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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 06 March 2018 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 08 February 2018 |
| 12:10:pm | General business:   * Noting section of agenda |
| 12:15pm | New applications (see over for details) |
|  | i 18/NTB/8  ii 18/NTB/25  iii 18/NTB/26  iv 18/NTB/27  v 18/NTB/33  vi 18/NTB/35  vii 18/NTB/36  viii 18/NTB/37  ix 18/NTB/40 |
| 4:10pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2015 | 01/07/2018 | Present |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 20/05/2017 | 20/05/2020 | Present |
| Mrs Kate O'Connor | Lay (ethical/moral reasoning) | 14/12/2015 | 14/12/2018 | Present |
| Dr Nora Lynch | Non-lay (health/disability service provision) | 24/07/2015 | 24/07/2018 | Present |
| Mrs Leesa Russell | Non-lay (intervention studies), Non-lay (observational studies) | 14/12/2015 | 14/12/2018 | Apologies |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Apologies |
| Mrs Jane Wylie | Non-lay (intervention studies) | 20/05/2017 | 20/05/2020 | Present |

## Welcome

The Chair opened the meeting at 12pm and welcomed Committee members, noting that apologies had been received from Mr John Hancock.and Mre leesa Russell

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 08 February were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/NTB/8** |
|  | Title: | Lens protein adhesives for use in ocular surgery |
|  | Principal Investigator: | Professor Trevor Sherwin |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 16 January 2018 |

Professor Trevor Sherwin and Ms Judith Dyson were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates novel techniques for the extraction of cystallin proteins from donor lenses. The resulting product has potential therapeutic uses for corneal repair and intraocular drug delivery
2. Donor lenses will be obtained from living donors undergoing surgery and from organ and tissue donors through Organ Donation New Zealand.

Summary of ethical issues (resolved)

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

1. The Committee noted that funding had been granted from the Ministry of Business Innovation and Employment for the project.
2. The Committee asked how recruitment of donors who are undergoing surgery will work. The Researcher explained that persons scheduled for cataract surgery will be approached once they are on the public waiting list or by private ophthalmologists when surgery is planned
3. The Committee asked where patients will be recruited from. The Researcher explained that public patients at ADHB and private patients will be recruited.
4. The Committee asked how far in advance patients will be approached. The Researcher explained that patients will be approached about several weeks before their surgery and so will have enough time to discuss with their family and whānau.
5. The Committee queried why the Researchers need to access health information as part of the study. The Researcher explained that this is to ensure that they only receive lenses from patients who do not have a condition that would mean the lens components may be unsuitable for use.. The Committee noted that the information will be provided in a de-identified form to the researchers.

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 asked about how donated cadaveric tissue will be sourced. The Researcher explained that people can consent for their eyes to be donated. The Committee asked that the Researcher clarify that consent is sought for the use of lenses as part of the organ donation process if possible.
2. The Committee asked that the protocol be updated to include all study procedures and rules for data storage etc. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
3. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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

1. Remove tickboxes except for those items where ticking no would not exclude participants.
2. Disclose that there is a commercial interest, who that is, and that participants will not receive any benefits from any findings from the project.
3. Please include the option that participants can receive a lay summary of the study if they wish.
4. Remove statements about pregnancy or tissue going overseas.
5. Please state where tissue will be going and who will be using it.
6. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
7. Please rewrite the final bullet on p2 that explains what the study will involve.
8. Explain that the study will not cost anything but that there is also no therapeutic benefit for participants.
9. Explain that participants will still have to pay for post-operative medication or surgery.
10. Explain specifically when it will be no longer possible for participants to withdraw from the study.
11. Please add details for a Māori cultural support person.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please provide an updated study protocol. (*Ethical Guidelines for Observational Studies* *para 5.11*)
* Please seek consent for the use of lenses from organ/tissue donors. *(Ethical Guidelines for Observational Studies para 6.11)*

This following information will be reviewed, and a final decision made on the application, by Mrs Kate O’Connor and Mrs Stephanie Pollard.

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| **2** | **Ethics ref:** | **18/NTB/25** |
|  | Title: | Resolving the research gap - what factors may influence cleft lip and cleft palate? |
|  | Principal Investigator: | Associate Professor John Thompson |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 01 February 2018 |

Associate Professor John Thompson, Professor Peter Stone, and Ms Louise Ayrey were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates genetic and environmental interactions for Cleft Lip and Cleft Palate in New Zealand.

Summary of ethical issues (resolved)

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

1. The Committee noted that that the issues identified in the previous decline letter had been addressed.
2. The Committee asked how ante-natal recruitment for the study would work. The Researchers explained that once a case is identified antenatally by ultrasound, the cleft management unit was notified and then the unit will contact the Researchers and an independent nurse will approach the family.
3. The Committee asked if Future Unspecified Research might occur with any samples collected during this study. The Researchers confirmed that this is not the case.

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 stated that they had concerns with a 25 NZD reimbursement per successful recruitment and that this presents a risk for coercion. The Committee asked that the researchers amend the protocol so as to provide a single payment based on a forecasted number of recruitments. (*Ethical Guidelines for Observational Studies* *para 5.11 & 6.11*).
2. The Committee also asked that researchers consider a family koha following interviews which could take the form of a voucher for product or service which would benefit all members. (*Ethical Guidelines for Observational Studies* *para 6.25* )
3. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
4. Please provide evidence that Māori consultation has been completed. *(Ethical Guidelines for Observational Studies para 4.4)*

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

1. Add that the questionnaire may take up to 60 minutes.
2. Remove potentially leading statements such as describing the research as important.
3. Change the statement about ‘the care that you are receiving’.to refer to the care the child is receiving.
4. The Committee suggested the information sheet be condensed as it was quite long and doubled up on information.
5. Please remove information from the consent form that is a duplication of information already explained in the information sheet.
6. Please check that no new information is introduced in the consent form. All study information should be in the information sheet.
7. Remove the requirement that participants initial each clause on the consent form.
8. Remove tickboxes for those items that are not truly optional.
9. Remove the statement from the >16 information sheet that refers to ‘many years of treatment and lots of surgeries’ as it is potentially upsetting and unnecessary.
10. Specify researchers will only follow up for one year.
11. Explain that participants can take a break during the interview.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please provide evidence that Māori consultation has been completed. *(Ethical Guidelines for Observational Studies para 4.4)*
* Please amend the study protocol around reimbursement. (*Ethical Guidelines for Observational Studies* *para 5.11 & 6.11* )
* Please consider adding a koha aspect to the project in line with the suggestions made by the committee. (*Ethical Guidelines for Observational Studies* *para 6.25)*

This following information will be reviewed, and a final decision made on the application, by Ms Maliaga Erick and Dr Nora Lynch.

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| **3** | **Ethics ref:** | **18/NTB/26** |
|  | Title: | Unravelling mechanisms of cross protection to gonorrhoea |
|  | Principal Investigator: | Dr Fiona Radcliff |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 22 February 2018 |

Dr Helen Petoussis Harris and Dr Fiona Radcliff were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates whether or not the MENZB vaccine for N. meningitidis also provides cross-reactivity to N.gonorrhoeae.
2. The samples used in the study have been collected as part of previous clinical trials and no informed consent exists for their use outside of this setting.

Summary of ethical issues (resolved)

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

1. The Committee noted that the Researchers had obtained legal advice around the use of the tissue samples that stated that the use of the samples is consistent with New Zealand law.
2. The Committee asked the Researchers to justify their rationale for the use of tissue in this way. The Researchers explained that they cannot practicably seek consent as the tissue is de-identified and there are no other identifying or contact details associated with it. The Researchers also stated that the tissue is of high scientific value as it is the only extant tissue from those who have been vaccinated with an effective meningitis vaccine.
3. The Committee asked what steps had been taken by the Researchers to determine that the use of tissue is acceptable to Māori. The Researchers stated they have spoken to Māori community groups and Māori colleagues.
4. The Committee asked if the results of the study might be fed back to the community. The Researcher explained that they have done this with several previous studies and they are working with Iwi to help guide feedback to the community.
5. The Committee asked if the results of the study might be commercialised. The Researcher explained that they would not.

Decision

This application was *approved* by consensus.

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| **4** | **Ethics ref:** | **18/NTB/27** |
|  | Title: | In-Vitro Blood Reactivity to Xenoantigens |
|  | Principal Investigator: | Professor Stephen Munn |
|  | Sponsor: | NZeno Limited |
|  | Clock Start Date: | 22 February 2018 |

Professor Stephen Munn and Dr Paul Tan were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates serum reactivity to porcine xenoantigens using a glycochip in New Zealand patients with end stage renal failure.

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 Māori people are overrepresented in the study population. The Researcher explained that Māori have unique tissue types that make it difficult to find donor matches and that this study could eventually help reduce these wait times.
2. The Committee asked how recruitment for the study would work. The Researchers explained that nephrologists will be recruiting and explaining the project.
3. The Committee asked how long patients would have to decide if they wish to participate. The Researchers explained that patients would have as long as they wished.
4. The Committee asked if individual results will be fed back to participants. The Researcher stated that they would not.
5. The Committee noted that there could be cultural concerns with the mixing of human and pig’s blood or tissue. The Researchers stated that they had consulted with Jewish and Muslim groups and that these groups were not opposed to the research.

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 asked that evidence of Māori consultation be provided as there are cultural concerns for Māori with the study. *(Ethical Guidelines for Observational Studies para 4.4)*
2. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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

1. Clarify the statement about access to patient medical records to inform that only access to the hospital records would be needed.
2. Clearly state that human tissue will be mixed with porcine tissue and that some persons may object to this.
3. Check that terms unsuitable for lay persons, such as xenotransplantation or antigen, are explained in a lay-friendly way when first used.
4. Remove reference to genetic tissue from the Māori tissue statement.
5. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whānau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
6. Please explain that data will be held in identifiable form, or clarify that data will not be held in identifiable form as only year of birth is needed.
7. Please create a lay-friendly title.

Decision

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

* Please provide evidence that Māori consultation has been completed. *(Ethical Guidelines for Observational Studies para 4.4)*
* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

This following information will be reviewed, and a final decision made on the application, by Mrs Kate O’Connor and Dr Stephanie Pollard.

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| **5** | **Ethics ref:** | **18/NTB/33** |
|  | Title: | Do Cardio selective Beta-Blockers Affect the Use of Beta-Agonist Inhalers Following Bronchoconstrictionin Asthma? |
|  | Principal Investigator: | Dr Miriam Bennett |
|  | Sponsor: | Respiratory Research Unit Waikato Hospital |
|  | Clock Start Date: | 22 February 2018 |

Dr Miriam Bennett and Dr Cat Chang 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 investigates the effects of cardio selective Beta-Blockers on airways reactivity and on the response to Beta-Agonist inhalers following controlled bronchoconstriction in asthma.

Summary of ethical issues (resolved)

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

1. The Committee queried the design, in particular the absence of a washout period between crossover arms and the use of a third nonrandomised arm in the trial. The Researcher explained that they have used crossover trials without a washout period previously when investigating airways reactivity The third arm of the design will help improve the scientific validity of the study and to allow an unblinded collaborator to check and advise blinded individuals.
2. The Committee queried how long the study will run for. The Researcher explained that the project will run for one year.
3. The Committee asked how recruitment for the study would be managed. The Researcher stated that they have a database of interested persons, facebook advertising, and have approached local clinics.

Summary of ethical issues (outstanding)

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

1. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. The Committee asked that a protocol be developed around communication between the unblinded assessor and participants to help maintain the blind. (*Ethical Guidelines for Intervention Studies* *para 5.41*).
3. The Committee asked if the study was powered. The Researcher stated that they have confirmed that their sample size is powered and that the design based on a previous study that was shown to be statistically powered. Please provide the sample size calculation. (*Ethical Guidelines for Intervention Studies* Appendix 1)
4. The Committee stated that there should be an independent data safety monitoring committee. Please provide an updated data safety monitoring plans *(Ethical Guidelines for Intervention Studies para 6.50).*

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

1. Explain that data will be given a code to help protect privacy and that a master code list will be held separately.
2. Clearly state what capsules are being referred to on page 3.
3. State which beta blockers will be used as the intervention and which screening beta blocker will be used.
4. Explain that a pregnancy test will occur
5. Explain how the symptom diaries work and that the ACQ5 questionnaire will happen.
6. Please rephrase the aim of the study
7. Clearly state what participants should do if they have an exacerbation of their condition.
8. Include information from f.2 of the application 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* *para 6.22*).
* Please provide the sample size calculation. (*Ethical Guidelines for Intervention Studies* Appendix 1)
* Please provide an updated data safety monitoring plans *(Ethical Guidelines for Intervention Studies para 6.50).*
* Please amend the study protocol taking into account the suggestions made by the Committee. (*Ethical Guidelines for Intervention Studies* *para 5.41*)

This following information will be reviewed, and a final decision made on the application, by Mrs Maliaga Erick and Dr Stephanie Pollard.

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| **6** | **Ethics ref:** | **18/NTB/40** |
|  | Title: | A study on the effects of oral everolimus alone or in combination with BEZ235 on the immune response to influenza vaccine in the elderly |
|  | Principal Investigator: | Dr Simon Carson |
|  | Sponsor: | Pharmaceutical Solutions Ltd |
|  | Clock Start Date: | 22 February 2018 |

Dr Simon Carson 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 study investigates the effects of oral everolimus alone or in combination with BEZ235 on the immune response to influenza vaccination in the elderly at increased risk of influenza illness.

Summary of ethical issues (resolved)

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

1. The Committee noted that the Researcher is experienced with consenting the study population.
2. The Committee asked if the study population will be all over 65s or only those who are over 65 and vulnerable to the flu. The researcher stated it is those who are over 65 and at high risk of catching influenza or at high risk of flue complications.
3. The Committee noted the project is going to the Standing Committee on Therapeutic Trials.

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 professional indemnity document was not submitted, just the signed page of the protocol.. Please provide an updated MPs certificate.
2. The Committee queried the Sponsor insurance certificate which lacks NZ as a named trial site, does not specifically name this trial and expires March 28 2018.
3. The Committee had concerns about the length of the information sheet and the way the information is presented. The Committee asked that the information sheet, consent form, and advertisement be amended according to their suggestions. (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

1. Add the length of the study and how many visits to the advertisement.
2. Explain more clearly that participants in group b will have their vaccination delayed.
3. Please shorten the information sheet and remove duplications or overly technical information.
4. Shorten the amount of information per side effect, one paragraph is too long per effect.
5. The Committee suggested a simplified table of study procedures that explains the where, what will happen, and for how long for each study visit or interaction.
6. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
7. Explain that group B will have to agree to a limited genetic analysis and that if they do not agree to this then they will be unable to participate.
8. Clarify what type of genetic analysis will be performed and explain what will happen in the event of incidental findings. Seek consent for these findings to be fed back to participant’s GPs.
9. Explain the confidentiality of data in more detail – who will have access to identifiable study data and what form will data be held in.
10. Explain that the study drug has been tested in humans.
11. Check that the font is consistent throughout the documents and large enough to be read by the elderly.
12. On p3 of the future unspecified use information sheet explain that data going overseas would be de-identified and for the purposes of FDA audit and not for research.
13. State that enrolment is competitive and that participants may not actually get into the trial after consenting and screening.

Decision

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

* Please amend the advertisement, information sheet, and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide an updated medical indemnity document and evidence of sponsor insurance. *(Ethical Guidelines for Intervention Studies section 8)*

This following information will be reviewed, and a final decision made on the application, by Mrs Tangihaere MacFarlane and Dr Nora Lynch.

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| **7** | **Ethics ref:** | **18/NTB/36** |
|  | Title: | Comparison of Mindfulness and Exercise During and After Cancer Treatment |
|  | Principal Investigator: | Ms Virginia Eggleston |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 February 2018 |

Ms Virginia Eggleston 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 study investigates the effects of mindfulness and exercise on psychological and physical wellbeing in people with cancer during and after treatment.

Summary of ethical issues (resolved)

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

1. The Committee queried if people with metastatic cancer will be excluded and how. The Researcher explained they would be checking with participant’s doctors to rule out these people.

Summary of ethical issues (outstanding)

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

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

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

1. Please rephrase the text of the advertisement in a way that does not imply therapeutic benefit.
2. Please add text to the advertisement that explains that those with metastatic cancer will not be able to participate.
3. The Committee suggested a more appropriate picture for the advertisement.
4. Please add a better introductory sentence that explains what the purpose of the study is.
5. Please explain that reasonable travel costs will be refunded.
6. Please explain that there will be some homework tasks.
7. Explain what a body composition measure is and that one will occur.
8. 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.”*
9. Please remove reference to medical clearance from the consent form as participants should have been signed off as part of screening.
10. Please add a local Māori cultural support person’s details to the information sheet.

Decision

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

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

This following information will be reviewed, and a final decision made on the application, by Mrs Kate O’Connor and Dr Nora Lynch.

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| **8** | **Ethics ref:** | **18/NTB/37** |
|  | Title: | AEGIS-II - Study to Investigate CSL112 in Subjects with Acute Coronary Syndrome. (AEGIS-II). |
|  | Principal Investigator: | Professor Harvey Douglas White |
|  | Sponsor: | CSL Behring LLC |
|  | Clock Start Date: | 22 February 2018 |

Dr Caroline Alsweiler and Dr Darshana Karelia were present in person and Dr Ruth Lucas 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 study is a phase 3, multicentre, double-blind, randomized, placebo-controlled, parallel-group study to investigate the efficacy and safety of CSL112 in subjects with acute coronary syndrome.

Summary of ethical issues (resolved)

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

1. The Committee queried how the recruitment process would work. The Researcher explained that after patients have been stabilised then patients will be approached and given the information and an opportunity to discuss the project with family and whānau.
2. The Committee noted that an American patient advocacy group had been consulted.
3. The Committee asked if all participants would be able to provide informed consent. The Researchers confirmed that they will only be recruiting patients who can provide full informed consent.
4. The Committee asked how patient distress would be managed. The Researcher explained that their team are very experienced at recruiting patients in this setting and will not be approaching distressed patients.
5. The Committee noted the project is being reviewed by the Standing Committee on Therapeutic Trials.

Summary of ethical issues (outstanding)

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

1. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. The Committee stated that studies that may be stopped out of commercial interest are not able to be approved in New Zealand. Please remove this as a potential stopping criteria. (*Ethical Guidelines for Intervention Studies* *para 6.65*).

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

1. Please localise the information sheet to New Zealand English, for example refer to HDECs and not IRBs.
2. Please create a lay-friendly title.
3. Explain what a placebo is.
4. Remove requirements to initial, for example on page 6, from the information sheet.
5. Remove references to United States law.
6. Explain what the FDA is when the term is first used.
7. Remove references to the study being terminated for commercial reasons.
8. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
9. Remove references to future unspecified use and use of biologic samples from the main ICF and put these in the future unspecified use information sheet. Please make sure that all of these items are adequately explained in the future unspecified use information sheet.
10. Clarify what will happen with incidental findings and give the option for these results to be returned to participants if they choose.
11. Explain that there is currently no information about the study drug and breastfeeding and participants should therefore refrain from breastfeeding.
12. Check that information is not repeated in the information sheets.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please confirm that the study will not be terminated for commercial reasons and remove this as a stopping criterion. (*Ethical Guidelines for Intervention Studies* *para 6.65*).

This following information will be reviewed, and a final decision made on the application, by Ms Tangihaere Macfarlane and Mrs Stephanie Pollard.

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| **9** | **Ethics ref:** | **18/NTB/35** |
|  | Title: | (duplicate) Effective therapy method for obstructive sleep apnea |
|  | Principal Investigator: | Professor Ahmed Al-Jumaily |
|  | Sponsor: | Institute of Biomedical Technologies |
|  | Clock Start Date: | 22 February 2018 |

Professor Ahmed Al-Jumaily and Ms Dahlya Al-Mohammadin were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates the effect of continuous positive airway pressure (CPAP) using oscillating CPAP at 70% of the participant’s usual treatment level compared with standard non humidified CPAP at the participants usual pressure level. Outcomes studied will be airway dryness and. number of arousals.

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 participants will be recruited through Fisher & Paykel’s database of CPAP users. Participants will receive a letter asking them if they are interested.

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 stated that this study is considered a commercially-sponsored intervention study and that ACC-equivalent insurance and professional indemnity will need to be provided. Please provide evidence that these are held by the sponsor or co-ordinating investigator. *(HDEC Standard Operating Procedures paras 155 – 159 & Ethical guidelines for Intervention Studies para 4.5)*
2. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
3. Please provide evidence of favourable independent peer review of the study protocol from a respiratory physician. (*Ethical Guidelines for Intervention Studies* Appendix 1)
4. Please provide an updated recruitment protocol that involves researcher’s not screening health information. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
5. The Committee had concerns over the scientific basis of reducing participant’s CPAP pressure to 70% as 100% pressure has been established as what is best for their condition. Please provide the scientific basis for this decision. (*Ethical Guidelines for Intervention Studies* *para 5.5*)
6. The Committee queried. the basis for statements in the protocol and PISC that prolonged use of CPAP may produce a stroke. This might result in people being reluctant to continue with CPAP which had been prescribed for them. Please provide evidence to support this statement or modify the wording in the documents.
7. Please provide evidence that Māori consultation is being sought or obtained. *Ethical Guidelines for Intervention Studies para 5.58)*

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

1. Justify or remove the inclusion of statements about risk of stroke. Please provide evidence that this is the case or remove statements about this from the information sheet. Remove the contact details of the executive secretary for the study.
2. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured as a result of treatment given as part of this study, which is unlikely, you* ***won’t*** *be eligible for compensation from ACC. However, compensation would be available from the study’s sponsor, [x], in line with industry guidelines. We can give you a copy of these guidelines if you wish. You would be able to take action through the courts if you disagreed with the amount of compensation provided. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
3. Please use Statistics New Zealand's ethnicity classifications when collecting ethnicity data to ensure the options available are suitable for New Zealand participants. These classifications are: New Zealand European, Maori, Samoan, Cook Islands Maori, Tongan, Niuean, Chinese, Indian, Other (such as Dutch, Japanese, Tokelauan) please state.
4. Please check the initial contact letter for readability.
5. Change references to patients to participants.
6. Please simplify the language of the information sheet. For example participants do not need to be told the project is an intervention study.
7. Explain that compensation is pro-rata and that if participants only stay for one night then they will only receive eighty dollars.
8. Explain that Fisher and Paykel will receive a copy of the study data.
9. State that health information associated with the study will be held for ten years and then destroyed.
10. Remove yes/no boxes from the consent form except for those items that are truly optional.

Decision

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

* Please provide evidence of sponsor insurance and professional indemnity on behalf of the co-ordinating investigator. *(HDEC Standard Operating Procedures paras 155 – 159 & Ethical guidelines for Intervention Studies para 4.5)*
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide evidence of favourable independent peer review of the study protocol from a respiratory physician. (*Ethical Guidelines for Intervention Studies* Appendix 1)
* Please provide an updated recruitment protocol that involves researchers not screening health information. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
* Please justify reducing participant’s CPAP pressure to 70% as 100% pressure has been established as what is best for their condition. (*Ethical Guidelines for Intervention Studies* *para 5.5*)
* Please provide evidence that Māori consultation is being sought or obtained. *Ethical Guidelines for Intervention Studies para 5.58).*

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

## 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:** | 03 April 2018, 08:00 AM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

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 4:10pm