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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 27 November 2018 |
| **Meeting venue:** | Room GC.3, 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 23 October 2018 |
| 12:30pm | New applications (see over for details) |
|  | i 18/CEN/219  ii 18/CEN/220  iii 18/CEN/221  iv 18/CEN/222  v 18/CEN/224  vi 18/CEN/225  vii 18/CEN/226  viii 18/CEN/227  ix 18/CEN/228  x 18/CEN/229  xi 18/CEN/230 |
| 5:05pm | General business:  Noting section of agenda |
| 5:15pm | 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 |  |
| 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 Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Present |  |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 23 October 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/CEN/219** |
|  | Title: | FULL REVASC |
|  | Principal Investigator: | Dr Madhav Menon |
|  | Sponsor: | Karolinska University Hospital |
|  | Clock Start Date: | 15 November 2018 |

Mrs Liz Low and Ms Rosalind Pillay 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 ethical issues (resolved)

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

1. The Committee asked how often the FFR assessment of non-culprit lesions is done during the primary PTCA when the patient comes in with an acute myocardial event. The Researchers explained that an FFR is not done at the primary PTCA because it is immediately clear that an occluded artery is the cause of the cardiac event. The Committee noted that the Protocol documented that there is some flexibility in relation to how much of the data was collected at the original assessment which is prior to the study itself.
2. At question p.4.1 in the application form that asks whether the study may benefit Maori, it is stated that Maori have a greater incidence of heart attacks than non-Maori. There are known statistics about this and the Committee noted that for future reference any known statistics would be helpful to include in this section. The Committee noted that for future reference that cultural issues that could be noted in relation to p.4.2 is that of ‘Whakama’ (shame or embarrassment).
3. In relation to peer review of this study protocol, the application included three letters from funding bodies that each had reviewed the science of the protocol. The Committee agreed that it was satisfied with this evidence and would not seek further comment to be provided.
4. The Committee did not have any significant ethical concerns in relation to this study noting that the application was well completed and the study a worthwhile one. The Committee noted some minor points that it would like to see addressed in a revision of the participant information sheet and consent forms.

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

1. The Committee noted that the information given in relation to the procedure is brief. While all of the patients have had a recent PCI, it has been done in a different situation i.e. an acute event and the consent for that would be more limited. In this study patients are being asked to have the same TPI procedures compared to other people in the study who won’t have had those procedures but treated with standard of care. Please include more information about the PCI including what will be done and potential risks and side effects associated with PCI.
2. Page 1, under the heading ‘Background and Aim of the Study’ please revisit the last sentence and reword so that it is simpler and clearer.
3. Page 2, under the heading ‘Do I have to take part?’: please make clear what is meant by “you can choose to, for example, be followed by your medical records”. The Researchers will revisit this and will include the following for clarification: if patients don’t wish to receive the follow up telephone call there is also the option of the researchers checking for medical events in their hospital records if they agree.
4. Page 4, under the heading ‘Who has reviewed the study?’: please note that the Committee has approved the *ethical* aspects of this study.
5. Please put the advocacy contact details alongside the other contact details at the end of the document. Please include contact details for the Maori support person who is independent of the study and who participants can contact as needed.
6. Consent Form, number 4 states that “films of my heart may be looked at by the teams” but this is not mentioned prior in the body of the information sheet. The researchers will review the document for this information and include if it is not currently in the main sheet. Please also include the data from the study will also be sent overseas to Sweden.

Decision

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

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| **2** | **Ethics ref:** | **18/CEN/220** |
|  | Title: | Sexually transmitted infection diagnoses, testing and risk in New Zealand |
|  | Principal Investigator: | Dr Antoinette Righarts |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 November 2018 |

Dr Antoinette Righarts 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 ethical issues (resolved)

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

1. The Committee sought clarification in relation to what people have given prior consent for in relation to the use and matching of their information. The Researcher explained that people who completed the National Health Survey 14/15, which had a module on sexual and reproductive health, gave permission or not to link their data to external data sets. The Researchers will not have access to, use or link data for those who did not give consent as part of that survey.
2. The data set that the Researchers want to link to is the ESR surveillance of STIs from laboratories. It is a routine data surveillance set and as such specific consent is not sought from people as data is routinely collected and reported on as part of the laboratory service. The ESR surveillance data set includes data on samples that are sent to a laboratory for testing of Chlamydia or Gonorrhoea such as age group, region where testing was done, testing site and ethnicity.
3. The Researchers’ aim is to link the consented data from NZ National Health Survey to the testing and diagnosis of Gonorrhoea and Chlamydia captured in the ESR laboratory surveillance data set and also to add social deprivation scores to the ESR data set so that they can further look at the effect of ethnicity independent of deprivation or, in other words, see whether there is a deprivation effect. ESR database STI data gained by default for those who have given consent won’t be linked. In other words, the Researchers will not have access to any of the data from people who have not consented to linking as part of the NZ Health Survey.
4. The Researchers want to link two data sets so that they can get a confirmed report of whether or not people have been tested for Gonorrhoea or Chlamydia. If possible they also want to add social deprivation to the ESR routinely collected data set because that would be useful to look at as an indicator for testing and diagnosis of STI.
5. The Committee asked whether the Researchers are satisfied that the people who gave consent for linking in the survey would have understood the type of linking that the Researchers intend to do. The Researcher explained the question in the survey noted linking to “other health related data sets”. The questionnaire was administered by MoH trained and experienced interviewers who would have ensured that the person would understand the questions.
6. The Researchers won’t be generating any new data for this study, they just want to link the two data sets. They will not retain any of the data after their analysis and will discard it after two years which the Committee accepted.
7. The Committee queried whether the Researchers have consulted with Maori in relation to this application. The Researchers explained that they have consulted with Ngai Tahu as part of their original application and at their recommendation, have worked with a Maori health researcher on an ongoing basis since then for advice.
8. For future reference it would be helpful to include any known statistics for incidence rates in Maori at question p.4.1 in the application.
9. The Committee noted a peer reviewer’s comment that there doesn’t appear to have been an attempt to do a pilot project. The Researcher explained that a pilot project wasn’t attempted because the data has already been collected by the Ministry of Health. The peer reviewer’s comment was in relation to the extent to which data linkage can be achieved successfully. The Researcher explained that the MoH has already been through the process and is able to link around 70% of the data set to NHI and 95% with probabilistic matching. The Researchers couldn’t pilot the same as the data is with the Ministry of Health.

Decision

This application was *approved* by consensus.

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| **3** | **Ethics ref:** | **18/CEN/221** |
|  | Title: | Subcutaneous Injection Versus Intravenous Infusion of MK-3475/Pembrolizumab in Participants with Advanced Melanoma |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: | Merck Sharp & Dohme (New Zealand) Limited |
|  | Clock Start Date: | 15 November 2018 |

Dr Chris Wynne and Ms Georgie Staples 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 of two different cohorts comparing intravenous administration with subcutaneous administration of Pembrolizumab.

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

1. The committee suggested that the schema on page 31 of the protocol could be added to the participant information sheet to clarify what group participants could be in and what drug combination they could get.
2. Under the heading ‘What is the purpose of this study?’ 2nd paragraph: The Researcher explained that is possible that a person could have Melanoma and not be approved to receive Pembrolizumab in New Zealand and, that this would only be in rare cases. The Committee recommended however, that this part of the sentence be removed as it may be confusing for people who already have advanced Melanoma, for which the drug is approved in NZ.
3. In relation to number of visits the Committee recommended that a simple table be included that shows when the visits will happen, what is being done and how long they’ll take. The Protocol has a table that is 11 pages long and the Committee recommended that this table be abbreviated and included in the information sheet.
4. Cohort A, page 11 of the patient information sheet in relation to patient codes that the sponsor will receive the Committee noted initials and date of birth may be included. The Researcher explained that there are a number of aspects of health data. One is the CRF that the sponsor will have access to that may have initials and date of birth which depends on the protocol specific electronic case report form. Samples going overseas will not be identified with initials and will be coded so as to be completely de-identified.
5. Page 12 of the patient information sheet: the second paragraph states that “Results obtained from planned genetic and biomarker research will not be provided back to you or the study.” The Researcher advised that genetic and biomarker research is specifically excluded under protocol sections 8.8-8.10.4 and that this statement will be removed from the information sheet.
6. Please put the interpreter statement up front in the document.
7. Please include a statement about samples being sent overseas on both of the consent forms.

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*).

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

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| **4** | **Ethics ref:** | **18/CEN/222** |
|  | Title: | Prospective, Single-Center, Single Arm, Feasibility Study of thePAVmed CarpX Device for the Treatment of Carpal TunnelSyndrome |
|  | Principal Investigator: | Mr.Terrence Creagh |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 November 2018 |

Mrs Houda El Banna and a Sponsor representative 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 ethical issues (resolved)

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

1. The Committee asked for further information on how participants will be recruited to the study. Patients who are scheduled for the lead investigator’s patient list for carpal tunnel surgery who meet the criteria for entry into the study i.e. they are scheduled for carpal tunnel surgery, they have not responded to conservative therapy, they have carpal tunnel confirmed by neurological testing. The Researchers confirmed that recruiting 25 people over a 12 month period is achievable given the number of people who are scheduled to have carpal tunnel surgery.
2. In relation to the answer given at question p.4.2 that asks that main cultural issues for Maori be identified and explanation given for how they will be managed the Committee explained that in New Zealand cultural issues for Maori that could be noted here include that knowledge is a treasure or Taonga, making sure that face to face meetings are had where it is ensured that people understand what is happening.

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

1. This is the first time that the device will be tested in humans and as such the Committee asked that this be made clear up front in the information sheet. Please state it in bold, in a box so it is clearly stated.
2. Please review the information sheet to check that the terminology used is stated in lay language and is relevant to a New Zealand audience. The Committee gave the following specific examples at the meeting:
3. Page 1: please simplify the last paragraph with less technical language and or separate out into a number of sentences.
4. Please replace the word “race” with “ethnicity”.
5. Under the heading ‘Risks’, “wound dehiscence” could be more accessibly stated as “failing to heal”.
6. Under the heading ‘Benefits’ please state “you may or may not receive benefits”.
7. Page 3, first paragraph: please state “due to the risks *from* or *of* anaesthesia.”
8. In relation to the statement that talks about the compensation process for people who may be injured as a result of being in this trial, please include 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 *approved* by consensus with non-standard conditions.

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| **5** | **Ethics ref:** | **18/CEN/224** |
|  | Title: | PantoCIN: Pantoprazole as prophylaxis against delayed chemotherapy-induced nausea and vomiting (CINV) in patients receiving adjuvant or neoadjuvant breast cancer chemotherapy |
|  | Principal Investigator: | Dr Richard Isaacs |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 15 November 2018 |

Ms Louise Clement, Dr Richard Issacs and Mr Navin Wewala 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 ethical issues (resolved)

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

1. The Committee complemented the Researchers on a well written application, participant information sheet and consent form.
2. The Researchers want to use a proton pump inhibitor in addition to what patients are already taking for nausea that comes on a couple of days after receiving chemotherapy for breast cancer.
3. The Committee asked whether participants will continue to have access to the proton pump inhibitor after they have completed the trial. They will have access to the drug which is freely available and fully subsidised in New Zealand on prescription. A decision will be made about whether to continue after two cycles of treatment.
4. The peer reviews for this study protocol from Australia contain comments that may not have taken into account the incidence of delayed nausea despite optimal treatment with initial antiemetics is still over 50% which is an unacceptable side effect of chemotherapy. One of the drugs referred to in the peer review is a rescue drug that has still not been shown to prevent delayed nausea. The use of the proton pump inhibitor is being trialled here to see whether it can be used to prevent nausea and not just rescue it.
5. Other comments in the peer review state that proton pump inhibitors may be associated with gastric cancer risk. The Researchers explained that in this study the PPI course will be taken for only four months.. It is a short course exposure for maximum benefit and that peer reviewer comment is not appropriate as it relates to long term use.
6. In relation to cultural questions in the application form, specifically p.4.1 that asks whether and how the study might benefit Maori, the Committee noted that for future reference that they would like to see any known incidence rates. In this case, any known statistics about incidence rates of breast cancer in Maori and the incidence rates of nausea in Maori participants in comparison to non-Maori participants. If they are over represented then the Committee wants to know how the study might benefit Maori. Question f.1.2 asks the same question but in relation to ethnicities other than Maori or European. i.e. Pacific people and Asian people. Also for future reference one of the cultural issues that could have been identified at question p.4.2 in the application form is ‘Whakama’ especially given the part of the body where the disease is.

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

1. Please include a short study title that is simpler than the one currently stated.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **18/CEN/225** |
|  | Title: | Neurodevelopmental Outcomes of Adolescents Prenatally Exposed to Methadone |
|  | Principal Investigator: | Dr Jacki Henderson |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 November 2018 |

Dr Jacki Henderson 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 the study

1. The Researcher has been looking at the neurodevelopmental outcomes of children who were born to mothers who were on methadone treatment during pregnancy since 2002. The mothers were first recruited to the study from Christchurch women’s hospital. A control group was recruited around the same time.
2. Maternal interviews were conducted at term of pregnancy, 18 months following the birth, at 4 and a half and again at 9 and a half years of age which has just been completed. Retention rates have been high and the researchers have built lasting relationships with the mothers and their families over this time.
3. The overarching aim of the study is to look at neurodevelopmental outcomes. At term MRI data was collected to look at brain volume of the infants alongside in-depth maternal psychometric measures and also assays for drug testing alongside self-report.
4. With this particular phase of the study when the children turn 16 the Researchers want to reassess them again as adolescents to continue to monitor their neurodevelopment and in particular their mental health given that they come from high psychosocial risk backgrounds.
5. The researchers have to date noted that some children have learning difficulties tracking since they entered school relative to the control children. They are interested to see what is now happening for the children now that they are adolescents. Adolescents will be asked to complete an online form with questions. The Researchers would also like to look at the genetic factors that might be underlying some of the differences in neurodevelopmental outcomes at the age of 15. Further the Researchers would like to look at whether there are any psychobiological correlates with risk taking or other mood disorders that can be objectively measured beyond a self-reported mood report. Comprehensive caregiver interviews will continue to be done mainly online rather than administered solely by a clinician.
6. Both groups will complete the same tasks with one exception which is only the methadone exposed group will be asked to consent or not to salvia samples being collected and analysed.

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 had answered in the application form that there is no risk of stigmatising individuals or population groups and asked the Researcher for further explanation as to why they thought this. The Researcher explained that they would like to further address the risk of stigmatisation in light of potential findings. Previous research has shown that some children exposed to Methadone are doing more poorly than peers who have not. Social adversity, particularly maternal or caregiver social adversity, has been identified as a potential risk factor for this rather than the Methadone exposure itself. The Committee noted a way to mitigate stigmatisation is to note those other factors.
2. For future reference in relation to question p.4.1 that asks whether and how the study would benefit Maori the Committee would like to see any known incidence rates for Maori in the Methadone programme. In relation to p.4.2 which asks researchers to identify any cultural issues, the Committee noted that the concept of ‘whakama’, collection and use of tissue for genetic testing could be included here.

Summary of ethical issues (outstanding)

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

1. The Researcher noted that they are taking much care to ensure that there is no mention of Methadone in the information for the young people or in external sources such as their website. Some participants have requested that there is no reference to Methadone as neither their child nor their families know they were in a Methadone programme and the Researchers noted that the responsibility to disclose this information is with the Mother or caregiver of the young person.
2. The Committee was concerned about the non-disclosure of the fact that the young people have been exposed to Methadone which is the reason why they are in this study. The Committee noted that this amounts to deception and, that the Researcher would need to be able to satisfy the Committee that this non-disclosure is warranted. The Committee was not satisfied that a reason had been given at this meeting as to why non-disclosure of this information is warranted and especially now that the participants are adolescents and able to consent for themselves.
3. To date, the younger participants in this study think that they are part of a study looking at neurodevelopmental outcomes. The Committee noted however that the premise of the study centres around exposure to Methadone and when participants receive the findings of the study, which they are entitled to, that it is only at this point that they will find out that they have been exposed to Methadone and that they had not been told about this. The Committee asked the Researcher to consider how to approach this issue with the young person’s parents/guardians to think about how they might themselves disclose this information to the young person so that they can continue on the study.
4. The Committee would also like to know what will happen should one of the pair (either mother or young person) decide to withdraw from the study and whether the Researcher needs to match the pair for validity of results.

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

1. The Researcher confirmed that for this study the ages of the adolescents are mostly 15 and that some will soon turn 16 years old. The Committee noted that as the young people have been involved in the study since birth that they would likely be able to consent for themselves at age 15 and 16. For those children who are 15 unless they are not Gillick competent then they should be able to consent for themselves. With this in mind the Committee would like to see the following information sheets and consent forms:
   * Information sheet for the adult parent/guardian
   * Information sheet for the young people who are aged 16 years and over
   * Information sheet for the young people who are 15 years old along with assent or consent forms depending on competence
   * Reconsent forms for those who turn 16 while in this study
2. The forms submitted refer to the young participants as “child” when in fact they are now adolescents and the Committee asked that reference to “child” be replaced with young person or adolescent.
3. Under the heading ‘what does the study involve?’ no mention is made of the reason they are involved in the study (i.e they were exposed to Methadone) and the Committee was concerned that the non-disclosure of this information amounts to deception.
4. Assessment of emotional well-being will be done online and the Committee asked what support will be in place should the participants become distressed or experience suicidality. The Researcher noted that they do a risk assessment that a clinical psychologist does with the children via interview. A screener for suicidality is also in place that sends a message to the researchers who will then talk to parent or caregiver followed by a referral to the GP. The Committee was concerned that the Researchers are passing on confidential information about the young person without their knowledge or consent. The Researcher clarified that a clinical psychologist would do an assessment with the young person and that consultants would make the appropriate referral. The Committee noted that this information needs to be clearly stated in the information sheet.
5. Please provide contact numbers for support organisations and people who are independent of the study. You are welcome to refer to the HDEC PIS/CF proforma on the HDEC website for guidance on the details to include.
6. Please include footers on each of the revised information sheets and consent/assent forms so that it is clear both to participants and the Committee which the current version is.
7. On the Consent/assent forms please include a statement that asks participants to consent or not to information about them being passed on to their GP.
8. Under the heading ‘Salvia Samples’, in the information sheet the Committee noted the sentence “With your permission” and then the Consent form states “will involve me providing a saliva sample from which genetic information will be extracted.” The Committee asked whether the genetic sample is a requirement of being part of the study. The Researcher advised that this is optional and the Committee asked that the Researchers make this clearer in the information sheet and consent forms. The Committee would also like to see more information stated about what kind of genetic testing will be done.
9. Please include yes/no boxes for statements that are truly optional only.

Decision

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

Study conduct, deception and concealment (*Ethical Guidelines for Intervention Studies, paras 6.30-6.31*)

Free and informed consent *(Ethical Guidelines for Observational Studies paras 6.10-6.11)*

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| **7** | **Ethics ref:** | **18/CEN/226** |
|  | Title: | GS-US-493-5342 A Phase 1b Study to Evaluate the Safety and Efficacy of Novel Combination Therapies in Patients with Chronic Hepatitis B |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 15 November 2018 |

Prof Gane and Ms Chin Kuh 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 will look at novel combination treatments for chronic Hepatitis B. There will be three different cohorts:

* Nivolumab only,
* Nivolumab with Ledipasvir/Sofosbuvir,
* Nivolumab with GS9688.

1. The first monotherapy arm builds on a previously approved study using a single low dose of Nivolumab that has never been associated with adverse events. One person was cured of Heptatitis B and others showed a reduction in surface antigens. This drug offers a potential way to get people off long term treatment. In this study three doses will be given a month apart and the Researchers expect that this will be more effective than a single dose.
2. In the second and third arms the reason for combining Nivolumab with other immune enhancer treatments as these have been shown to be potent antivirals against Hepatitis C and Hepatitis B as well.

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

1. Please review the compensation statement in all of the forms. The Committee asked that the Researchers include the statement from the HDEC pro forma in place of the one that is currently stated:

*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.*

1. The Committee would like to see that the Cohort 1 information sheet explains that there are other cohorts involved in this study. Please provide an introduction that states that there will be three cohorts involved but that these participants are going to be enrolled in Cohort 1. Information in the application stated at a.1.5 in the application form would be useful to include here.
2. Page 3: bullet point that states that participants must not get pregnant or get someone pregnant during the study. Please think about providing more detail here or note that participants can refer to information on page 12 of the information sheet.
3. Page 10: two bullet points that refer to risks of being in the study. One notes that participants may not be able to carry out daily functions. This is a vague statement. Please provide some indication about what sort of things people should be concerned about.
4. There is a statement under the heading ‘Allergic Reaction’ that states participants may have an allergic reaction to a drug that they have not taken. This means that a true allergic reaction can occur the first time a drug is taken. Please include that it is possible for a drug that they have not *previously* taken.
5. Page 12: under ‘Pregnancy and Breastfeeding’ please remove the words “you are aware”.
6. Page 15: The Researchers confirmed that patients get paid until the time they are found to be ineligible for the study. They get paid for their visits and parking. Please rephrase to say “for any further involvement”.
7. Consent form notes that patients consent to their samples being sent overseas but this was not mentioned in the information sheet. Please include this information. Please also include the cultural statement in relation to tissue that will be sent overseas.
8. Partner Pregnancy follow up consent form: please include provision for follow up for female subjects that will be signed after baby is born for consent to health data about the baby being collected by female subjects or partners by removing the word “partner”. Please clearly state that it is information about the baby’s health rather than the outcome of the pregnancy.
9. Optional sub-study information sheet and consent form: please specify the name of the lab and location for where the white blood cells will be sent.
10. The Committee noted that the sponsor is intending to store samples for 15 years and this is for a number of tests or assessments that although related to Hepatitis B seem nebulous and not necessarily specific for this research. The purpose of the immune studies is to work out if immune exhaustion occurs and makes a difference to prevention and infection in this condition. The Researcher noted that while there is a large amount of immunological data being collected it is related to Hepatitis C immunological data so related to Hepatitis B infection and control thereof.
11. The Committee acknowledged this but clarified that the point it wishes to raise is that “Better treatment of Hepatitis B” is a vague statement and the samples could be used to test other drugs for the treatment of Hepatitis B or another condition not related to this study. The Committee noted that there is a separate optional future unspecified research information sheet and consent form and at the same time the Researchers need to justify to the Committee why they want to retain samples for 15 years as a mandatory part of the main study. The Researchers noted that they could remove this statement and the Committee suggested that alternatively, they could define this further in the participant information sheet and reduce the duration of storage so any mandatory storage of tissue is clearly related to this specific study.

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

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| **8** | **Ethics ref:** | **18/CEN/227** |
|  | Title: | A Phase III Efficacy Study with QIVc in Paediatric Participants V130\_14 |
|  | Principal Investigator: | Dr. Thorsten Stanley |
|  | Sponsor: | IQVIA RDS Pty. Limited |
|  | Clock Start Date: | 15 November 2018 |

Mrs Marina Dzhelali and Dr Thorsten Stanley 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 ethical issues (resolved)

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

1. In the application the Researchers have stated that the placebo arm of this study, where children would receive placebo at visit 1 and visit 2, is not to run in New Zealand. The Researchers confirmed that this is correct and in New Zealand the children will get meningococcal vaccine or the study vaccine. The Study design and wording in the information sheet suggests that there are three arms to the study: the study drug, the meningococcal control and a placebo. The Researchers confirmed that in New Zealand the children will only receive an influenza vaccine or a meningococcal vaccine.
2. To further clarify what will happen the Committee asked whether children randomised to receive the meningococcal C vaccination will also receive the second vaccination at the end of the study and whether this means they are effectively un-blinding the children to do this. The Researchers confirmed this is the case and that they are the only children who are getting vaccinated at the end of study visit.
3. For future reference, in relation to p.1.2 where it is stated that all participants will give consent, the Committee noted that in this study the participants are young children who will not have given consent given their age.
4. For future reference the Committee noted that it would have expected to see responses at question p.4.1 that include any known statistics of incidence rates under study in Maori and in particular vaccination rates and responses to vaccination rates. An answer which references Article 1 of the Treaty is not relevant.

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

1. The Committee noted reference to “parents” and “legally acceptable representatives” throughout all the documents. The Committee advised that the Care of Children Act refers to “parent” or “guardian” and asked that the Researchers include this terminology instead as it is New Zealand legislation language.
2. Page 2: The use of the word “dummy” in relation to placebo is potentially confusing and the Committee asked that placebo be used instead.
3. Page 3: please include a more careful explanation of the randomisation to treatment in this study. In particular, it is stated that “your child will have a 50% chance of receiving either the QIVC flu vaccine or the control vaccine or placebo.” This suggests that there are three arms to the study. Please rework so this is clearer.
4. Page 4: please review the sentence “if your child experiences one or more of the following influenza like symptoms” which is followed by “sore throat”.
5. Page 4 has conflicting information on the volume of blood taken. 10mls is stated at the top of the page and three teaspoons at the bottom of the page. Please make this consistent. The Researchers noted that the volume is 5mls and that they will change and make consistent throughout the document. The Researchers will not accept more than two draws at any one time given the age of the participants.
6. Page 9: under the ‘risks’ section please clearly state that there is a 50% chance that children going into the study will not be vaccinated against influenza as some will receive the meningococcal vaccine and they have been instructed not to get non-study influenza vaccination during the duration of the study. Please state that they won’t be eligible to to participate the study if they want to get vaccinated against influenza outside of the study.
7. The Committee noted that the wording about eligibility for compensation in the event of a treatment injury happening as a result of being in this study needs to be updated. Please replace 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.*

1. In relation to the future use of samples for reasons not related to this study the Committee asked that a re-consent form be provided for the young person after they turn 16 years old as the samples will be held for 25 years by the sponsor and they have the right to re-consent once adult, to samples being held or destroyed. Another option is to include the proviso that once the child reaches the age of 15 years, 11 months their samples will be destroyed.
2. In relation to sending samples overseas, 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.”*

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*).

This information will be reviewed, and a final decision made on the application, by Dr Dean Quinn and Mrs Helen Walker.

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| **9** | **Ethics ref:** | **18/CEN/228** |
|  | Title: | AXL-1224-2004-001: Study of the Safety and Tolerability of AB-1224 and AB-2004 in Young People with Autism |
|  | Principal Investigator: | Dr Barney Montgomery |
|  | Sponsor: | Axial Biotherapeutics |
|  | Clock Start Date: | 15 November 2018 |

Mrs Kathryn Johnstone and Dr Griffith were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of study

1. In this group of young and adult males with high functioning Autism, the Researchers would like to test to see if either the bacterial organism may benefit them in terms of their gut symptoms but also their autistic spectrum disorder symptoms particularly around anxiety. Animal models have suggested it might be beneficial in these two areas.
2. The protocol will test the bacterial component first in adult participants in an increasing dose and tolerability will be monitored each time the dose is ascended. Once that cohort of 5 is completed there will be analysis of the data before the bacterial component will be tested in adolescents in ascending dose. Again, once data has been tested for safety and tolerability the next group aged 5-12 would receive the bacterial component in ascending dose and be monitored.

Summary of ethical issues (resolved)

1. The main ethical issues considered by the Committee and addressed by the Researcher are as follows.
2. Only males will be included in this study for a couple of reasons: the trial is not a large one and the Researchers want to reduce heterogeneity. Most of the data currently available on metabolites comes from boys and presently this is where the researchers will put their focus.
3. For future reference, the Committee noted that at question p.4.1 on the application form that asks whether and how the study might benefit Maori that any known statistics about incidence rates in relation to the condition in Maori and in light of these how the study might benefit Maori. At question p.4.2 which asks that cultural issues for Maori be identified the Committee noted that taking and sending tissue overseas is a cultural issue for Maori.

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

1. Please make clear in the study title that this study is specific to males only.
2. The Committee asked the Researchers to review the current information sheets and consent/assent forms and to group them in the following age ranges: 5-11 years old, 12-15 years old, 16 years old and over. The Committee noted that the information may be a little oversimplified for the high functioning older children and asked that the Researchers revisit this. The Researchers noted the challenge of specifying an age and development range on this group of children. The Committee acknowledged this and noted that it is up to the Researchers to make the decision about which information sheet is appropriate for each child.
3. In relation to the visits and the procedures the Committee recommended that a summary table be added to help make the information readily accessible and clearer to participants. The protocol has some tables that could be helpful to include.
4. In the information sheets for parents or guardians please remove reference to “legal ward” and rephrase this to reflect the legal language of New Zealand. The Care of Children Act talks about “parents” or “guardians”. Please also amend the statement “if your son does not wish to take part he doesn’t have to” to include “or if he does not wish to take part” as a way of also respecting the young person’s right to choose not to take part.
5. Under the heading ‘what is the purpose of this research?’ Please amend the information to say “there is currently no known cure”.
6. Please describe for parents to what extend the study drugs have been used in humans previously.
7. The Committee noted that seven questionnaires are to be completed over three hours and queried how the participants might tolerate this length of time. The Researchers noted that the person administering the questionnaires is often commenting on the child’s behaviour and the child himself does not have to answer all the questions. An outside estimate of time has been given to allow families the opportunity to plan for time allowed. The Committee asked that a statement be provided in both the parents and child information sheets that reads along the lines of “if a young person is unable to continue for that length of time we will stop and have a rest” so that it is tolerable for them.
8. Page 5, 3rd paragraph: please remove the words “and avoid study doctors jumping to conclusions”.
9. In relation to the optional future unspecified research consent the Committee queried whether it is the same as the genetic testing mentioned in the main information sheet or additional. Please make clear in the main information sheet when you talk about genetic testing that it is optional and that there is a separate information sheet for participants to look at and consent to.
10. The Committee noted the expectation set out in the information sheets that the young person 16 years and over would be discussing the methods of birth control and sexual activities with parents. The Committee asked that in information sheets for competent young people that they are given information about what is required of them. The Researchers noted that they would normally state that they would discuss the information with them and talk to the young person alone if it is okay with them. The information will remain confidential unless there is a concern for the young person’s safety. The Committee asked that this information be set out in the information sheet for the older group of young people.
11. Please also remove the information from the parent information sheet that states their son is responsible for informing his partner about the risks to the unborn child and include it in the young person’s information sheet as they are responsible for this.
12. Please review the information sheets to reflect that for competent participants the information about them is in their information sheet.

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*).

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

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| **10** | **Ethics ref:** | **18/CEN/229** |
|  | Title: | EXPANDER-1 |
|  | Principal Investigator: | Dr Madhu Koya |
|  | Sponsor: | MedeonBio, Inc. |
|  | Clock Start Date: | 15 November 2018 |

Ms Michelle Xia and KT Venkateswara-Rao 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 Researchers will treat participants in this study in blocks of five with a space in between each block of five to make sure that patients do not inadvertently participate in both arms.
2. The first five patients will be treated in arm one and have their device inserted for one month. Then the device will be removed and the patient followed up for six months.
3. The second group of five (arm two) will have their device in place for six months. The device will then be removed and they will be followed up for a further six months.
4. The Committee asked that the above information be included in both information sheets so that potential participants are informed about what will happen.

Summary of ethical issues (resolved)

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

1. r.2.1.1 in the application form states that the study coordinator will review the patient files for those who are on the public waiting list for treatment of their prostate disease. The Committee noted that this approach would mean a breach of their privacy as the information collected on their public file is not for the secondary use of research. The Committee asked that one of the clinicians involved with the patient’s treatment to ask them whether they would be interested in being on a study and having information sent to them.
2. r.5.4 in the application form that asks whether the investigator will be the health care provider does not talk about how the conflict of interest will be managed. The answer given is that there is no conflict of interest as the relationship is a standard doctor/patient one. The Committee noted that what ‘conflict of interest’ means here that if you are engaged as a researcher in the study that may impact on the doctor/patient relationship. The Committee asked that the Researcher think about how to manage this and in particular how the research will be kept separate from the treatment.
3. p.2.1 in the application form mentions a PI designee. The Researcher explained that this person will be the sub investigator or study coordinator and they will talk to the patient.
4. p.4.2 in the application form that asks for cultural issues for Maori to be identified has not been answered appropriately. “Inability to understand the information sheet because of language or literacy issues” is not a cultural issue and is not true. The Committee noted that ‘whakama’ (embarrassment or shame) could be an issue for all men but also a cultural issue. The Committee noted that the researchers have answered ‘no’ to the need to Maori consultation and it advised the researchers that any research involving Maori requires consultation.

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

1. The study has been approved in Australia where it will be done in an office-based facility. In New Zealand it will be done in the outpatients’ department not in the operating theatre. The Committee asked that this be explained in the participant information sheet.
2. Wording under the photograph states that the EXPANDER has been designed to be removed after implantation of a minimum of one month. Please reword to state it will be removed at least a month after implantation.
3. In the statement “it is thought that the prostate would have expanded” please replace the word “prostate” with “prosthetic ureter”.
4. Please include the name of the cohorts in the footers in each of the information sheets/consent forms.
5. Please provide more information about how any pain or discomfort will be managed with the participant should they experience it.
6. Please state that the Central HDEC has approved the ethical aspects of the study.
7. Page 6: states the procedure has similar risks to normal prostate surgery. Please include further information about what those risks might be. The Committee noted a good explanation was provided in the application form under r.1.6 on page 14 and suggested that some of that information might be included.
8. Page 6: states that participants might have side effects after they are discharged from hospital. Please change this to after they are discharged from outpatients’ clinic.
9. Under the heading ‘What are the rights of participants in the study?’, the third paragraph includes the statement that personal information about a participant’s health and treatment being collected. The Committee recommended that this be moved to under the heading ‘what will your participation involve?’ as it doesn’t fit within the rights section.
10. Please include a heading ‘What will happen to my samples?’ after the rights section that explains that samples will tested in a local laboratory and samples will not be stored.
11. Page 8: the Committee noted the statement about people having the right to leave the study and asked what will happen if they leave the study and whether they get the device removed. This will be the case and the Committee asked that a statement to this effect be included here.
12. Consent form: includes information about risks in the event of “myself or my partner” becoming pregnant. Please remove reference to this as it doesn’t affect the male participant himself and there is no risk to a partner should she become pregnant.
13. Please check the information sheet for the second arm in relation to information given about the timeframe for the EXPANDER to be removed so that it is relevant to this arm of the study.
14. r.3.10 in the application form states that PSA testing and assessment of creatinine levels. The information sheets do not mention these tests, only blood and urine testing. Please include creatinine testing.

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*).

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

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| **11** | **Ethics ref:** | **18/CEN/230** |
|  | Title: | A MAD study of ACH-0145228 in healthy participants |
|  | Principal Investigator: | Dr Paul Hamilton |
|  | Sponsor: | Clinical Network Services (CNS) Ltd |
|  | Clock Start Date: | 15 November 2018 |

Miss Shuruthi Balachandran and Dr Paul Hamilton 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 ethical issues (resolved)

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

1. The Committee did not have any significant ethical concerns in relation to this application. It noted a number of changes that it would like to see addressed in relation to the participant information sheet and consent forms for both the MAD and the SAD components of the study as they are similar.

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

1. Page 1: The Committee noted that the first paragraph talks about the drug for the treatment of complement alternative pathway mediated diseases. Please reword this so that it is more accessible to a lay audience. The Committee noted that the explanation given further on in the information sheet could be used when first mentioned.
2. Page 3: The Committee noted the information around how many people will be in the study was confusing as it stands in terms of the different cohorts and their numbers and asked that it be more simply explained or that approximate numbers of patients are given.
3. Page 7: in relation to standardised meals the Committee noted that with early phase studies it is important to have this information and to also take into account those with special dietary requirements such as vegetarian, gluten intolerant people and to include this information. In other words if such meals are not provided then it is helpful to include this so that people can decide whether they will take part.
4. Page 9: the Committee noted that a “burning sensation” was noted in relation to side effects but this was not elucidated. The Researchers noted that this was in relation to reflux symptom and that they would clarify this.
5. Page 11: please specify for people what “barrier methods” of contraception are.
6. Page 12: the statement that sets out participant rights in relation to applying for compensation in the event they are injured in this study appears to be truncated. Please review and complete the statement.
7. Page 13: the amount of blood that will be taken is highly specific and to be that accurate in collection may not be possible. The Committee asked that the Researchers reword this to state how many teaspoons will be taken as this is an easier reference for participants to understand.

Decision

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

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. Dr Chris Wynne acknowledged the good work that the HDEC administration team have been doing while under a great deal of stress given a lack of resource. Dr Wynne suggested advocating for more resource to support the team.
3. Dr Chris Wynne asked that the wording in the PIS/CF pro forma consent form that states participants note they have read/had explained study information in their “first” language be amended.
4. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 17 December 2018, 08:00 AM |
| **Meeting venue:** | Room GC.6, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington, 6011 |

The following members tendered apologies for this meeting.

* Dr Dean Quinn

The meeting closed at 5:15pm.