participants whose cancer has progressed and subsequently censored from the study that their treatment will continue as normal.
9. Please consider adding a simplified flow diagram / table to the Participant Information Sheet to explain more clearly the study design. The Committee noted the diagram and tables in the protocol were helpful and could be added to the Participant Information Sheet.
10. Please review all participant facing documents to remove all typographical errors.

Decision

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

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

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

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| **7** | **Ethics ref:** | **18/CEN/46** |
|  | Title: | The Taranaki retreat: An alternative response to suicidality and distress? |
|  | Principal Investigator: | Mr Rowan Magill |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 March 2018 |

Rowan Magill and Dr Gabrielle Jenkin 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. This project aims to undertake a realist evaluation of the Taranaki Retreat, a community-based support service for people experiencing emotional distress and thoughts of suicide.
2. There is concern in New Zealand about the inadequacy of support options for people experiencing acute distress and suicidal thoughts.
3. This realist evaluation will not only identify the outcomes experienced by guests of the Retreat, it will also uncover the key underlying mechanisms and contextual factors which contribute to these outcomes.
4. The study will adopt a single case study design, utilising four qualitative research methods. The research methods to be used are: interviews, focus groups, document analysis, and participant observation.
5. Realist evaluations typically involve several phases and the proposed study will follow this broad design. First a tentative programme theory is made explicit, then the hypothesised theory is tested, and finally the theory is refined.

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 how participants will be recruited into the study. The Researcher noted that programme coordinators who will distribute the participant information sheet to incoming guests at the retreat. Programme coordinators would make verbal contact with potential participants to study in more details. The Researcher confirmed that participants would confirm with their clinical lead their interest in participating in the study which would be fed back to the Researcher, who could then seek fully informed consent.
2. The Committee note that the application form states that the retreat has relationships with local Kaumātua, and has agreed to support arrangements for this if requested. The Researcher clarified that he has not these people yet and had only visited the retreat once and didn’t have the chance to meet with Kaumātua on that occasion. The Researcher confirmed that the Programme Coordinators had advised the Researcher that Kaumātua have strong relationships with Taranaki iwi and that Māori support would be available at the interviews if required.
3. The Committee noted that there were several suggestions in the peer review provided with the application. The Researcher confirmed that he had considered these and made some changes to the protocol and still has some outstanding changes to make to the data analysis section.
4. The Committee queried if the Researcher will be transcribing the audio recordings of the interviews. The Researcher confirmed that it would be him.
5. The Committee queried whether the interview transcripts will be made available to the participants. The Researcher confirmed that transcripts would be made available to participants if they requested them but he won’t be seeking feedback on them.
6. The Committee asked the Researcher about his level of expertise to identify when people are at risk. The Researcher confirmed that he has worked in mental health for 4-5 years as a social worker including working in crisis team, which included conducting risk assessments.
7. The Committee suggested having a separate Participant Information Sheet and consent form for participants aged 14 to 16 years. The Researcher confirmed the reading age for the current Participant Information Sheet was just below 16 years. The Committee agreed that it would be sufficient to use this Participant Information Sheet for 14-16 years given that the Researcher would also go through the study verbally with the participants.
8. The Committee noted that some interviews will take place at the participant’s home and sought clarification around the safety protocol for this. The Researcher confirmed that prior to any home visit he would check with the study coordinator whether there are any risk issues as well as reviewing case notes. The Researcher advised that he would check in with his supervisor prior to any home visit.

Summary of ethical issues (outstanding)

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

1. Please add details of a Māori cultural support contact person independent from the study to the Participant Information Sheet. The Committee suggestion that it could be one of the Kaumātua at the retreat.
2. Under the section “What is the purpose of the study?” please remove the sentence to “Support options in New Zealand for people who are experiencing distressing emotions and/or suicidal thoughts seem to be inadequate”.
3. The Committee noted that participant confidentiality may be difficult to manage in this study. Please may it explicit in the Participant Information Sheet that there is not an absolute guarantee of confidentiality, for example, if there are risks identified.
4. Please ensure the information on safety currently in the consent form is included in the Participant Information Sheet.
5. Please add headers and footers to the Participant Information Sheet and consent forms to ensure clearly labelled and version controlled.
6. Focus Group Participant Information Sheet – Under the section “What will I have to do?” the form states “If you provide written consent, you will be asked to participate in a 60-minute focus group with the Researcher, at a time convenient for participants”. Please add more detail to fully explain who else will be in the focus group, i.e. other staff and how many participants.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the Committee *(Ethical Guidelines for Observational Studies para 6.10)*

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

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| **8** | **Ethics ref:** | **18/CEN/47** |
|  | Title: | DETECT |
|  | Principal Investigator: | A/Prof Max Petrov |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 March 2018 |

No members of the Research Team were 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 Study

1. The aim of the study is to provide a way to distinguish between Type 3c diabetes, also referred to as pancreatogenic diabetes, and type II diabetes. T3cDM describes diabetes that arises as a consequence of an inherited or acquired disease of the exocrine pancreas.
2. Patients with Chronic Pancreatitis and Pancreatic Cancer with T2DM and no known pancreas disease, admitted to Auckland City Hospital and North Shore Hospital over a 12-month period will be assessed at baseline.
3. Patients will be divided into three groups: 1. Chronic pancreatitis with T2DM 2. Cancer of the Pancreas with T2DM 3. No known pancreas disease. Individuals with pancreatogenic DM, type 2 DM, and normoglycemic individuals will be invited to participate in the study of islet cell hormonal responses to mixed nutrient meal testing. This will include pancreatic polypeptide, glucagon, insulin, and C-peptide. The level of each hormone before and after the test meal will be compared between the three groups. All participants will also be asked to undergo magnetic resonance imaging (MRI) of the pancreas (a state-of-the art non-invasive imaging technique that does not expose you to ionizing radiation) to determine the amount of fat in the abdomen.
4. Patients without pancreatic disease and those with normal blood sugars at the time of the study visit will be contacted 12 months later to provide a health status update. All other participants will complete the study following the initial visit.

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 Committee noted p.3.1 of the application form states that potential participants will be identified by the treating clinician who will be made aware of the study. The study team will then be notified, who will then approach the patient and discuss with them the study, to gain informed consent. The Committee noted that the clinician must obtain potential participant’s agreement before approaching the study team.
2. The Committee noted the information under the section “What will happen after the study ends, or if you pull out?” is confusing. The Committee would like future clarification around the use of samples collected in the study and their use in future studies.
3. The Committee queried the response to a.6.1 in the application form. Is this study being conducted at the university or DHB? Please provide clarity to the Committee.
4. The Committee noted there was a discrepancy between the sample size stated in the protocol and the application form. Please confirm sample size.
5. The Committee queried the response to r.3.8 in the application form. The form states human tissue collected in New Zealand will not be sent overseas as part of your study. Information provided in the application states blood samples will be sent to the USA. Please correct this.
6. r.3.11. in the application forms states human tissue will be returned to donor, whānau, or family member at the end of the study, or if participants withdraw consent for its use in this study. The Committee noted that the there is no reference in the Participant Information Sheet that human tissue would be returned to whānau. The Committee queried how this would happen if tissue is sent to the USA in an anonymised form. Please provide clarity to the Committee.
7. r.4.1 is answered incorrectly and contradicts information in the Participant Information Sheet regarding unexpected findings.
8. p.1.1 should also include reference to having an MRI.
9. p.2.7 is answered incorrectly. The answer should provide information on participants receiving information on unexpected findings.
10. p.4.2 states that “It is unlikely that any specific cultural issues will arise in this study for Māorii”. The Committee noted that taking blood samples is an issue for Māori
11. P.4.1 - the Committee noted that referencing the key principles of the Treaty of Waitangi is not a health benefit for Māori.
12. The Committee noted the response to f.1.2 did not address other ethnic minorities.
13. The Committee noted the helpfulness of the covering letter accompanying the application form.
14. The Committee noted the study is well designed but the method used to approach participants needs addressing.
15. Please ensure there is a procedure in place to manage a situation where a participant may go hypoglycaemic due to fasting. Please ensure this is covered with the participant (i.e. at a pre-study visit).
16. The Committee noted there is no information on reimbursement to participants (there is a section on this on the HDEC Participant Information Sheet template). Please consider some form of reimbursement for participant’s time / travel costs and the provision of a meal given it’s a full day’s commitment.

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

1. The Participant Information Sheet is lacking information. Please add more detail to ensure the Participant can give fully informed consent.
2. Please consider using a flow diagram chart to explain the study procedure.
3. Please use simple, lay language in the Participant Information Sheet.
4. The Committee suggested using the standard HDEC template (available at: [https://ethics.health.govt.nz/system/files/documents/pages/Participant Information Sheetcf-template-july-2015.doc](https://ethics.health.govt.nz/system/files/documents/pages/piscf-template-july-2015.doc)).
5. Please ensure study contact details are at the end of the Participant Information Sheet and not spread throughout the document.
6. Page 1 of the Participant Information Sheet should state that this is an international study sponsored by X, the number of participants involved overall and in New Zealand, and the main inclusion / exclusion criteria.
7. The Committee noted that the information under the section of the Participant Information Sheet “What would your participation involve?” is very important but the way it is presented is unclear. Please use the information in the study protocol around inclusion / exclusion criteria for the different drugs. It should be explicit to the participant that those who cannot miss a day of their diabetic medication are excluded.
8. The Committee whether there is an intention to contact participants prior to study to confirm they fully understand the study procedure. The Committee suggested a pre-study visit to ensure participants fully understand what is involved.
9. The Committee noted the answer to question r.1.1 in the application form provides more detail about the study visit than the Participant Information Sheet. It should be made be clear in the Participant Information Sheet that prior to study visit the participant must have fasted for more than 8 hours, that a venous catheter will be inserted for the repeat blood tests and that an MRI must be arranged for the same day. Please clarify who is responsible for arranging the MRI.
10. The Participant Information Sheet must have information about the MRI and the risks to people with metal implants other than titanium, pacemakers etc. The Committee noted that if an MRI is vital to the research study, those people must be excluded.
11. The Participant Information Sheet should state how long the study process will take to complete (including MRI) and where (e.g., all day at hospital).
12. The Follow Up section of the Participant Information Sheet states “You may be contacted in the future if your doctor thinks you may qualify for another study”. Please ensure “with your permission” is added to this sentence and there is an optional tick box included on the consent form.
13. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: “If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. 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.”
14. The consent form includes a statement “I agree to my data or other information being stored for use in a different study for which ethics Committee approval would be required”. The Committee noted that this suggests future unspecified research. Please provide clarification if data from this study is intended to be used for future unspecified research. If this is the case, please include information about this in the Participant Information Sheet.
15. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The Committee recommended the following statement: “You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”
16. The consent form has the statement “I consent to my blood samples being sent to the hospital laboratory for testing. The blood samples will be destroyed once the tests have been performed”. The Committee would like clarification around this statement. This should use a tick box rather than a yes/no option.
17. The access to data statements in the consent form should use a tick box rather than a yes/no option.
18. r.3.11. in the application form states human tissue will be returned to donor, whānau, or family member at the end of the study, or if participants withdraw consent for its use in this study. The Committee noted that the there is no reference in the Participant Information Sheet that human tissue would be returned to whanau. The Committee queried how this would happen if tissue is sent to the USA in an anonymised form. Please provide clarity to the Committee.
19. In the section “What are the rights of participants in this study?” there is a statement

“Participation in this study will be stopped should any harmful effects appear or if the doctor feels it is not in your best interests to continue”. Consider putting this information under the “risks” section of the Participant Information Sheet.

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 and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* All payments, reimbursements and health services provided to study participants must be disclosed to an ethics Committee (Ethical Guidelines for Intervention Studies para 6.36).
* Please address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed (*Ethical Guidelines for Intervention Studies* *para 4.7*).
* Please respond to the outstanding ethical concerns detailed above.

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| **9** | **Ethics ref:** | **18/CEN/48** |
|  | Title: | EMDR for post-traumatic stress disorder in a mental health setting |
|  | Principal Investigator: | Dr Susanna Every-Palmer |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 March 2018 |

Dr Susanna Every-Palmer and Dr Tom Flewett were present in person and Dr Elliot Bell 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 single blind randomised controlled trial to compare Eye Movement Desensitisation and Reprocessing Therapy (EMDR) versus treatment as usual for people with post-traumatic stress disorder within a forensic and rehabilitation long stay setting.
2. This study is a three-phase project to test efficacy, acceptability and risk of harm of EMDR treatment.
3. EMDR is a psychotherapy (talking) treatment based on information processing model of trauma (Adaptive Information Processing model) to alleviate the distress associated with traumatic memories.
4. The study aims to find out:
   * Does outcome data suggest efficacy of EMDR for the treatment of PTSD compared to waitlist in a psychiatric forensic and rehabilitation population with Serious Mental Illness (SMI)?
   * Does outcome data suggest safety of EMDR for the treatment of PTSD compared to waitlist in a psychiatric forensic and rehabilitation population with SMI?

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 how the research team will decide if a participant is appropriate to undertake the therapy. The Researcher confirmed that diagnosis of PTSD is an inclusion criterion for the study. The assessment progress for suitability includes a full psychiatric assessment and in particular an assessment of the persons capacity to hold trauma memories whilst holding here and now mindfulness.
2. The Committee queried the number of sessions involved for participants enrolled in the study. The Researcher confirmed that there would be 9 sessions in total – the first session would be an assessment session followed by 8 weekly sessions of EMDR therapy.
3. The Committee queried whether the suggestions made in the peer review had been considered. The Researcher confirmed that changes to the protocol and methodology had been made. The Researcher noted that they had introduced the use of a treatment acceptability scale which is an important psychological measure to capture the client’s experience of the treatment. The Researcher noted they had also introduced two social functioning outcome measures; the World Health Organization Disability Assessment Scale (WHODAS) and second is a more comprehensive social outcome functioning measure that was designed particularly for people with mental illness.
4. The Committee noted the response to p.4.3.1 which states, “All potential participants are from the central region and all potential Māori participants are affiliated to North island iwi. The Whaea and kaumātua are well placed to comment on local tikanga”. The Committee queried how the research team would be able to determine this? The Researcher acknowledged that this is a generalisation and their catchment area is the lower North Island and therefore the majority of participants will be affiliated with North Island iwi. The Researcher confirmed that they are doing a dual consultation process through the Ngāi Tahu Research committee through Otago University as well as local lower North Island consultation.

Decision

This application was approved by consensus.

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| **10** | **Ethics ref:** | **18/CEN/49** |
|  | Title: | (duplicate) BELIEVE 1 |
|  | Principal Investigator: | Ms Lynette Sadleir |
|  | Sponsor: | Zynerba Pharmaceuticals |
|  | Clock Start Date: | 15 March 2018 |

Mrs Marina Dzhelali and Donna Gutterman 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. This is an open-label, multi-national, multiple-center, multiple-dose study to assess the long-term safety and tolerability of ZYN002 (transdermal CBD gel) in child and adolescent epilepsy patients 3 to <18 years of age with seizures associated with developmental and epileptic encephalopathies (DEE) according to the International League Against Epilepsy (ILEA) classification (Scheffer et al. 2017).
2. Patients will undergo a baseline period of 4-weeks, followed by a 2-week titration period, and a 24-week maintenance period.
3. Patients will be treated for a total of 26 weeks. Following Week 26 or early termination, study drug will be tapered over a 1 to 3-week period (depending on dose).
4. After the final dose, patients will be followed weekly for 4 weeks by telephone to complete the Marijuana Withdrawal Checklist short form (Behaviour Checklist).
5. After the 4 weeks, the patient will be discharged from the study.

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 noted that for future application the answer to question p.4.1. **“**Please describe whether and how your study may benefit Māori” should acknowledge the specific study population and provide information on existing evidence on the health condition, is the study likely to benefit Maori etc.

Summary of ethical issues (outstanding)

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

1. Please add Maori support contact numbers to the Participant Information Sheets.
2. Please ensure the Participant Information Sheets and consent forms are consistent with regards to taking blood samples for epilepsy gene testing. The Committee noted that if the Research team decide to include taking blood samples for gene testing then this - p should be included as a tick box option on the consent from.
3. Please clarify in the Participant Information Sheets that only women who are not pregnant can be included.
4. 12-15 years old Participant Information Sheets - please remove the reference to emergency care.
5. 12-15 years old Participant Information Sheets – please clarify that it will be the parent and study participant collecting information on about the number and types of seizures the participant is having.
6. Please correct all typos in the Participant Information Sheets and Consent Forms.

The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured as a result of treatment given as part of this study, which is unlikely, you* ***won’t*** *be eligible for compensation from ACC. However, compensation would be available from the study’s sponsor, [x], in line with industry guidelines. We can give you a copy of these guidelines if you wish. You would be able to take action through the courts if you disagreed with the amount of compensation provided. 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.”*

1. The main PIS states “Do not use the study drug in or near your child/adolescent’s eyes. In case of contact, rinse their eyes thoroughly with water, and call the study staff if irritation or rash appears and lasts more than 72 hours.” Please rephrase to clarify the study participant should contact study staff rather than wait 72 hours.
2. Please ensure the consent forms state that the samples will be sent overseas.
3. Please ensure it is clear to potential participants what type of questions will be asked in the questionnaire prior to them consenting.
4. 7-11-year-old Participant Information Sheets -please correct the typo on the last page “gree” should be “I agree”.
5. 12-15-year-old Participant Information Sheets - please correct the typo on page 3 – reference to “upper arms”.
6. Please ensure the Participant Information Sheets says that participants would be admitted to hospital for a 24-hour EEG.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the Committee *(Ethical Guidelines for Observational Studies para 6.10)*

This following information will be reviewed, and a final decision made on the application, by Dr Angela Ballentyne and Dean Quinn.

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| **11** | **Ethics ref:** | **18/CEN/52** |
|  | Title: | Improving function of the pancreas and decreasing diabetes risk using a plant-polyphenol rutin |
|  | Principal Investigator: | Prof Sally Poppitt |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 15 March 2018 |

No members of the research team were 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 Study

1. This study will be conducted in 2 phases in male and female participants.
2. The first will assess pharmacokinetics of 250 and 500mg of rutin (once a day) in 2 delivery methods; capsule and within a food, in a cross over study over 24 hours in healthy participants.
3. The second will investigate efficacy of rutin (500mg q.d), in a double blind randomised 3-arm placebo controlled parallel study over 6 months, in participants with demonstrated prediabetes.
4. The study aims to determine optimal dose and pharmacokinetics of rutin, investigate the efficacy of rutin to target pancreatic amylin aggregates and restore insulin secretion to prevent progression to T2D, and determine response of T2D related blood biomarkers to rutin intervention

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 Committee noted question r.2.5 of the application form states “The PI will maintain records of the signed consent forms, Case Report Forms/records, all correspondence and supporting documentation for a minimum of 5 years after the study.” Please ensure data will be stored for a minimum of 10 years after completion of the study, in accordance with New Zealand law.

Decision

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

* Please ensure data will be stored for a minimum of 10 years after completion of the study, in accordance with New Zealand law.

## . 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:** | 24 April 2018 |
| **Meeting venue:** | Room GN.6, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington |

1. **Problem with Last Minutes**

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

The meeting closed at 4:30pm.