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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 22 May 2018 |
| **Meeting venue:** | Room GN.6, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 24 April 2018 |
| 12:30pm | New applications (see over for details) |
| 12.30-12.55  12.55-1.20  1.20-1.45  1.45-2.10  2.10-2.35  2.35-3.00  3.00-3.25  3.25-3.50 | 1. 18/CEN/89 2. 18/CEN/81 3. 18/CEN/82 4. 18/CEN/83 5. 18/CEN/85 6. 18/CEN/78 7. 18/CEN/90 8. 18/CEN/92 |
|  | General business:   * Noting section of agenda |
| 4.00pm | Meeting ends |

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

## Welcome

The Chair opened the meeting at 12:00 and welcomed Committee members, noting that apologies had been received from Dr Melissa Cragg and Dr Patries Herst.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mrs Jane Wylie confirmed her eligibility, and was co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 24 April 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/CEN/90** |
|  | Title: | Zoonotic disease transmission in rural communities |
|  | Principal Investigator: | Dr. Pippa Scott |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 May 2018 |

Dr Pippa Scott 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. Around 60 per cent of microorganisms causing human disease are passed between animals and humans ('zoonotic' pathogens). Changing farming practices in New Zealand are creating conditions promoting pathogen transfer between species.
2. This project aims to identify interventions to control transmission to humans.
3. Two types of zoonotic bacterial pathogens will be examined in this project: those associated with the skin and those associated with the gastro-intestinal tract. These two groups will be represented by: Staphylococcus aureus; and Campylobacter spp. and STEC respectively.
4. Data will be included a mathematical model simulating transmission of bacteria within and between species. Intervention effects will be tested in the model. Identifying effective interventions will help reduce the disease burden from gastrointestinal infections, particularly in young rural New Zealanders, and reduce transfer of antibiotic resistant Staphylococcus aureus to humans, maintaining treatment options for infections.

Summary of resolved ethical issues

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

1. The Committee queried whether children would be swabbed during school time. The Researcher confirmed that swabs would be taken during school time and all children at the school would be given the information and the option to participate and so stigmatisation of participants was unlikely.
2. The Committee queried why date of birth would be included as an identifier. The Researcher noted that the lab would only process samples with a date of birth included. The Researcher noted that once the sample leaves the lab it only includes the participant ID number which is only known by the Researcher.
3. The Committee queried how the letters would be issued to participants found to have Staphylococcus aureus in wounds/sores. The Researcher confirmed that letters would go directly to the child’s parent.
4. The Committee queried if a child tests positive how would the Researcher know the farm was the source. The Researcher noted that there are uncertainties around directness but with whole genome sequencing they can see how closely related samples in cattle versus people living on a farm versus children living in the community but not directly living on a farm and test how closely related those bacteria are.
5. The Committee queried if the researcher would identify sensitives of organisms being cultured. The Researcher confirmed that they would be for ones where they hold genome sequence and from that they can derive the sensitivities.

Summary of outstanding ethical issues

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

1. The Committee noted that under question r.2.5 of the application form it states that health information would be retained until the youngest participant turns 18. The Committee noted that health information should be stored for a minimum of 10 years, and information collected about child participants should be retained for 10 years after the child turns 16 years old.
2. The Committee queried that if healthcare workers would be informed if it was identified that they were carrying Staphylococcus aureus, MSRA etc. The Researcher agreed to inform those individuals in relevant occupations, such as nurses, paramedics, doctors, if they are carriers and to add an option to the adult consent form to select if they wish to be informed.
3. The Committee requested a copy of the shorter versions of the study questionnaires.

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

1. Dairy Participant Information Sheet for Children – please be explicit that the study involves 3 nasal swabs.
2. Participant Information Sheet - please ensure all documents include a document specific title in the footer.
3. Parental consent form - please provide a copy of this form.
4. Please provide contact details for the Māori advisory/support person and HDEC contact details on all Participant Information Sheets.
5. The Committee requested the compensation wording is included in all Participant Information Sheets, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
6. Information Sheet for Parents of Child Participants – under the section “What is the aim of this project?” Please add the missing words to the first sentence.
7. Information Sheet for Parents of Child Participants – under the section “Who are we seeking to participate in the project?” please be more specific in terms the adult group being recruited, i.e. teachers and support staff.
8. Information Sheet for Parents of Child Participants – under the section “If you agree that your child can participate, what will they be asked to do?“ please ensure the statement “The swabs will be destroyed after processing and no human material will be stored or analysed in any way” is explained in more simple terms.
9. Information Sheet for Parents of Child Participants – under the section “If you agree your child can participate, can you withdraw them later?” please ensure the information under this incudes details on what actually happens if the participant decides to withdraw.
10. Assent form for children - Please remove the yes/no tick boxes from the assent form for all statements that aren’t truly optional, that is a participant could select ‘no’ and still participate in the study.
11. Information Sheet for Child Participants – under the section “ Information Sheet for Child Participants” please ensure this includes correct information i.e. illnesses spreading from cows, not schools.
12. Information Sheet for Child Participants – under the section “What if I agree now but then change my mind later?” please be clear and explicitly state that they would be out of the study if they change their mind.
13. Information Sheet: Sample Collection on Farms –. The Committee suggested using the first person throughout the document to ensure consistency.
14. The committee noted the good response to question f.2.1 in the application form and suggested using this in the Participant Information Sheet.
15. Study Title – please consider using a lay title in participant facing documents.
16. Please add an option to the adult consent form to select if they wish to be informed if they are carriers of the bacterial pathogens.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies* paragraph *6.10)*.
* Please provide a copy of the Parental consent form.
* Please respond to the outstanding ethical concerns detailed above.

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

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| **2** | **Ethics ref:** | **18/CEN/81** |
|  | Title: | Concussion Recovery in Children and Adolescents |
|  | Principal Investigator: | Dr Nicola Starkey |
|  | Sponsor: | University of Waikato |
|  | Clock Start Date: | 10 May 2018 |

Dr Kelly Jones 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. Concussion is one of the most common injuries in New Zealand (749 per 100,000 person years), with children and adolescents accounting for 30% of all cases. As most post-acute care for concussion is provided outside of a hospital setting in New Zealand, clear guidelines for managing the condition are needed urgently.
2. Detailed guidelines are available for adults, but they are unsuitable for younger people due to differences in the effects of concussion and their recovery. Specific evidence-based guidelines for concussion management in children and adolescents are needed but, as highlighted by the Consensus Statement on Concussion in Sport, are unable to be developed due to the lack of high quality systematic studies.
3. The study aims to fill this gap by carrying out a prospective longitudinal study of concussion recovery in the acute post-injury period in children and adolescents aged 5-17 years to provide a detailed description of typical patterns of symptom resolution and predictors of recovery.
4. This specific application is for a feasibility study of the identification, recruitment and assessment protocols to assist with developing the full study protocol.

Summary of resolved ethical issues

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

1. The Committee queried if the parent would consent on behalf on the participant aged over 16 years. The Researcher confirmed the participants aged over 16 years would be invited to consent for themselves and permission for their parent to be involved would be sought from the participant.
2. The Committee queried the role of the parent in the study. The Researcher advised that parents would complete questionnaires on their own health as well as the young person’s wellbeing.
3. The Committee noted that all parents would be invited to participate in the study, regardless of their child’s age, and queried whether the child and parent needs to consent as a pair. The Researcher noted that it would be acceptable for a young person over 16 years to participate without their parent and vice versa.
4. The Committee noted, for future applications, question p.4.2 on cultural issues, touching the head, especially for concussion patients, is considered a tapu area. Upper limb injuries there could be whakamā depending on how and where the injured occurred and how the facts are reported which could lead to some challenging situations.
5. The Committee noted that under question r.2.5 of the application form it states “In line with Health Regulations, data will be stored for ten years after the participants have reached 16 years of age (as the youngest participants in this study will be 5 years of age their data will be kept for 21 years).” The Committee noted that some study documentation and states all data will be kept for 21 years and queried whether all data will be kept for 21 years or only a subset. The Researcher clarified that all data will be kept for 21 years.

Summary of outstanding ethical issues

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

1. The Committee queried whether a parent would still be asked to provide information on their child if the child did not want their parent to be involved in the study. The Researcher agreed that this aspect of the study was not clearly defined and would provide more detail in the study protocol.
2. The Committee asked for clarification on the recruitment process. The Researcher noted that eligible families would be contacted by a Researcher employed by the hospital who has access to the Emergency Department records, noting that this is not standard follow up and only potential research participants would be contacted. This study involves accessing health information without consent. The Committee noted that they can approve access to identifiable health information without consent for research in certain circumstances. The Ethical Guidelines for Observational Studies states at Paragraph 6.43:
   * *Access to identified or potentially identifiable data for research without the consent of the people the data identifies or makes potentially identifiable may be justifiable when:*
     1. *the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; and*
     2. *there would be no disadvantage to the participants or their relatives or to any collectives involved; and*
     3. *the public interest in the study outweighs the public interest in privacy.*

To approve a study involving access to health information without consent the Committee must be satisfied that these requirements are met by the study concerned. It is the applicant’s responsibility to justify the use of health information without consent, and to explain how these requirements are met. The Researcher agreed to alter the recruitment process to include a poster in the waiting room, a handout in the participant’s aftercare home pack and a flyer with the ACC form instead of accessing identifiable health information to contact potential participants directly. Please provide assurance to the Committee that the participants’ health information will remain confidential and an opt-out option will be available. Please consider how the opt-out option will work and address this with the clinical team.

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

1. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
2. Consent forms - Please remove the yes/no tick boxes from the consent form for all statements that aren’t truly optional, that is a participant could select ‘no’ and still participate in the study.
3. Children Participant Information Sheets - Please provide contact details for the Māori advisory/support person, HDEC and the research team contact details on all Participant Information Sheets. Please make it clear that participants can use these contact to make a complaint / comment / feedback.
4. Participant (14 – 16 years) Assent form – please replace the word “consenting” with “assenting”.
5. Participant (8 - 13 years) Information Sheet – the committee noted that they are the only group not being offered a $20 voucher. Please ensure consistency with koha.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies* paragraph *6.10)*
* Please respond to the outstanding ethical concerns detailed above.
* Please provide assurance to the Committee that the participants’ health information will remain confidential and an opt-out option will be available. Please consider how the opt-out option will work and address this with the clinical team.

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

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| **3** | **Ethics ref:** | **18/CEN/82** |
|  | Title: | A pilot study of the efficacy of erector spinae block |
|  | Principal Investigator: | Dr Kelly Byrne |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 May 2018 |

Dr Kelly Byrne 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 erector spinae block is a newly described regional anaesthetic technique which claims to provide pain relief after a number of different surgeries. There have been several case reports and small case series that seem to support this claim of pain relief after a variety of different types of surgery.
2. This study is a pilot study that will attempt to test whether it is feasible to undertake this technique in a range of different surgeries and attempt to gauge whether there are benefits in terms of pain relief, and the size of this benefit.
3. The aim of this pilot study is to recruit 80 patients, all of who will have a regional anaesthesia catheter placed into the erector spinae space (which is adjacent to the bones which make up the spinal column).
4. Half the group will have a placebo injection and infusion following surgery, and the other half of the group will have the active medication (a local anaesthetic) injection and infusion following surgery.
5. All patients will be provided with other forms of pain relief, specifically a patient controlled analgesic infusion, and data will be collected about the quality of the patient’s recovery, the amount of pain killer used, and the pain scores of the patients following surgery.

Summary of resolved ethical issues

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

1. The Committee queried the safety monitoring procedures for the study and how adverse events would be monitored and recorded. The Researcher noted that that the study is a collaborative study with other institutions and adverse events would be reviewed by a team to determine if any events are specific to the block being investigated. Adverse events are reviewed locally at a monthly meeting and shared with other institutions involved in the study.
2. For future applications, questions p.4.1 and f.1.2 – please include some statistics relevant to the different populations and the health condition rather than a blanket statement.
3. The Committee noted that the peer review does not use the HDEC standard template and asked for assurance that the peer reviewer was independent from the study. The Researcher confirmed that the peer reviewer, Dr Chris Nixon, is not associated with the study.

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

1. The Committee requested the compensation wording is included in the Participant Information Sheet, for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
2. Please ensure Central HDEC is referenced in the Participant Information Sheet as the approving ethics committee (not National Ethics committee)
3. Please include whanau (along with relative, friend or healthcare worker) in the Participant Information Sheet introduction.
4. Page 2 of the Participant Information Sheet under section 3 please explain more clearly the following sentence “As part of the study, data about pain scores, quality of recovery, pain killer use, and numbness in the distribution of the surgery will all be collected.” The Committee suggested using “mapping out the area that is numb”.
5. Page 2 of the Participant Information Sheet under section 4 – the Committee suggested stating “there may be no direct benefit to you”.
6. Page 2 of the Participant Information Sheet under section 5 - the Committee suggested stating for example, “all blocks of this type do have these potential risks but there are not any additional risks that the Researcher is aware of”.
7. The inclusion / exclusion criteria refers to drug / alcohol abuse – please ensure this is included in the Participant Information Sheet.
8. Page 1 of the Participant Information Sheet - please remove the reference to “This plain language statement is six pages long”.

Decision

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

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

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| **4** | **Ethics ref:** | **18/CEN/83** |
|  | Title: | Vitamin D (25-OHD) levels in adolescent mental health inpatient services in New Zealand |
|  | Principal Investigator: | Doctor Enys Delmage |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 May 2018 |

Dr Enys Delmage 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. Vitamin D deficiency has been linked with mental disorder in a number of studies including in New Zealand. It is important to manage any deficiencies to assist with physical and mental well-being.
2. This study aims to highlight any potential treatable deficit and may serve to promote further research in other settings.

Summary of resolved ethical issues

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

1. The Committee queried the age range of participants to be recruited to the study. The Researcher confirmed that that the minimum admission age is 13 years (however, occasionally 12 year olds are admitted) and the maximum age is 19 years but for this study 18 years would be the cut off.
2. The Committed queried whether additional funding had been secured as noted in the application form. The Researcher confirmed that Research for Life had declined the funding application but they may apply in the next round of applications and are currently exploring further funding options.
3. The Committee noted, for future applications, question p.4.2 on cultural issues especially in a mental health unit should include whakamā**,** tapu of the head, meeting with people face to face, etc.
4. The Committee queried whether the study involves an additional blood draw or additional tests on a sample that would usually be taken. The Researcher confirmed that it would be an additional test on an already collected blood sample.
5. The Committee queried at what point in the admission process is the sample taken. The Researcher confirmed that this would be within the first few days of admission.
6. The Committee queried who is collecting the medical data for the project. The Researcher confirmed that the House Surgeon would collect the vitamin D level and other medical elements, such as pre-existing medical conditions, GI absorption disorder. Wider patient demographics would be collected by the administration team within each unit and would be information collected as part of routine care. Information would be shared with the Researcher in a de-identified format.

Summary of outstanding ethical issues

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

1. The Committee noted that health information should be stored for a minimum of 10 years, and information collected about participants should be retained for 10 years after the youngest person turns 16 years old.

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

1. Consent forms - Please remove the yes/no tick boxes from the consent form for all statements that aren’t truly optional, that is a participant could select ‘no’ and still participate in the study
2. Please ensure there is a Participant Information Sheet and Assent form specifically for participants under 16 who are unable to provide their own informed consent. The Committee suggesting using the brief pamphlet and replacing the word “consent” with “assent”.
3. The Committee requested the compensation wording is included in the Participant Information Sheet, for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*

Decision

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

* Please ensure there is a Participant Information Sheet and Assent form specifically for participants under 16 who are unable to provide their own informed consent.
* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies* paragraph *6.10)*
* Please respond to the outstanding ethical concerns detailed above.

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

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| **5** | **Ethics ref:** | **18/CEN/85** |
|  | Title: | What does helpful supported decision-making look like to people with intellectual disabilities? |
|  | Principal Investigator: | Mrs Elizabeth Waring |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 May 2018 |

Mrs Elizabeth Waring and Carolyn Stobbs were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study aims to find out from people with intellectual disabilities, what support they find helpful to make choices and decisions.
2. The objective is to use this knowledge to promote the voices of people with intellectual disabilities and improve our training and support in this area to achieve better outcomes.

Summary of resolved ethical issues

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

1. The Committee queried whether there are any health statistics on the prevalence of intellectual disability amongst Māori and noted these should be included in question p.4.1 for future applications. The Researcher noted intellectual disability is usually quite consistent across different population groups and it is normally the perception which varies quite markedly in different cultures and this is what effects individuals seeking diagnosis or support. The Researcher noted that Māori individuals rarely seek help with regards to intellectual disability as it’s regarded differently in this group.
2. With regards to cultural issues and Māori involvement in the study the Researcher noted that there is a Māori Advisory Group as part of the service who can offer support with the study, if required.
3. The Committee the useful comments provided as part of the peer review and queried whether these had been addressed. The Researcher confirmed that the final protocol has addressed all the issues.
4. The Committee queried whether the study would include home visits. The Research confirmed that interview location would be the participant’s preference which could be at their home, a coffee shop, the vocational service they are using.
5. The Committee queried whether the Researcher had safety protocols in place for these visits. The Researcher confirmed that IDEA Services have their own risk assessments and formulas which the Research team would follow.
6. The Committee queried who would be doing the coding and transcribing for the study. The Researcher clarified that they would be using a transcribing company and the Researcher would be doing the coding and confirmed that they have adequate experience in coding.
7. The Committee noted that question r.2.5 of the application forms states data would be stored for 5 years. The Committee noted that the data must be stored for 10 years. The Researcher agreed to this.

Summary of outstanding ethical issues

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

1. The Committee noted that semi-structured interviewed would be conducted as part of the study and requested to see copies of these. Please provide the Committee with copies of study questionnaires.

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

1. Consent Form – number 10 on page 5. The Committee suggested adding “about what you tell them” after “Lizzie and Anjela will not talk to any other person”.
2. Participant Information Sheet – page 9 under “What else will happen?” the Committee suggested adding a statement to inform that participant to let the Researcher know if they do not want any information included.
3. Please provide contact details for the Māori advisory/support person the Participant Information Sheet.
4. Consent Form – the Committee suggested on the front page stating “no consent” where the red cross is.
5. Participant Information Sheet – the last page “Is it safe for me to take part in this study?” the Committee suggested considering the wording around the study being approved by an ethics committee and to consider adding some information that to suggest that some questions may make the participant feel upset and what to do in this situation.
6. Participant Information Sheet – The Committee suggested adding a contact for whom to complain / make an objection, if necessary.
7. Participant Information Sheet – the Committee queried why there is reference to Anjela learning about why people commit crime. The Researcher noted that this was to inform participants about what the Research Team are studying, and in particular Anjela would be working with people who have committed crimes. The Committee suggested removing this statement as it may deter people from participating.

Decision

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

* Please provide the Committee with copies of study questionnaires.
* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies* paragraph *6.10)*

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| **6** | **Ethics ref:** | **18/CEN/78** |
|  | Title: | Malaghan Institute of Medical Research Tissue Bank |
|  | Principal Investigator: | Dr Robert Weinkove |
|  | Sponsor: |  |
|  | Clock Start Date: | 10 May 2018 |

Philip George was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The application seeks to establish a tissue bank to store samples for future research about the immune system and its use to treat disease.

Summary of resolved ethical issues

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

1. The Committee queried the purpose of collecting ethnicity data. The Researcher noted that the study has been submitted the Capital & Coast DHB’s Research Advisory Group Māori who preferred an ethnicity question.
2. The Committee queried how the samples would be labelled. The Researcher confirmed that an application is made to the tissue governance group, this group provide the Researcher with a 3 digit study code to verify that that that study has been approved to use a tissue bank, for that particular study a participant is given a study ID by the study investigator on that particular study so that there are two identifiers.
3. The Committee queried how the collected data would be identified. The Researcher confirmed that consent forms are stored in a secure cabinet with authorised access and the samples are stored in a database system called Freezer Pro which does not contain personal identifiers, only the study code and the 3 digit participant ID.

Summary of outstanding ethical issues

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

1. The Committee noted that the Researcher proposed that the tissue stores would be stored indefinitely. The Committee noted that HDEC approval for tissue banks is given for a period of ten years, subject to the submission of annual progress reports within the timeframes set out in section 12 of the HDEC Standard Operating Procedures. Annual progress reports should contain a brief summary of the research projects for which tissue has been made available during the year.

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

1. The Committee noted that page 2 of the Participant Information Sheet states “Samples will not be stored overseas long-term”. The Committee suggest including a specific timeframe such as “Samples will not be stored overseas for longer than XX number of years”.
2. Please make it clear in the Participant Information Sheet that if the tissue does go overseas then a karakia before disposal would not be available.
3. The Committee requested that the statement on the consent form “If I decide to withdraw my samples from the tissue bank, I agree that scientific findings from my tissue up to the point when I withdraw can continue to be used” is changed to “If I decide to withdraw my samples from the tissue bank, I **understand** that scientific findings from my tissue up to the point when I withdraw can continue to be used”.
4. Page 2 of the Participant Information Sheet states “Live cell tissue samples will be frozen and stored in a freezer or cold storage tank”. The Committee queried whether this actually means collection for potential living cell cultures.. The Researcher confirmed that only frozen samples would be stored, unless samples had been pre-treated with preservatives. The Committee would like clarification whether the tissue bank will provide cells for culture from the cells that are being stored. If this is the case, the Committee suggested referring to the Auckland Regional Tissue Bank Participant Information Sheet and consent form asthey break down the cell types into living cells for tissue culturing or whether they will be stored frozen. If the cells are to be stored for live cultures please provide the Committee with information on the kind of cell culture and how they will be used.
5. The Committee requested that the consent form include clauses on how protection of confidentiality of the samples and the participant health information, such as diagnosis would occur. Please ensure it is clear to the participant that their health information may be subsequently disclosed to other researchers and how their health information will be stored and released.
6. Please include in the Participant Information Sheet and consent form that the governance committee will need to approve applications for use of the tissue samples.
7. Under the section “What will my participation in the tissue bank involve?” the Committee requested that the following statement “We can also provide information that arises from future research to you, if you would like” is replaced with a reference to providing a summary of pooled results on the study website. Please ensure the option to receive a summary of results from projects is clarified in the consent form.

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* paragraph *6.22*).

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

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| --- | --- | --- |
| **7** | **Ethics ref:** | **18/CEN/89** |
|  | Title: | Safety, Tolerability, and Pharmacokinetics of AB-506 in Healthy Subjects and Subjects with CHB Infection |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Novotech (New Zealand) Limited |
|  | Clock Start Date: | 10 May 2018 |

Professor Edward Gane and Olivia Thame were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study drug AB-506 is being developed as a potential new treatment for Chronic Hepatitis B virus infection (HBV). This is the first clinical study where AB-506 will be given to humans.
2. The main goal of the study is to determine whether AB-506 is safe and well tolerated when given at different doses.
3. The study will be conducted in 3 parts. First two parts will be conducted on approximately 28 healthy people. Third part will be conducted on 48 patients who have chronic hepatitis B .
4. Part 1 (Cohorts A and B): Each cohort will have 8 participants receiving up to 4 single escalating doses of AB-506. Within each cohort and each dose level, 6 participants will be assigned to the study drug, the remaining 2 participants will receive placebo.
5. Part 2 (cohort C):12 participants receive once daily dose of AB-506 for up to 10 days.
6. Part 3 (up to 4 cohorts): participants receive once daily dose of AB-506 for the duration of 28 days.

Summary of resolved ethical issues

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

1. The Committee commended the Researcher on their excellent response to question f.1.2 in the application form which provided details on how the study would reduce inequalities in health outcomes between different populations, and particularly between Māori, Pacific peoples and other New Zealanders
2. The Committee queried if participants enrolled in part 3 of the study would miss any treatment as part of standard care. The Researcher noted that withholding treatment for 28 days is not a risk to participants as chronic hepatitis B a slow, progressive disease and treatment is often withheld for 3-6 months between appointments.

Summary of outstanding ethical issues

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

1. The Committee noted that the application form and other study documentation states that the participant’s initials and date of birth as well as the unique study number will be included on samples, whereas the Māori section of the application form states that samples will be anonymised. The Committee requested that all study information and samples are de-identified before being sent off-shore, and if feasible, to utilise the barcoding system to ensure safety from the study sponsor and Researcher perspective.
2. Pregnant Partner Data Release Form – page 2 states “You are giving permission for the study doctors to contact the doctors involved in your pregnancy care and your baby’s care.” The Committee suggested amending this to say ‘baby’s health’ instead of ‘baby’s care’.

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

1. Participant Information Sheet (Part 1) – page 3 states “We may screen more participants than we need and so you may be asked to be a reserve. This will mean you will be asked to come to the clinic and undergo the tests and procedures until the point that we have enrolled enough eligible participants. You will then be discharged and where possible we will try to include you in a later group.” Please ensure it is clear to participants that if they are not a reserve then after 28 days they will be asked to attend the clinic.
2. Participant Information Sheet (Part 3) – page 3 under the section “What would your participation involve?” the Committee suggested moving the information on why the participant has been chosen to participate in part to the front of the Participant Information Sheet.
3. The Committee suggested including figure 1 in the protocol, especially for Part 1 and Part 3, in order to help participants understand the study design.
4. The Committee noted that the Pregnant Partner Data Release Form states “You can learn about the study drug by reading your partner’s copy of the informed consent document”. Please ensure the pregnant partner is provided with a Participant Information Sheet.
5. The Committee queried whether any human genetic testing would take place and noted inconsistency on the study documentation. The Committee noted that question r.3.1.0 indicates that there is no genetic sequencing performed in the main study whereas the page 11 of the main Participant Information Sheet suggests it is. The Researcher advised that Māori consultation requested a genetic testing be included. The Researcher agreed to rewrite this part of the Participant Information Sheets and make relevant to each part of the study.

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* paragraph 6.22).
* Please see (*Ethical Guidelines for Intervention Studies* paragraph7.2) for more information on levels of data confidentiality

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

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| --- | --- | --- |
| **8** | **Ethics ref:** | **18/CEN/92** |
|  | Title: | Safety and Immunogenicity of V114 in Adults at Risk for Pneumococcal Disease |
|  | Principal Investigator: | Dr. Diane Hanfelt-Goade |
|  | Sponsor: | Merck Sharp & Dohme (Australia) Pty Limited |
|  | Clock Start Date: | 10 May 2018 |

Charlie Stratton and Michelle Raitak were present by teleconference for discussion of this application.

Potential conflicts of interest

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

Dr Dean Quinn member declared a potential conflict of interest and the Committee decided to Dr Quinn would take no part in the discussion or decision relating to this application.

Summary of Study

1. V114-017 is a double blind, phase 3 study to evaluate safety, tolerability, and immunogenicity of V114 followed by administration of PNEUMOVAX 23 six months later in immunocompetent adults between 18 and 49 years old at increased risk for Pneumococcal Disease.
2. Participants will receive the vaccine at Visit 2 (Day 1) and will stay in the study for approximately 7 months from the time they sign the Informed Consent until the final contact.

Summary of resolved ethical issues

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

1. The Committee noted that this is a phase 3 and some phase 2 studies were complete and asked the Researcher whether they were satisfied that these studies had covered of any adverse effects from the new vaccine or whether there were any foreseeable new risks. The Research confirmed the principle investigator is happy with the profile of the new compound (V114) as are the other five principle investigators in New Zealand.
2. The Committee queried how the patient group would be identified and approached. The Researcher clarified that for their individual study recruitment would be internal via the trial unit. Doctors at the hospital will be aware of the inclusion criteria and refer to the trial unit, if appropriate. Recruitments methods for other sites would be via advertising and GP referrals. This aspect of the study would be submitted as a separate post approval form.
3. The Committee noted that p.1.1 of the application form refers to participants being asked to complete an Electronic Vaccination Report Card. The Committee queried whether paper copies would be available. The Researcher confirmed that paper copies would be available and noted that from previous experience participants have found the Electronic Vaccination Report Card quite easy to use and support and guidance would be available, if required.
4. The Committee queried whether the Electronic Vaccination Report Card were secure and if there are safeguards in place to protect participant information. The Researcher confirmed the hand-held device are compliant with the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) regulations on data security.
5. The Committee noted a very good response to question p.4.2 on cultural issues, however suggested that for future applications should consider whakamā, especially as participants with obesity and diabetes are included.

Summary of outstanding ethical issues

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

1. The Committee queried if patients’ permissions for referral is sought when referred on from hospital clinics and/or primary care. The Researcher confirmed that potential participants would be informed of the study using the new pneumococcal vaccine and their permission would be sought for a member of the Research team to contact them if interested in participating. Please provide the Committee with advertising material used in the study.
2. The Committee stated that the insurance certificate should specify the particular study title for legality purposes. Please ask the sponsor check with their insurance company that the study is actually ACC equivalent.

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

1. The Committee requested the compensation wording is used for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
2. Participant Information Sheet – Section 20 (page 8) – please remove “Decisions made in the commercial interests of the Sponsor or by local regulatory/health authorities”.
3. Participant Information Sheet/Consent Form Future Biomedical Research – please ensure it is clear at the top of the form that this aspect of the study is optional.
4. Please ensure a Māori statement is included in the Participant Information Sheet/Consent Form Future Biomedical Research. The Committee suggested referring to the HDEC template available at:[ethics.health.govt.nz](file:///C:\Users\fswindells\AppData\Local\Temp\notes58426C\ethics.health.govt.nz)
5. Please ensure the Māori support contact is separate from the section which states participants can contact an independent health and disability advocate which is a free service provided under the Health and Disability Commissioner Act.
6. Participant Information Sheet/Consent Form Future Biomedical Research - the Committee noted that page 4 states “Your samples may be stored for longer than 20 years if the Sponsor needs to answer questions from a regulatory or government agency. If this happens, samples will be stored until these questions have been answered.” The Researcher agreed to reword this section this section to clarify that the standard is 20 years but this may be longer if there is a regulatory requirement to do so.

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* paragraph 6.22).
* Please provide the Committee with advertising material used in the study.

This following information will be reviewed, and a final decision made on the application, by Mrs Jane Wylie and Mrs Helen Walker.

## 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:

|  |  |
| --- | --- |
| **Meeting date:** | 26 June 2018, 08:00 AM |
| **Meeting venue:** | Room GN.6, Ground Floor, Ministry of Health, 133 Molesworth 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 4:00pm