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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 07 November 2017 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:15pm | Confirmation of minutes of meeting of 05 September 2017 |
| 12:30pm | New applications (see over for details) |
|  | i 17/NTB/189  ii 17/NTB/195  iii 17/NTB/198  iv 17/NTB/197  v 17/NTB/199  vi 17/NTB/206  vii 17/NTB/209  viii 17/NTB/210  ix 17/NTB/212  x 17/NTB/213  xi 17/NTB/214  xii 17/NTB/215 |
| 5:15pm | General business:   * Noting section of agenda |
| 5:30pm | 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 | Apologies |
| 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 | Present |
| Mrs Jane Wylie | Non-lay (intervention studies) | 20/05/2017 | 20/05/2020 | Present |
| Ms Toni Millar | Lay (consumer/community perspectives) | 11/11/2016 | 11/11/2019 | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Miss Tangihaere Macfarlane, Mrs Leesa Russell, and Mr John Hancock.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Ms Toni Millar confirmed their eligibility, and were 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 5 September 2017 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **17/NTB/189** |
|  | Title: | BEST - CLI Trial |
|  | Principal Investigator: | Mr Andrew Hill |
|  | Sponsor: | New England Research Institutes, Inc. |
|  | Clock Start Date: | 05 October 2017 |

Mr Andrew Hill 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 study is a randomized, multicenter, controlled trial to compare best endovascular versus best surgical therapy in patients with critical limb ischemia.
2. 20 patients will be recruited in New Zealand.

Summary of ethical issues (resolved)

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

1. The Committee noted that both arms of the study are standard care at the study locality.
2. The Committee noted that participant follow up for the study will last for two years and that the project may be extended so that all participants receive a full two years’ followup.
3. The Committee queried if the timelines for study participation would be different depending on which arm participants were randomised to. The Researcher confirmed that this was the case.

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

1. Please make it clear that all risks associated with each arm of the study are associated with standard care.
2. Please amend the statement on page three of the information sheet that begins “After you have read through” to make it clear that while patients can discuss with family and whānau the only person that can provide consent is the patient themselves.
3. Please include that reasonable travel expenses will be reimbursed for visits extra to standard care..
4. Please correct references to the approving ethics committee to Northern B or NTB.
5. Specify that information collected will be sent overseas in a de-identified format.
6. Please include the rates of incidence for risks.

Decision

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

The non-standard conditions are:

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

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| **2** | **Ethics ref:** | **17/NTB/214** |
|  | Title: | Swallowing skill-training in neurodegenerative disease |
|  | Principal Investigator: | Ms Emma Burnip |
|  | Sponsor: | Rose Centre for Stroke Recovery and Research |
|  | Clock Start Date: | 26 October 2017 |

Ms Emma Burnip 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 skill-based dysphagia therapy as an intervention for individuals with Amyotrophic Lateral Sclerosis or Huntington’s Disease.

Summary of ethical issues (resolved)

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

1. The Committee queried how participants would be recruited. The Researchers explained that motor neurone and Huntingdon’s disease associations will help identify if people are interested and then have them contact the Researcher.
2. The Committee asked if all participants would be able to provide informed consent. The Researcher stated that they would.
3. The Committee asked about the different age groups for participation. The Researcher explained that this is due to the different diseases in the study.

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 potential participants must be confirmed as able to provide informed consent by their neurologist. (*Ethical Guidelines for Intervention Studies* *para 6.9*).
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 the outcome of Māori consultation. (*Ethical Guidelines for Intervention Studies* *para 4.9)*

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

1. Please amend the information sheet to explain that reasonable travel costs will be reimbursed. The Committee suggested using a formula such as the IRD mileage reimbursement rate.
2. Include that participants can continue to have access to the intervention after the study has finished.
3. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
4. Please explain videofluroscopy as the risk for pregnant participants and what this means.
5. Please provide contact details for the Health and Disability Commissioner’s Advocacy Service, the Health and Disbility Ethics Committees, and Māori cultural support in the information sheet. The First two may be found in the HDEC template information sheet and consent form.
6. Please refer to the study skill-training as an intervention or training and not as treatment.
7. Please correct the age limit on the ALS information sheet.
8. Please include confidentiality statements about data generated in this study. These can be found in the HDEC template information sheet.
9. Clarify when the MOCA will be administered, by whom and how the result will be used.
10. Please add page and version numbers to the footer.

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 outcome of Māori consultation. (*Ethical Guidelines for Intervention Studies* *para 4.9)*
* The Committee asked that potential participants must be confirmed as able to provide informed consent by their neurologist.

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

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| **3** | **Ethics ref:** | **17/NTB/215** |
|  | Title: | (duplicate) Upper limb muscle characteristics in Cerebral Palsy |
|  | Principal Investigator: | Mr Lukas Wiedemann |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 26 October 2017 |

Mr Lukas Wiedemann 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 upper limb muscle characteristics in children with Cerebral Palsy. It is a case-control study with age and gender-matched typically developed children.

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 had responded to the concerns raised by the Southern HDEC as part of their decline decision.
2. The Committee asked about how participants would be identified and contacted. The Researcher explained that the case group will be recruited from patients who are seen by the patient coordinator (a paediatrician at the Wilson Centre) and those who are eligible will be approached by the coordinator and asked about participation. The Researcher will send the information sheet and consent form to those who 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 if the Researcher intends to visit participants at their homes then the Committee will need to be satisfied that there are adequate safety procedures in place. Please provide the safety protocol for visiting patients in their homes. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
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. The Committee requested that the physical signing of the consent form should be delayed until participants have had a face to face conversation with the researcher. *Ethical Guidelines for Intervention Studies* *para 6.22*)
4. Please specify where EMG electrodes and tonometer will be placed on participants’ arms in the study protocol in order to generate consistent results between subjects. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
5. The Committee stated that health information must be retained for ten years after participants turn 16. *(Health (Retention of Health Information) Regulations 1996)*

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

1. The Committee requested that the phrase cerebral palsy with spasticity be used in order to avoid negative connotations with the term spastic cerebral palsy.
2. Clarify that all participants will receive at least one phonecall to discuss the study.
3. The Committee suggested the Researcher check with children for the readability of the document.
4. Explain that there will be no electric shock from electrodes and where they will be placed.
5. Remove references to pushing a footplate.
6. Participants under the age of 16 should receive an assent form. Those who are over 16, or competent to consent, should sign the full adult consent form not a separate competent adolescent document.
7. Make sure information sheets refer to the correct person, either “you” or “your child“.
8. Remove the statement “Hereafter referred to as you” and correct the references after this.
9. Use lay terms such as doctor.
10. Please remove all tickboxes from the consent forms except for those that are truly optional and would not exclude participants from the study.
11. Remove statements about future benefits for people with cerebral palsy as this may be considered a leading statement.

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 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 Jane Wylie and Ms Kate O’Connor

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| **4** | **Ethics ref:** | **17/NTB/197** |
|  | Title: | Connected Catheter Clinical Feasibility Study (CFS) |
|  | Principal Investigator: | Mr. Giovanni Losco |
|  | Sponsor: | Spinal Singularity Inc |
|  | Clock Start Date: | 26 October 2017 |

Mr. Giovanni Losco 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 single arm open study of a new urinary catheter for men with a neurogenic bladder who currently use either clean intermittent catheterisation ~ 3 times daily- or have an indwelling catheter. This is a first-in-human study.

Summary of ethical issues (resolved)

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

1. The Committee queried how recruitment for this study would work. The Researcher explained that the project will be advertised to people who attend the spinal unit at Canterbury District Health Board
2. The Committee asked if the Researcher was formally trained in the use of the device. The Researcher explained that they will be undergoing training once ethics approval has been acquired.

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. Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1)
3. Please explain what restrictions on publication have been placed on the trial by the study sponsor. (*Ethical Guidelines for Intervention Studies* *para 7.18*).
4. Please provide criteria for study termination. (*Ethical Guidelines for Intervention Studies* *para 6.64*).
5. The Committee stated that using initials and date of birth when sending the data to the study sponsor did not provide sufficient anonymity for participants and requested that a study code be used instead. (*Ethical Guidelines for Intervention Studies* *para 7.2*).
6. Please provide details of compensation arrangements.

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 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.”*
2. State that there is a hypothesised reduced risk of infection.
3. Remove the statement from page two about benefits outweighing the risks as this is not yet known.
4. Please include how infections or incidental findings will be managed.
5. Check for and remove statements that imply that participants are responsible for device failure.
6. Include a statement that the contribution of those who do not proceed to home use was valuable.
7. Include wording to reassure participants that they can withdraw at any time and that the research doctors will be available if needed.
8. Remove the requirement that withdrawal must be in writing.
9. Correct references to the Northern B (NTB) ethics committee.
10. Correct statements that participants will be unable to look at and correct their health information. New Zealand law allows persons to do this.
11. Check the information sheet and consent forms for grammatical errors.
12. Remove statement from page three about obtaining contact details for a relative in case the participant has passed away, to a wording which indicates the contact for a relative is requested in case contact is lost with the participant.

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 evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1)
* Please provide criteria for study termination. (*Ethical Guidelines for Intervention Studies* *para 6.64*).
* Please explain what restrictions, if any, have been placed on publication. (*Ethical Guidelines for Intervention Studies* *para 7.18*).
* Please use a study code be used instead of participants’ initials to ensure confidentiality of data. (*Ethical Guidelines for Intervention Studies* *para 7.2*).
* Please provide criteria for study termination. (*Ethical Guidelines for Intervention Studies* *para 6.64*).

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

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| **5** | **Ethics ref:** | **17/NTB/199** |
|  | Title: | CPAP Interface Product Evaluation |
|  | Principal Investigator: | Dr Arun Nair |
|  | Sponsor: | Fisher & Paukel Healthcare |
|  | Clock Start Date: | 26 October 2017 |

Ms Mrinal Murali and (there was a second F +P person there too) 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 evaluates a new device in infants who are receiving continuous positive airway pressure (CPAP) therapy at neonatal intensive care units in Auckland and Waikato.

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 recruitment would occur, noting that parents were in the midst of a distressing time and would need time to think about the research, and not mistake it for care, especially if approached by NICU staff. The committee suggested that an information poster about the research would aid familiarity.

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. Please provide information sheets and consent forms for nurses. (*Ethical Guidelines for Intervention Studies section 6)*
3. Please define in the protocol where likely changes to the device will be made. (*Ethical Guidelines for Intervention Studies section 5.41)*
4. Please provide updated evidence of Coordinating Investigator Indemnity cover.
5. Please address how the cultural issues associated with tapu of the head will be dealt with. (*Ethical Guidelines for Intervention Studies section 4.9)*
6. Please provide evidence of favourable independent peer review of the study protocol as the committee were not satisfied with the review provided. (*Ethical Guidelines for Intervention Studies* Appendix 1)

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

1. Please consider using a photograph to help show how the device works.
2. Check the information sheets for lay people for readability.Terms such as CPAP interface, patient interface and prototype may not be understood..
3. Explain that the 3D scan team will not visit every child and will only visit once.
4. Please check that the device is clearly and simply explained.
5. Make sure that the information sheet for parents refers to the child as the participant.

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 evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1)
* Please amend the study protocol taking into account the suggestions made by the Committee. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
* Please provide information sheets and consent forms for nurses. (*Ethical Guidelines for Intervention Studies section 6)*
* Please address how cultural issues associated with this study will be managed. (*Ethical Guidelines for Intervention Studies para 4.9)*

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

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| **6** | **Ethics ref:** | **17/NTB/206** |
|  | Title: | SACNZS |
|  | Principal Investigator: | Dr Donald Campbell |
|  | Sponsor: | Ministry for Primary Industries |
|  | Clock Start Date: | 26 October 2017 |

Dr Donald Campbell 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. This is a case-control study aiming to identify risk factors for contracting campylobacterial disease from an environmental or animal source and the transmission pathways.

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 disease in question is a notifiable disease and that the researcher is interested in the circumstances around contracting the disease.

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. Please provide the control group questionnaire to be administered by a survey company.
3. Please provide an amended case group telephone introduction script which clearly explains the difference between the public health questions which are asked of every notified case of campylobacter infection and the voluntary research questions which are entirely optional.
4. The Committee noted that there would be tissue collected in this project, but only in order to isolate campylobacter and that the tissue itself would not be used. The Committee asked that the protocol be updated to explain the arrangements for use, storage, and disposal of tissue. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
5. Please provide age-appropriate assent sheets for child participants under the age of 16.

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

1. In the telephone scri[pt introducing the research please explain that participants will need to take an extra ten minutes to answer questions associated with this project.
2. Explain the arrangement for use, storage, and disposal of tissue. Include an option for disposal with karakia if possible or explain that this will not be an option.
3. Please explain that previously given samples will also be used in this study.
4. Include that participants will be able to receive a lay summary of the study if they wish and include this as an option in the consent form.
5. Explain that genomic testing is on the bacteria and not participants.
6. Clarify that the only people who will receive identifiable health information and contact details will be the public health service.

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 amend the study protocol taking into account the suggestions made by the Committee. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
* Please provide the control group questionnaire.

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

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| **7** | **Ethics ref:** | **17/NTB/209** |
|  | Title: | The SCORED Trial |
|  | Principal Investigator: | Dr John Baker |
|  | Sponsor: | Sanofi Aventis Australia Pty Ltd |
|  | Clock Start Date: | 26 October 2017 |

Dr John Baker and Ms Catherine Howie were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is an industry-sponsored Phase 3 DBPCRT of an oral anti diabetic agent for Type 2 diabetes, sotoglifozin.
2. Participants are Type 2 diabetics who are over 18 years old and who have mild through to moderately severe renal impairment (GFR 25-60 ml/min) that do not yet need renal replacement 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 asked if participants who show clear benefit from the study drug could continue to receive it after the study ends. The Researcher stated that this was not possible.

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 it was unclear why information collected in the study would need to be retained for 25 years after the study has concluded. Please provide justification for this. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
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 the outcome of Māori consultation. (*Ethical Guidelines for Intervention Studies* *para 4.9*).
4. The Committee had concerns about the sponsor being able to withdraw participants for any reason. Please explain why this is included as it may prejudice the scientific value of the study. (*Ethical Guidelines for Intervention Studies* Appendix 1)

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

1. Please localise English in the information sheet to New Zealand English.
2. Please amend statements about risk to state that this study aims to investigate risks, not that there are no risks.
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. Remove references to race data as this concept is not used in New Zealand.
5. Remove references collecting information on participants sex lives as this is not needed to inform them of risks associated with contraception.
6. Remove duplications of information from the information sheet.
7. Include the location of the laboratory where samples will be sent and if there will be an option for these to be sent overseas with a karakia.
8. Correct the references to the approving HDEC.
9. Mention that if patients have hypoglycaemia then they should eat food.
10. Check the the pregnant partner information sheet for duplications of information and use headings to break up paragraphs.
11. Review the layout within the combined genetic and future unspecified research information sheet so it is clearer as to the potential uses, timeframes and risks which apply to each situation.

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 amend the study protocol taking into account the suggestions made by the Committee. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
* Please provide the outcome of Māori consultation. (*Ethical Guidelines for Intervention Studies* *para 4.9*).

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

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| **8** | **Ethics ref:** | **17/NTB/210** |
|  | Title: | Mongo Guide Wire First In Man Study |
|  | Principal Investigator: | Prof Scott Harding |
|  | Sponsor: | Bio-Excel (Australia) Pty Ltd |
|  | Clock Start Date: | 26 October 2017 |

Prof Scott Harding was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is an open pilot study of 10 people, trialling a new guide wire for percutaneous coronary revascularisation in patients with a complete coronary artery occlusion.

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 acutely unwell patients would be included in the project. The Researcher stated that they would not.

Summary of ethical issues (outstanding)

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

1. Please provide an up to date insurance certificate for the study.
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 criteria for study termination. (*Ethical Guidelines for Intervention Studies* *para 6.64*).

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 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.”*
2. Please correct the reference to the approving ethics committee.

Decision

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

* Please provide criteria for study termination. (*Ethical Guidelines for Intervention Studies* *para 6.64*).
* 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 updated insurance certificates for the study.

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

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| **9** | **Ethics ref:** | **17/NTB/212** |
|  | Title: | REVISE trial |
|  | Principal Investigator: | Dr Paul Young |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 26 October 2017 |

Dr Paul Young was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study investigates randomising ventilated patients 1:1 to either intravenous pantoprozole (to prevent bleeding from stress gut erosions) or placebo to determine if pantoprozole prevents gut bleeding and whether it is associated with an increase in adverse events including ventilator-associated pneumonia.

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 it would be possible to seek informed consent from participants. The Researcher explained that it would not.
2. The Committee queried how participating in this study might be considered in participants’ best interests. The Researcher stated that both treatments are consistent with standard care and that there would closer monitoring with evaluation of a potential complication (ventilator induced pneumonia).
3. The Committee queried whether assessment for this condition was already standard care by clinicians. The Researcher stated that it was not always considered.
4. The Committee asked what would change for participants by being in this project. The Researcher stated that clinicians would be able to make an assessment of participants’ wellbeing and that this would be site-specific. Research coordinators will be visiting patients each day and that information can be fed back to the care team to inform clinical decision making.

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 requested that the researchers seek legal advice in order to confirm that the project is consistent with New Zealand law. Specifically Right 7.4 of the Health and Disability Commissioner’s Code of Patient Rights. *(Ethical Guidelines for Intervention Studies para 1.10).*
2. Please provide details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies para 6.50).*

Decision

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

* Please provide details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies para 6.50).*
* Please provide evidence that the research project is consistent with the HDC code of patient rights. *(Ethical Guidelines for Intervention Studies para 1.10).*

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

|  |  |  |
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| **10** | **Ethics ref:** | **17/NTB/213** |
|  | Title: | Establishing the prevalence of delirium in hospital inpatient settings. |
|  | Principal Investigator: | Professor Roger T Mulder |
|  | Sponsor: |  |
|  | Clock Start Date: | 26 October 2017 |

Professor Roger T Mulder and Dr Colin Peebles 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 utility of 2 tools to screen for acute delirium in the medical and surgical wards. Both tests are currently standard care.

Summary of ethical issues (resolved)

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

1. The Committee asked if both methods of assessing delirium are standard care. The Researcher explained that they are.
2. The Committee asked how participants would be recruited. The Researcher stated everyone over age 65 would be recruited and that while most can provide informed consent some may not be able to.
3. The Committee asked how participation in this project might be considered best interests. The Researcher explained that all patients over 65 will undergo the screening test. Currently it is not routine to administer a delirium screen to patients in these wards. Current figures indicate delirium in 25% of patients with only 6% being detected. By detecting delirium earlier then participants will benefit as their care can be changed accordingly. The Researcher stated that undetected delirium has serious effects.
4. The Committee asked how many patients would get a delirium screening test as part of standard care. The Researcher explained that not all patients get a delirium screening test.

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 suggested that an information sheet for family and next-of-kin be produced that explains the project. This would not be for the purposes of obtaining familial consent for research and would be for information only. *(Ethical Guidelines for Intervention Studies Appendix 2.)*

Decision

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

* Please develop a family or next-of-kin information sheet that relatives of participants can use to understand why their relative has been enrolled in the study. *(Ethical Guidelines for Intervention Studies Appendix 2.)*

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

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| --- | --- | --- |
| **11** | **Ethics ref:** | **17/NTB/195** |
|  | Title: | 64041575RSV 2004 |
|  | Principal Investigator: | Dr. Thorsten Stanley |
|  | Sponsor: | Janssen-Cilag (New Zealand) Limited |
|  | Clock Start Date: | 05 October 2017 |

Ms Marina Dzhelalai was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a placebo controlled phase 2 study of a new antiviral agent lumicitabine (which stops the RNA virus reproducing its own RNA so it can't divide) in children aged 1 month to 3 years, who are admitted to hospital with respiratory syncytial virus infection.

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 about not including the dosage and randomisation ratios in the participant information sheet. The Researcher explained that the studies that determine these figures had not yet been completed but when they have been these figures they will be added to the participant information sheet. (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. The PRESSOR questionnaire collects information about the parent/caregiver including education level, employment, age and any drugs taken by a breastfeeding mother but currently the Participant Information Sheet and Consent does not take account of this.
3. 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*).
4. The Committee stated that information should not be collected from any persons apart from children’s parents or legal guardians. Please amend the study protocol. (*Ethical Guidelines for Intervention Studies* *para 5.41*)

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

1. Correct definitions of study drug as different definitions are given on page two and four.
2. Explain what randomisation means.
3. Add a lay title.
4. Add full information on drug doses to be used, number of treatment arms and randomisation ratios to Participant Information Sheet
5. Include the time commitment required from parent/caregiver.
6. Correct references from scientific research to future unspecified research.
7. Please check terms in the questionnaire for suitability. Phrases such as phase I and spit up are not common parlance.
8. Obtain consent from parent/caregiver and breastfeeding mothers to disclose their personal information.
9. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*

Decision

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

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

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| **12** | **Ethics ref:** | **17/NTB/198** |
|  | Title: | 64041575RSV2002 |
|  | Principal Investigator: | Dr. Thorsten Stanley |
|  | Sponsor: | Janssen-Cilag (New Zealand) Limited |
|  | Clock Start Date: | 12 October 2017 |

Ms Marina Dzhelalai was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a 2 year observational follow up study of participants in the lumicitabine intervention study (suffix-2004,17/NTB/ 195) It seeks out information on the incidence of asthma development, frequency of daily wheezing, frequency, type of of respiratory infections and use of medical resources by the children who took lumicitabine or placebo. It also collects information from parents about the effect of their child’s illnesses on work productivity, days lost from work, their own health and time spent with other family members..

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 over the burden of the 2 year study to parents/caregivers when weighed against the scientific validity of the study as the number of participants was low. The Researcher explained that this project is partially a feasibility study to determine if the followup is possible. Please provide evidence that the project is scientifically sound. (*Ethical Guidelines for Intervention Studies* Appendix 1)
2. The Committee stated that if personal and health data was to be collected from parents/caregivers, that they should be advised of and consent to this through the Participant Information Sheet and Consent Form.
3. 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*).

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 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.”*
2. Include that participants must complete wheeze cards and daily logs every day for two years.
3. Include the duration of monthly visits and phonecalls.
4. Inform parent/caregiver of the information which will be requested about them and obtain their consent to participation.

Decision

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

* Please provide evidence of favourable independent peer review of the scientific merit of the study (*Ethical Guidelines for Intervention Studies* Appendix 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*).

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

## 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:** | 08 February 2018, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

**Problem with Last Minutes**

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

The meeting closed at 5:30pm