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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 24 November 2015 |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 20 Aitken Street, Wellington |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 27 October 2015 |
| 12:30pm | New applications (see over for details) |
|  | i 15/CEN/198  ii 15/CEN/193  iii 15/CEN/192  iv 15/CEN/194  v 15/CEN/195  vi 15/CEN/196  vii 15/CEN/207  viii 15/CEN/199  ix 15/CEN/200  x 15/CEN/202  xi 15/CEN/206  xii 15/CEN/190 |
| 5:30pm | General business:   * Noting section |
| 5:45pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Apologies |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 01/07/2015 | 01/07/2018 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | 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 (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Present |
| Dr Melissa Cragg | Non-lay (observational studies) | 01/07/2015 | 01/07/2018 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 01/07/2015 | 01/07/2018 | Present |

## Welcome

The Committee noted that Mrs Helen Walker, the Chair, had registered her apologies for the meeting. Dr Dean Quinn was voted in as interim chair by consensus.

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Mrs Helen Walker.

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 27 October 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/CEN/198** |
|  | Title: | A study to evaluate the safety, antiviral activity and PK of ARB-001467 in subjects with CHB |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Arbutus Biopharma Corporation |
|  | Clock Start Date: | 12 November 2015 |

Prof Edward Gane and Ms Rebecca Hu 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 Committee commended the high quality of the application and Participant Information Sheet.
2. The Committee particularly noted that the Māori Tissue statement from the Participant Information Sheet was of a high standard.
3. The Committee noted that for future applications they would appreciate a more detailed explanation of how a study will benefit other population groups.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether there was a time limit on participants to consent to participation in the study as the study has competitive enrolment. The Researcher agreed that the nature of competitive enrolment did place some pressure on when participants needed to consent by in order to be included in the study.
2. The Committee questioned whether participants in the placebo arm would continue to receive standard care. The Researcher confirmed that the study treatment is additional to standard care and all participants will continue to receive standard care.
3. The Committee questioned if there was any risk to participants in the placebo arm. The Researcher confirmed that there was no risk to participants in the Placebo arm.

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

1. The Committee questioned the statement in the Participant Information Sheet that stated that to date there had been no allergic reactions. The Committee noted that the general population may have a different understanding of what this meant and may confuse some of the reported side effects as an allergic reaction. The Committee requested that this was further explained in the Participant Information Sheet to ensure clarity.
2. The Committee requested that further information regarding the inclusion and exclusion criteria are included in the Participant Information Sheet.

Decision

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

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

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| **2** | **Ethics ref:** | **15/CEN/193** |
|  | Title: | STARRT-AKI |
|  | Principal Investigator: | Dr Shay McGuinness |
|  | Sponsor: |  |
|  | Clock Start Date: | 05 November 2015 |

Dr Shay McGuinness and two co-investigators 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 Committee noted that this is an interesting study.
2. This study aims to compare the timing of dialysis in patients who present at the ICU.
3. This study will consider 90 day mortality as the primary outcome, previous similar studies have only considered 24 hour mortality.
4. Currently, clinicians disagree regarding the best time to administer dialysis and there is some evidence to suggest that administering dialysis early may reduce a patient’s need for long term dialysis. Current practice is highly variable between both clinicians and clinics in New Zealand and Australia.
5. The vast majority of participants will be very unwell when they present to the ICU the researchers may be unable to obtain consent before enrolling them in the study. However, where possible the researchers intend to obtain consent from the patient in advance. Where the patient cannot consent the researchers will seek the views of family members where available regarding the patients interests, as per Right 7(4) of the Code of Rights.
6. Participants will be approached when they are well enough to provide informed consent and asked to consent to their data being included in the study and to consent to continuing their participation in the research by allowing follow-up.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether any participants who did not require dialysis would be enrolled in the study. The Researcher explained that dialysis is performed in approximately 6% of patients who present at the ICU and that all participants enrolled in the study would require dialysis. These patients will be enrolled into one of two study arms, either receiving the treatment right away or having it delayed until their clinician determined that it is required.
2. The Researcher explained that approximately 25% of participants enrolled in the delayed arm of the study would not end up requiring the study treatment and that these participants will not get this therapy at all.
3. The Committee questioned if this meant that 25% of participants in the early treatment arm would receive dialysis when it is not really required for them. The Researcher explained that it is possible that some participants in the early dialysis arm would not have received dialysis had they been randomised to the delayed treatment arm. However, the researcher assured the committee that there was no anticipated harm from participants in the early treatment arm receiving dialysis when they may not otherwise have as some clinicians believe that receiving dialysis early can improve patients’ long term outcomes including reducing the need for long term dialysis.
4. The Committee explained that if an individual cannot consent for themselves it must be shown that participating in this research is in the best interest of the individual pursuant to Right 7(4) of the Code.
5. Right 7.4 of the HDC Code of Rights states that “Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where –

a) It is in the best interests of the consumer; and

b) Reasonable steps have been taken to ascertain the views of the consumer; and

c) Either, -

i. If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or

ii. If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.”

1. Because of this, the Committee clarified that it is only possible (under Right 7.4) to perform research on individuals who have not given informed consent if it can be shown that participation is in the best interest of the consumer and they take into account the views of other suitable persons or believe that the consumer would wish to consent if they were able to. In these cases the participant’s clinician must attest that it is in the participant’s best interest to participate in the research.
2. The Researcher explained that they were experienced in applying Right 7.4 and using their graduated approach to consent. The Researcher explained that this meant that before the hospital would agree to run a research project that all of the senior medical staff must agree that that participation in the proposed research project was in the best interests of the patient population. Further, the participant’s treating clinician must also agree that participation in the research project is in the individual participant’s best interest before enrolling them in the study, and throughout the treatment process. Once these two requirements were met, if available the family of the participant, or other suitable persons, would be consulted to ascertain their views on whether or not the participant would want to be involved in the research project. The Researcher explained that participants would only be enrolled in a research project without their consent once all of these conditions are met.
3. To further assure the Committee, the Researcher also explained that whenever possible participants would provide informed consent before being enrolled in the study and if this was not possible they would be approached when they became available to provide informed consent and their data would only be included in the study if they provided informed consent when they became able to provide it.
4. The Committee noted that the forms provided seem to include a form for family to consent on the participant’s behalf, however this is not possible under New Zealand law. The Researcher explained that they did not intend this as a legally binding consent form as they understand that family members cannot consent on the participant’s behalf. The Committee suggested that it would be more appropriate to rephrase this form to ensure it is clear that this is a family consultation form. The Committee explained that although it is important to consult with the family when possible, and that it is appropriate to have a detailed information sheet available for the family, it must be clear from these forms that the family are not providing consent on behalf of their family member. Rather, this form is to record the family consultation process in accordance with Right 7.4.c of the HDC Code of Rights.
5. The Committee questioned what would happen to a participant’s data if they died during the study. The Researcher explained that they would still use the data as it would be completely anonymised. The Researcher explained that they would not attempt to obtain the views and consent of the participant’s next of kin as this may be distressing for them and no further follow up is required. The Researcher explained that it was essential for the validity of their results to include participants who died during the study as excluding them would bias the results.
6. The Committee noted that as both arms of the study were standard care, and it was not yet known which arm was more beneficial for participant’s to be enrolled in, as determining this was the purpose of this study, then they found it difficult to see how participation in the study would be in the participant’s best interest, rather than simply as good as had they not been enrolled in the study. Therefore, they questioned why the Researchers did not run the study as a retrospective review to compare standard care practices as this would avoid the legal and ethical issues associated with non-consensual intervention research.
7. The Researcher explained that they felt that it was important to run the study as a randomised controlled trial to assure its scientific validity and the uptake of its results by the medical community as it could show the benefits of one standard practice over another.
8. Further, the Researcher explained why they believe that this study meets the requirements for non-consensual research. The Researcher explained that there is evidence to suggest that being treated in an ICU with an active research programme correlates with a lower risk of death, this is further supported by evidence that suggests that patients enrolled in acute care studies have higher survival rates than those not enrolled in studies. Because of these reasons the Researcher assured the Committee that enrolment in the study can be in the best interest of the participants and meets the requirements for non-consensual research under Right 7.4.
9. The Committee questioned whether the Researchers had sought independent legal advice regarding whether this study meets the legal requirements under Right 7.4. The Researcher confirmed that both Bruce Northey from ADHB and the Auckland Research Office had considered the legal status of this study and confirmed that it met the legal requirements for non-consensual research. The Committee noted that they are not responsible for ensuring that the study meets legal requirements and appreciated that the Researchers had sought independent legal advice regarding this.
10. The Committee noted that it is important that it is recorded in each case how the treating clinician determined that it was in the participant’s best interest to enrol them in the study, and the steps they took to ascertain the views of their family or whanau.

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

1. The Committee requested that a separate consent form is developed for participants who are able to consent in advance and another form is provided for participants who were unable to consent in advance. The Participant Information Sheet for participants who were unable to consent in advance should clearly explain what has happened to them and their rights going forward and does not require the same level of detail about the study procedures as they have already occurred. The changing tenses in the Participant Information Sheet for those providing retrospective consent were confusing and the Committee requested that the researchers rewrite this to make it clear and comprehensible.
2. Please ensure that the Participant Information Sheet explains that the participant’s family have been consulted where possible.
3. Please modify the forms for the participant’s family or whanau to ensure it is clear that this is a consultation document rather than a consent form and that the family member is not consenting on their relative’s behalf.

Decision

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

1. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (Ethical Guidelines for Intervention Studies para 6.22)
2. Please provide copies of the legal advice received, both from the research office and Bruce Northey. The Committee requests that this includes their advice regarding the inclusion of data from participants who died during the study.
3. Please provide further information regarding how clinicians will record enrolling each patient under Right 7.4, this should include a copy of the form they will complete in these cases.

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

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| **3** | **Ethics ref:** | **15/CEN/192** |
|  | Title: | EuroNet-PHL-C2 |
|  | Principal Investigator: | Dr Tim Prestidge |
|  | Sponsor: | ANZCHOG |
|  | Clock Start Date: | 12 November 2015 |

Dr Tim Prestidge and Ms Sonia Alix was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The Committee thanked the researchers for their application and noted that the Participant Information Sheet was easy to follow.

Summary of ethical issues (resolved)

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

1. The Committee questioned when participants would be given the consent form. The Researcher explained that there is a few weeks between diagnosis and treatment starting and that the consent form would be presented during this time. The Researcher explained that the participant’s doctor would meet with the participant to discuss their diagnosis and treatment options, the clinical trial would be presented as one of these options.
2. The Committee questioned the number of different consent forms that were submitted with the application. The Researcher explained that they uploaded a version of each form for both of their study sites as these are slightly different in the section detailing what happens to participants’ samples. The Christchurch form explains that samples need to be sent to Auckland for analysis. The Committee noted that in future only a generic version of each form should be provided and any minor changes such as these could be made for locality approval without HDEC approval.
3. The Committee questioned if any participants 16 years old or older would not be proving consent for themselves. The Researchers explained that if the participant was too unwell to consent for themselves they intended to seek the consent of their parents instead. The Committee explained that all participants 16 or over must consent for themselves as they are considered an adult in their ability to consent and, therefore, no one could consent on their behalf, including their parents. The Researchers agreed to alter their practices to reflect this.
4. The Committee questioned if any data was available regarding the frequency of lymphoma in Māori children and consequently any specific benefit this research may offer Māori. The Researcher explained that the rates are similar between Māori and Non-Māori. The Committee requested that this kind of information is included in future applications.

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

1. The Committee noted that the Participant Information Sheet is quite comprehensive and although it is relatively easy to follow it may benefit from some refinement to ensure it only includes the necessary information.
2. The Committee noted that the statement regarding samples being sent to Labplus for confirmation was ambiguous and they did not know what was being confirmed. The Researcher explained that this was to confirm the diagnosis and agreed to modify the Participant Information Sheet to ensure this was clearer.
3. The Committee requested that the Participant Information Sheet for 7-11 year olds is simplified, they suggested the use of cartoons or pictures to make it more age appropriate.
4. The Committee requested that the child Participant Information Sheet is modified to include information regarding radiation.
5. Currently the information sheet for participants who turn 16 during the study is quite brief. The Committee noted that anyone 16 years old or over should be treated as an adult in terms of their ability to provide informed consent and provided with a full adult Participant Information Sheet. The Committee noted that this includes any participants who turn 16 during the course of the study. Please modify this Participant Information Sheet and Consent Form to ensure it is a fully informative adult information sheet.
6. Please ensure the consent form and Participant Information Sheet for participants 16 and over includes the information regarding pregnancy and sexual activity.
7. The Committee noted that children under 16 can also legally consent for themselves if they are deemed competent, please ensure the consent forms reflect this.
8. Please remove tick boxes from the consent form unless the section is truly optional.
9. Please ensure it is clear in the Participant Information Sheet that participants’ tissue samples will be stored long term and can be returned to participants if requested.

Decision

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

1. Please amend the information sheet 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 Peter Gallagher and Dr Cordelia Thomas.

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| **4** | **Ethics ref:** | **15/CEN/194** |
|  | Title: | Effects of irrigation fluid temperature on body temperature during TURP |
|  | Principal Investigator: | Dr Kimberley Sent-Doux |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 November 2015 |

Dr Kimberley Sent-Doux was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The Committee noted that this study had previously been declined at another HDEC meeting.
2. The Committee noted that some parts of the application form had been incorrectly completed and requested that in future more care is taken to answer all of the questions accurately.
3. The primary objective of this study is to reduce costs for clinics by removing the need to have warming cupboards in operating theatres, and having to use these to warm the irrigation fluid.
4. The research proposes that as the bags of fluid cool down anyway, because they are hung outside the warming cupboard during use that warming them prior to use does not make a difference to patients’ outcomes.

Summary of ethical issues (resolved)

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

1. The Committee questioned the Māori Consultation status. The Researcher explained that the study has been submitted for Māori consultation and they are awaiting the response, however they do not anticipate any specific Māori cultural issues.
2. The Committee noted the possible cultural issue of whakamā, especially from this kind of operation and the need to discuss it with their doctor or the researcher. The Committee noted that the researchers needed to be aware of this and how to address it during their consent process.
3. The Committee questioned the statistics of Māori patients with this kind of operation. The Researcher explained that they estimate that they have 2-3 Māori men having this operation per month. The Committee noted that this kind of information would be useful in future applications.
4. The Committee questioned why the participant’s health records needed to be accessed and their GP contacted. The Researcher explained that they do not need to contact the participant’s GP but they need to access their health records to factor co-morbidities into their data analysis.
5. The Committee questioned whether previous studies have found any difference between warmed fluid and not-warmed fluid. The Researcher explained that one study found no difference and other studies recommended warmed fluid. However, the study that found no difference had the most similar practice to the clinic’s standard practice.
6. The Committee questioned why the risk of hypothermia is not included in the Participant Information Sheet. The Researcher explained that they replaced the word ‘hypothermia’ with a statement that the participant’s body temperature may ‘drop too low’ in an attempt to improve readability.
7. The Committee questioned the statement in the Participant Information Sheet that when participants withdraw from the study their data that has already been collected can continue to be used. The Researcher explained that once data is included in the analysis it cannot be withdrawn as they cannot identify an individual participant’s data.

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

1. The Committee requested that it is clarified in the Participant Information Sheet that participants would only be able to withdraw their data before it is included in the analysis.
2. The Committee requested that a name was added to the Māori cultural support contact details.
3. The Committee noted that the Participant Information Sheet stated that participants must withdraw in writing, however verbal withdrawal is legally binding in New Zealand. The Researcher agreed and noted that this was a mistake in the form and they would remove this statement.
4. The Committee noted the importance of involving whanau in all studies, and request that it is mentioned in the Participant Information Sheet that participants may wish to involve their family or whanau.
5. The Committee recommends that the Participant Information Sheet is proof read to improve clarity and consistency of tense.
6. Please clarify in the Participant Information Sheet why participants are being invited to be in the study.
7. Please clarify what is meant by ‘study visits’ in the Participant Information Sheet.
8. Please explain in the Participant Information Sheet why participants’ health records will be accessed and what information will be collected from these.
9. Please remove the statement regarding contacting the participant’s GP as this is not required.
10. Please remove the statement from the Consent Form ‘I understand my responsibilities as a study participant’ as they do not have any in this study.

Decision

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

1. Please amend the information sheet 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 Melissa Cragg and Mrs Sandy Gill.

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| **5** | **Ethics ref:** | **15/CEN/195** |
|  | Title: | JAVELIN Lung 100 |
|  | Principal Investigator: | Dr Archana Srivastava |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 November 2015 |

Dr Archana Srivastava and Ms Wendy Thompson 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 Committee noted that although it was good to see the Treaty of Waitangi being referenced in the application they have referenced the wrong articles and should correct this in future applications.
2. The Committee noted that in future it would be beneficial to have statistics on incident rates in Māori included in future applications.

Summary of ethical issues (resolved)

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

1. The Committee questioned the status of Māori consultation. The Researcher stated that it has been submitted and covered how the study would benefit Māori. The Committee questioned why this information was not provided in the application form as they would find it useful. The Committee noted that lung cancer has a 3 times higher rate in Māori compared to non-Māori and, therefore, this study has potential to reduce inequalities and that they would have appreciated if this was explained in the study application.
2. The Committee questioned whether blood was being collected for future research and whether this blood would be stored identified or the storage limits on the blood. The Researcher explained that the study application has a number of parts, including the optional collection of tissue for future unspecified use. The Committee noted that currently this is confusing in the Participant Information Sheet.
3. The Committee questioned what is meant by ‘reanalyse’ in relation to tissue samples in the Participant Information Sheet. The Researcher explained that this referred to retesting tumour biopsy samples as the sponsor wants to confirm the analysis of the tumour at a central laboratory.
4. The Committee questioned what would happen to these tissue samples after they are reanalysed. The Researcher stated that it was intended that they would be stored for future use. The Committee clarified that if participants are only consenting to enrol in the main study that only the tests required for the main study can be done on their tissue samples and any future unspecified use of tissue must have a separate optional consent form.
5. The Committee noted that the consent form for the optional Pharmacogenomics aspect of the study is not unspecified future research use as it is not unspecified and has a specified timeframe for keeping the samples. Whereas, the samples collected under the future unspecified use of tissue form may be stored indefinitely.
6. The Committee questioned the consent form for the participant’s partner if they become pregnant, do they want to see the potential health effects on the pregnant partner or their child. The Researcher explained that they want to study the health effects on the child. The Committee explained that they should have a different consent form as legally the pregnant woman cannot consent on behalf of her future child, the parents will need to consent on the child’s behalf once the child is born.

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

1. There should be three separate consent forms – for the main study, optional pharmacogenetic testing, and future unspecified research. All biobanking, generic medical research and long-term unspecified analysis of samples needs to be covered in the future unspecified consent form. The main consent for and the pharmacogenetics testing consent form are both for specified research.
2. Please include in the Participant Information Sheet that tissue samples will be sent overseas and where they will be going.
3. Please clarify in the Participant Information Sheet the different aspects of the study to make it clearer which parts are optional.
4. The Committee requested that it is clarified in the Participant Information Sheet what is meant by ‘reanalyse’ participants’ tissue samples.
5. Please clarify the statements regarding reported side effects “more than 5%” as it is ambiguous as to how common they are expected to be.
6. Please provide a separate future unspecified use of tissue consent form that includes that future studies on these samples may not be approved by a New Zealand ethics committee. The Committee recommends that the researchers consider the HDEC template when developing this form this is available at http://ethics.health.govt.nz/home. Please remove the tick boxes regarding options A and C from the main consent form.
7. Please clarify in the Participant Information Sheet whether the participant could expect to be contacted regarding the study or their tissue samples in the future.
8. Please clarify in the Participant Information Sheet that cultural protocols will not be available for the disposal of tissue samples as they are being sent to overseas laboratories.
9. Please explain clearly in each separate consent form what will happen to tissue samples collected as part of this study, including that they will be sent overseas what they may be tested for, and how long they will be stored.
10. The Committee requested that vague statements in the Participant Information Sheet are clarified as it may be difficult for participants to work out what is happening and how it will be decided. The Researcher explained that participant’s treatment would be at the discretion of the investigator. The Committee requested that this is stated in the Participant Information Sheet.
11. Please replace the consent form for the pregnant partner with a consent form for the parents on behalf of their child, as the researchers want to see the health effects on the child rather than on the pregnant partner.
12. Please replace ‘obstetrician’ with ‘lead maternity carer’ in the Participant Information Sheet as most women in New Zealand are probably seeing a midwife.
13. Please rephrase the statement that Māori may ‘disagree’ with sending blood overseas to may have ‘strong feelings’.

Decision

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

1. Please amend the information sheet 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 Dean Quinn and Dr Angela Ballantyne.

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| **6** | **Ethics ref:** | **15/CEN/196** - **CLOSED** |
|  | Title: | A study assessing an investigational injectable gel formulation of dexamethasone, developed for the treatment of sciatica. |
|  | Principal Investigator: | Dr Richard Robson |
|  | Sponsor: | Quintiles Pty Ltd |
|  | Clock Start Date: | 12 November 2015 |

Decision

This application was *approved* by consensus, with non-standard conditions to be checked by the secretariat.

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| **7** | **Ethics ref:** | **15/CEN/207** |
|  | Title: | Gut microbiota and influenza vaccine |
|  | Principal Investigator: | Dr Irene Braithwaite |
|  | Sponsor: | Malaghan Institute of Medical Research |
|  | Clock Start Date: | 12 November 2015 |

Dr Irene Braithwaite, Mr Nick Shortt and two co-investigators 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 feasibility study to assess the viability of a larger randomised controlled trial.
2. The larger study will aim to consider the changes in gut microbes in response to an immune challenge. This feasibility study will use an influenza vaccine as a proxy for immune challenge.
3. The researchers hope to recruit 125 participants to ensure after dropout rates 100 participants complete the study.
4. This study lasts for 6 months and is relatively intense for participants in the first week as they are required to complete 3 study visits and collect stool samples in the first week.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether participants tissue samples would be sent overseas as part of the study. The Researchers confirmed that no tissue samples would be sent overseas.
2. The Committee questioned the statement in the Participant Information Sheet regarding what participants need to do for the first study visit. Specifically, the Committee questioned whether participants needed to collect a stool sample at the study visit, before, or after. The Researcher explained that participants needed to collect a stool sample up to 3 days before the first study visit and bring it with them.
3. The Committee questioned if every participant would be required to have a blood test taken. The Researcher explained that all participants would give a blood sample but that only some would be analysed.
4. The Committee questioned if there is a point that participants can no longer withdraw their data from the study. The Researcher confirmed that participants can withdraw their samples and information at any point.
5. The Committee questioned how participants would be informed of the study results or if unexpected findings is discovered. The Researcher explained that participants and their GPs will be informed about any unexpected information. The Committee noted that this was included in the Consent Form but not in the Participant Information Sheet.

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

1. Please clarify in the Participant Information Sheet when participants are required to collect and bring their stool samples to study visits.
2. Please clarify in the Participant Information Sheet when blood samples will be taken and what will happen to them.
3. Please rephrase the ACC wording to ensure accuracy, the Committee suggests considering the wording in the HDEC Participant Information Sheet template.
4. Please change the location of the statement in the Participant Information Sheet regarding participants being paid to participate in the study as it currently appears that this is a cost rather than a benefit.
5. Please include in the Participant Information Sheet that the participant and their GP will be contacted regarding any unexpected findings.
6. Please ensure that the side effect profile is updated when the vaccine strain to be used is determined. The Researchers agreed to submit this as a post approval form.

Decision

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

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| **8** | **Ethics ref:** | **15/CEN/199** |
|  | Title: | MAC-V |
|  | Principal Investigator: | Dr Douglas Campbell |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 November 2015 |

Dr Douglas Campbell and a co-investigator 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 Committee noted that the Mayo paper regarding obtaining consent on the day of surgery submitted with the application was interesting.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether all participants would provide informed consent to participate. The Researcher explained that all participants will consent and that most would consent on the day of surgery when they are consenting to the surgery and anaesthesia.
2. The Committee questioned whether it would be possible to consent participants prior to the day of surgery. The Researcher explained that they hoped to provide all participants with a Participant Information Sheet at their pre-anaesthetic appointment to allow them time to consider the study before consenting on the day of surgery, but that this may not be possible for all participants.
3. The Committee questioned the status of Māori consultation. The Researcher explained that they has consulted with a Māori advisor from the research office. The Committee noted that they had stated that they would not obtain Māori consultation in the application form. The Researcher explained that this was a mistake and that they had already sought Māori consultation.
4. The Committee noted that they had not stated any possible cultural issues in their application however they would be touching the head and this may raise cultural concerns, especially for Māori participants. The Researchers stated that they are aware of this potential issue and had not stated it in the application as participants would have their head touched even if they were not participating in the study. The Committee requested that in future applications any potential cultural issues are outlined.

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 Peer Review provided was very brief and did not cover any considerations that they had. The Researcher agreed to provide further evidence of independent peer review.
2. The Committee noted that the researchers did not intend to provide participants with the results of the study, however the Committee expects that at least a brief summary of the results will be available to participants who are interested.

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

1. Please use the New Zealand census question to collect ethnicity data.
2. Please include more information regarding why the study is being done.
3. Please add a statement to the Participant Information Sheet and Consent Form that explains that information already collected from a participant will continue to be included in the study results even if they withdraw from the study as it cannot be identified to be removed.

Decision

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

1. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (Ethical Guidelines for Intervention Studies para 6.22)
2. Please provide evidence of favourable independent peer review of the study protocol (Ethical Guidelines for Intervention Studies Appendix 1).
3. Please confirm that a summary of the study results will be available to participants if they would like to receive this.

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

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| **9** | **Ethics ref:** | **15/CEN/200** |
|  | Title: | Carrageenan Asthma Study |
|  | Principal Investigator: | Prof Julian Crane |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 November 2015 |

Prof Julian Crane and Dr Caroline Shorter 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 ethical issues (resolved)

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

1. The Committee noted that one of the largest challenges the researchers are likely to face is compliance. The Researchers explained that they have done a compliance study with participants taking the spray daily and checked compliance by weighing the bottles. They intended to weigh the bottles to check compliance in this study too.
2. The Committee questioned the use of the symptom diary. The Researchers explained that participants may mistake hay fever or asthma symptoms for a cold and the symptom diary is used to factor this into the statistical analysis of the results.
3. The Committee questioned the need for formal data safety monitoring arrangements. The Researchers explained that the HRC had confirmed that this was not required for this study.

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

1. The Committee noted that participants may not be good at controlling their asthma and request that participants are reminded in the Participant Information Sheet to continue their regular asthma treatment plan and that the study treatment is not a treatment for their asthma.
2. Please include the number of participants in the Participant Information Sheet.
3. Please include how long the data will be retained and that it will be sent overseas in the Participant Information Sheet.
4. Please add an ACC statement to the Participant Information Sheet stating that participants would be covered by ACC as this is not a commercially sponsored trial. The Committee suggests the statement from the HDEC template.
5. Please remove the yes/no boxes from any sections of the consent form that are not truly optional.
6. Please explain in the Participant Information Sheet that the optional nasal swab sample is not stored but is sent overseas. Please note in the Participant Information Sheet potential cultural concerns associated with tissue being sent overseas.

Decision

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

1. Please amend the information sheet 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 Dean Quinn and Mrs Sandy Gill.

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| **10** | **Ethics ref:** | **15/CEN/202** |
|  | Title: | APD334-005: Extension Study of APD334-003 |
|  | Principal Investigator: | Prof Richard Gearry |
|  | Sponsor: | Covance, New Zealand |
|  | Clock Start Date: | 12 November 2015 |

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

Potential conflicts of interest

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

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

Summary of Study

1. This application is for an extension of a previously approved study.
2. This study will recruit 9 participants in New Zealand.
3. The Committee noted that the Participant Information Sheet was very detailed.
4. The Committee commends the cultural statement in the Participant Information Sheet and notes that it could apply to a number of groups.

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 questioned whether participants had already been trained to use the E-diary, because it was used in the original study.
2. The Committee questioned why participants who had already been on the study drug for 12 weeks and had seen no improvement would continue on the study drug. The Committee questioned if keeping them on the study drug would restrict them from accessing other treatments.
3. The Committee questioned how many study sites there are in New Zealand.
4. The Committee questioned how potential conflicts of interests are being managed as the participants is being treated by the researcher who is consenting them to the study.

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

1. Please rephrase the statements in the Participant Information Sheet regarding the study being approved by Medsafe and given a favourable review by an Ethics Committee. The Committee noted that Medsafe does not approve studies and the Committee does not give studies favourable reviews, they approve them.

Decision

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

1. Please respond in a cover letter to the Committee’s outstanding ethical concerns.
2. Please amend the information sheet 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 Melissa Cragg and Dr Dean Quinn.

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| **11** | **Ethics ref:** | **15/CEN/206** |
|  | Title: | Segmentation Towards Enabling Pathways (STEP) |
|  | Principal Investigator: | Professor Matthew Parsons |
|  | Sponsor: | Ministry of Social Development |
|  | Clock Start Date: | 12 November 2015 |

Matthew Parsons and 5 co-investigators 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 noted that to approve access to identifiable health information without consent for the purposes of a study they must be satisfied that the public interest in the study outweighs the potential harm and loss of privacy.
2. The Committee noted that the primary purpose of the study was to provide information regarding prioritisation of resources in DHBs with the goal of increasing employment. The Researcher explained that MSD had been undertaking similar work for a number of years regarding linking beneficiaries’ data with that of housing and corrections. The purpose of this study was to allow linking of more information.
3. The Researcher explained that this study targeted a specific at risk group of people, who are often in a difficult financial position. They wanted to use this data to model different scenarios to inform the development of interventions at the DHB level to help this at risk group. The reason for linking the information from across departments is to allow a more complete picture of the make-up of their client base to ensure interventions are targeted effectively.
4. The Committee questioned whether individuals would be able to be identified once the data had been matched. The Researcher explained that identifying information would only be collected and used to allow the health data to be matched with data from other departments. Once the data matching had occurred all identifying information would be removed. All analysis will be performed on anonymous information.
5. The Researcher clarified that there was a number of steps to the project, first being linking the data, then the modelling phase. At the modelling phase all identifiable information will have been removed from the data. The third phase involved using this information to inform operational policy at a DHB level, this phase is outside the scope of this application.
6. The Committee asked the researchers to clarify the expected benefit from accessing this information. The Researcher stated that the expected benefit was to inform service development to help achieve policy goals, especially the better public services target of fewer long term beneficiaries.
7. The Committee questioned if the information would be used to force individuals off their benefits, or to coerce them in some way. The Researcher explained that the only reason people would be moved off a benefit is if they moved into employment. The Committee and the Researcher agreed that how interventions are altered by this information is outside the scope of HDEC review, however the Committee hoped that the use of this data would be guided by representatives of each key stakeholder group.
8. The Committee questioned why this research project was only considering beneficiaries. The Researcher explained that beneficiaries are considered an especially vulnerable group and they intended to target this group with any developed interventions. The Researcher also clarified that they are considering both long term beneficiaries and recent beneficiaries.
9. The Committee questioned whether stakeholders would be directly contacted and consulted. The Researchers confirmed that after the data had been collected and mapped they would have stakeholder engagement that included working with clients.
10. The Committee questioned what Māori consultation had occurred. The Researcher explained that they intended to pursue Maori Consultation but that it had not yet occurred.
11. The Committee questioned what variables would be considered when analysing the data. The Researcher explained that he could not answer that question as it was up to the DHBs, and other service providers, the variables that would be used in the data analysis.
12. The Committee questioned if all of the data being matched was retrospective. The Researcher confirmed that all data was retrospective and had been collected over the past 10 years.
13. The Committee questioned the appropriateness of the research team make-up. The Researcher explained that the research team involved a financial analyst, an engineering scientist specialised in large data set mapping, and a statistician.

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 questioned the lack of independent peer review, and the lack of peer review by a statistician. The Researchers agreed to follow this up for the Committee and supply further independent peer review.
2. The Committee stated their concern that the research project risked stigmatising certain population groups. The Researcher countered that one of the goals of the research was to prevent stigmatisation and reduce long term adverse outcomes. The Committee noted that working closely with key stakeholders would help to reduce the risk of stigmatisation by offering an important perspective to analyse and understand the results. The Researcher confirmed that stakeholders would help to drive the variables used to analyse the data.
3. The Researchers explained that although they intended to publish the study, any publications would focus on the technique and modelling exercise, rather than profiles of different client groups. The Committee responded that even if the results were not published they could be accessed by an OIA request once they were no longer under active consideration.
4. The Committee is concerned that the results could be used to reinforce stereotypes and increase stigmatisation, leading to harm to the at risk groups the information was collected about. The Committee noted that although they understand that the public interest in this information is high, and that it has the potential to provide benefits for these at risk groups, they must consider this against the potential for this research to cause harm as it was as yet unknown what results would be shown by the project.
5. The Researchers noted that statistics regarding the ethnic make-up of beneficiaries is published monthly by MSD and that, therefore, this research would not show new information regarding how many Māori receive benefits, for example. The Committee agreed, but stated that the linking of this information from MSD with Health Information may add to the stigmatisation of Māori by showing new relationships, such as between poor mental or physical health and being a beneficiary. The Committee also noted that there may be high public interests in this project because it involves linking government data and this public interest could lead to reinforced stereotypes even though the base data is not original.
6. The Committee expressed that although they held concerns about the potential for this study to increase stigmatisation and reinforce stereotypes, they also agreed that it had the potential to offer benefits and improve outcomes for at risk groups. The Committee noted that the potential for harm could be minimised by ensuring that the distribution and analysis of the results was guided by key stakeholders.
7. The Committee questioned whether representatives from key stakeholder groups were included on the study governance group. The Researchers stated that this was the intention. The Committee requested that further information regarding stakeholder representatives on the study governance group are provided before the study is approved by the Committee. The Committee noted that the purpose of this was to help ensure that the publication and distribution of the study results was influenced directly by key stakeholders to minimise the risk of harm.
8. The Committee questioned whether the departments that agreed to link their information for this project have any influence over the study or the results.
9. The Committee questioned which DHBs would be supplied with the study results and involved in the modelling of the study data.
10. The Committee requested further information regarding how the privacy and the safety of the data would be protected to minimise the potential harm from this data being analysed by a range of people with varying interpretations.
11. The Committee questioned whether anyone other than the research team named in the application form would have access to identifiable data, such as in the first part of the study. For example, any representatives from the departments supplying the information.

Decision

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

1. Provide further evidence of scientific peer review by an independent researcher who can comment on the different aspects of the methodology and analysis such as the statistical approach taken (Ethical Guidelines for Intervention Studies Appendix 1).
2. Provide further information regarding the Māori consultation process, including what consultation was done and the responses from this consultation.
3. Please provide further information regarding stakeholder inclusion on the study governance group, please include names and positions.
4. Please confirm whether departments that allowed their information to be linked and used in this modelling will have any control over how the information is used, interpreted, or distributed.
5. Please clarify which DHBs will be involved in this study.
6. Please confirm the data management protocols for this study.

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

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| **12** | **Ethics ref:** | **15/CEN/190** - **CLOSED** |
|  | Title: | RSV Vaccine in Pregnancy |
|  | Principal Investigator: | Dr Adrian Trenholme |
|  | Sponsor: | Clinical Network Services Ltd |
|  | Clock Start Date: | 12 November 2015 |

Decision

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

## 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:** | 15 December 2015, 08:00 AM |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 20 Aitken Street, Wellington , 6011 |

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 5:40pm