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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 08 November 2016 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 12:15pm | Welcome |
| 12:20pm | Confirmation of minutes of meeting of 04 October 2016 |
| 12:30pm | New applications (see over for details) |
|  | i 16/NTB/190  ii 16/NTB/186  iii 16/NTB/192  iv 16/NTB/193  v 16/NTB/197  vi 16/NTB/199  vii 16/NTB/201  viii 16/NTB/202  ix 16/NTB/208  x 16/NTB/205  xi 16/NTB/209 |
| 5:35pm | General business:   * Noting section of agenda |
| 5:45pm | 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) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Phyllis Huitema | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | 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 | Present |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Present |

## Welcome

The Chair opened the meeting at 12:15pm and welcomed Committee members.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 04 October 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/NTB/190** |
|  | Title: | Nasal Mesh Nebulizer Study |
|  | Principal Investigator: | A/ Prof Richard Douglas |
|  | Sponsor: | AFT Pharmaceuticals Ltd. |
|  | Clock Start Date: | 20 October 2016 |

Dr James Johnston 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. All current treatments available for these patients are topical, however, no current method of appropriately distributing the treatment throughout the nasal cavity exists.
2. This study investigates a new device to determine if it can effectively administer a saline solution in patients that have undergone functional endoscopic sinus surgery.
3. The Committee noted that the Participant Information Sheet has some good lay language sections.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether the dye being used is safe. The Researcher explained that the dye is commonly used and considered very safe.
2. The Committee questioned whether participation would be uncomfortable for patients. The Researcher explained that although the endoscopy can sometimes be uncomfortable for most people, for patients who have had the surgery these patients have had it is not expected to be uncomfortable as their nasal cavities have been merged in to one cavity that is large enough to fit the endoscope easily.
3. The Committee noted that the application form mentioned a skin prick test but this is not mentioned in the Participant Information Sheet. The Researcher explained that they are no longer doing the skin prick test.
4. The Committee questioned how participants will be recruited for this study. The Researcher explained that the participants will be patients of the CI and will be invited to the study by telephone. The Committee questioned whether the CI, the potential participants’ treating physician, will be inviting participants to the study. The Researcher explained that this could be done by another researcher not directly involved in the care of the potential participants if this is the preference of the Committee. The Committee stated that this is their preference, the Committee also requested that an information sheet is posted to them before they are called, then participants can be invited by phone to come in and discuss the study if they are interested.
5. The Committee questioned the funding arrangement for this study. The Researcher explained that the company that developed the study device is providing this device for the study.
6. The Committee questioned the status of Māori consultation. The Researcher stated that it has been undertaken already.
7. The Committee noted that the question regarding potential cultural concerns was not answered correctly and should have included information about the tapu nature of the head and the nose as the source of the breath of life. Please keep this in mind for future applications.

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 researchers have indicated that the study may be used to inform clinical practice and support the registration of the study device. However, the study seems insufficiently powered for this purpose. The Committee questioned whether a statistician has been consulted. The Researcher explained that a statistician has been consulted and believes that the study will be able to generate useful information. The Committee requested that a formal report from the statistician regarding the study, specifically addressing that this is not a pilot study but rather a definitive trial to support marketing and inform practice.

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

1. Please revise the Participant Information Sheet to improve readability. The Committee suggested that the HDEC Participant Information Sheet template is used to revise the Participant Information Sheet for this study to improve the layout and ensure all essential information is included.
2. Please move the confidentiality statement in the Participant Information Sheet to later in the document and edit this statement to explain how the records will be kept confidential, currently it states that it will be ‘at the discretion of the researchers.
3. The Committee questioned why the Participant Information Sheet states that if the researchers cannot contact the participant they will contact their GP. The Researcher stated that they feel it would be best to remove this statement as they have a good relationship with their potential participants and expect to be able to contact them. The Committee agreed it would be best to remove this statement from the Participant Information Sheet.
4. Please add information earlier in the Participant Information Sheet to inform participants that anaesthetic could be used if needed. Please also add information in the risk section about the use of anaesthetic.
5. 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.”*
6. Please include information in the Participant Information Sheet regarding what happens if someone decides to withdraw from the study. Specifically, include information about whether participants can withdraw their data from the study after it has been collected.
7. Please remove the yes/no tick boxes from the Consent Form for all statements that are not truly optional, meaning that the participant could select ‘no’ and still participate in the study.
8. Please remove the statement from the consent form regarding participants’ data being retained if they decide to withdraw from the study, as the participant does not need to make this decision until the time they decide to withdraw from the study (if they decide to do so).
9. Please remove all statements from the consent form that are not relevant to this study, such as the pregnancy statement and the statement about tissue being sent overseas.
10. The Committee questioned whether participants will be compensated for attending study visits as the Participant Information Sheet states that they will only receive reimbursement if they complete all intervention arms. The Researcher explained that they would be reimbursed even if they only completed some arms of the intervention. Please revise the Participant Information Sheet for accuracy.
11. The Participant Information Sheet states that participants will be asked a few questions, please clarify what kind of questions they will be asked.
12. Please revise the Participant Information Sheet to remove typographical errors, and ensure New Zealand spellings are used.
13. Please provide further information about the Mauranui clinic in the Participant Information Sheet as suitable context has not been provided.
14. Please ensure all technical terms, such as fluorescin-dyed saline, are explained in lay language.

Decision

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

* Please provide further evidence of favourable independent peer review of the study protocol (*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 Mrs Leesa Russell and Mrs Phyllis Huitema.

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| **2** | **Ethics ref:** | **16/NTB/186** |
|  | Title: | Tackling Preterm |
|  | Principal Investigator: | Dr Beverley Lawton |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 13 October 2016 |

Dr Beverley Lawton and two co-investigators were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study investigates the clinical care pathways to determine if there are disparities for women with preterm births. This will include investigating possible ethnicity disparities.
2. This study is a retrospective review of data over a 4 year period, NHI numbers will be used to link a range of data sets.
3. This is not a longitudinal study, the data will be stripped of identifiers once matching is complete and the researchers will be unable to re-link the data to individuals.

Summary of ethical issues (resolved)

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

1. The Committee questioned the justifications for not obtaining consent from participants. The Researcher explained that due to the number of records being accesses, from approximately 200,000 people, obtaining consent would be impossible. Further, the expected benefits from the study are high for the health system and the data confidentiality will be maintained well by the researchers.
2. The Committee questioned what period the data would be obtained from. The Researcher stated that data would be from births between 2010 and 2015.
3. The Committee questioned how ethnicity would be accurately recorded as it is important for this study. The Researcher explained that they would primarily base the child’s ethnicity from the mother’s ethnicity, however, the father’s ethnicity will also be used. The Researcher explained that they will compare data sets to try get the most accurate information.
4. The Committee questioned whether study data would be available for future research. The Researcher stated that they believe it would be good for this data to be available to other researchers in the future.
5. The Committee questioned the rates of preterm birth for different ethnicities in New Zealand and whether all ethnicities will be looked at. The Researcher explained that they intend to investigate any ethnic differences between outcomes, they stated that they believe the rate of preterm birth is slightly higher for Māori than NZ Europeans.

Decision

This application was *approved* by consensus.

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| **3** | **Ethics ref:** | **16/NTB/192** |
|  | Title: | D5290C00003 |
|  | Principal Investigator: | Dr Thorsten Villiers Stanley |
|  | Sponsor: | MedImmune, LLC |
|  | Clock Start Date: | 27 October 2016 |

Dr Thorsten Villiers Stanley 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 a potential vaccine against RSV for pre-term infants.
2. This is a serious and common virus that only has one currently available protection that is expensive and only moderately effective.
3. Two new products have emerged, one recently studied requires two doses and the one being studied in this trial only requires one dose.
4. Pre-term babies are at a higher risk from RSV as they have fewer antibodies from their mother.
5. The Researcher stated that they feel the biggest challenge for their study will be recruiting participants as it is difficult to convince parents to let their baby have an injection. The Researcher explained that they will try to inject babies before they leave the hospital as it is difficult to get them enrolled once they are at home. Similarly, follow up is the hardest part of the study as it is essential to get accurate information about the effectiveness of the study treatment but difficult to ensure parents complete this as required.
6. The Committee stated that this is an interesting application, which is clear and well put together.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether the researchers will be able to recruit enough people. The Researcher explained that they have a range of strategies for recruitment and feel that they will be able to recruit enough people.
2. The Committee questioned whether participants born slightly outside the RSV season will be able to be in the study. The Researcher confirmed that they may be able to.
3. The Committee questioned whether the NZ census questions will be used to collect ethnicity data. The Researcher confirmed it would be.

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 application indicates that the study has data safety monitoring and requested further information about this. The Researcher explained that this is an international study and the data safety monitoring will be organised by the sponsor. The Committee requested further information about the data safety monitoring arrangements, including their charter if possible.
2. The Committee questioned whether there is a standard questionnaire about the baby’s health. The Researcher explained that it is more a general set of questions that will be asked. The Committee requested that further information about this is provided.
3. The Committee questioned the options for parents with the unscheduled illness visits, as the burden of participation is quite high for parents of sick infants to attend a visit at another clinic. The Committee suggested that the participant’s GP may be able to take a swabs or a study nurse could go to participants to take the swabs. The Researcher explained that the GP cannot do it but they will try to have a study nurse available to go to participants to take the swabs an alternative option to clinic attendance. Please confirm the arrangements for this.

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

1. Please remove the information from the Participant Information Sheet about the other treatment not being available due to cost, it is sufficient to say it is not standard care.
2. The Committee noted that the study should not be stopped for commercial reasons, please do not state this in the Participant Information Sheet.
3. The Committee questioned the statement in the optional sample Participant Information Sheet that states that the tissue will be stored for 25 years. The Committee questioned if the tissue would be completely anonymous or if it would be able to be withdrawn by the participants when they turn 16 if they wanted to. The Researcher indicated that the samples will be completely anonymous and unable to be withdrawn. The Committee stated that this must be clearly stated in the Participant Information Sheet.
4. Please see the HDEC Future Unspecified Research Participant Information Sheet template to ensure that this optional sample Participant Information Sheet contains all essential information. For example, please add a Māori tissue statement to this form and Māori cultural support contact details.
5. Please remove the reference to US law from the main Participant Information Sheet.
6. Please remove the flipping a coin analogy from the Participant Information Sheet as this is not accurate for this study with 2:1 randomisation and not preferred by the Committee in general.
7. Please explain the randomisation process in the Participant Information Sheet.
8. The Participant Information Sheet currently uses some language about what people could do (such as see their medical information), where these things are actually rights. Please revise this to make it clear that participants have these rights, although they may be withdrawn from the study if they do this due to it breaking the blinding (if this is the case).
9. The Participant Information Sheet indicates that participants cannot withdraw their data from the study if it is deemed essential to protect the study integrity. The Committee noted that if it would be possible or participants to withdraw their data they must be able to. Please revise the Participant Information Sheet to reflect this.
10. The Participant Information Sheet indicates that the study sponsor could stop the study for any reason. Please revise this as studies should not stop for commercial reasons in NZ.
11. Please remove the statement in the Participant Information Sheet that if participants decide to withdraw from the study they may be asked by the doctor to continue with the study.
12. Please explain in the Participant Information Sheet what an adverse event is.
13. Please explain what happens to blood samples taken during the study.
14. Please revise the Participant Information Sheet as currently it indicates that the child is being invited to be in the study, however, the child is an infant and the parents are being invited.
15. Please bullet point the risk section in the Participant Information Sheet.
16. Please explain in the Participant Information Sheet what costs will be reimbursed.

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 respond to the Committee’s outstanding ethical concerns detailed above, including providing details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies para 6.50).*

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

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| **4** | **Ethics ref:** | **16/NTB/193** |
|  | Title: | Measuring changes in vaginal pressure before and after prolapse surgery |
|  | Principal Investigator: | Dr Jennifer Kruger |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 27 October 2016 |

Dr Jennifer Kruger and Dr Joy Marriott, co-investigator, were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study involves a novel device that has been developed to measure participants’ vaginal pressure profile.
2. In this study the participants will be patients having vaginal prolapse surgery to investigate how pelvic floor muscles work before and after surgery. This group is being studied as it is important to try prevent recurrence of prolapse. 1/3 of patients will have recurring prolapse and each time the surgery is done it is more complicated and difficult.
3. The study will also help to clinically validate the study device.
4. Participants will have the study device inserted by the study doctor for consistency, although in a real life situation people would be able to place it themselves.

Summary of ethical issues (resolved)

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

1. The Committee questioned why psych data is being collected about study participants. The Researcher stated that it was to get a more general picture of participants and the results. The Committee explained that the psych data should not be collected as it may be stigmatising and is not relevant to the study.
2. The Committee noted that Māori consultation is required for this study, please approach the University for this before beginning the study.

Summary of ethical issues (outstanding)

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

1. The Participant Information Sheet states that 25% of women have symptoms related to weakness of the pelvic floor, the Committee questioned whether this was international data. The Researcher confirmed that it is. The Committee requested that this is clarified in the Participant Information Sheet.
2. Please revise the ‘what you need to do’ section of the Participant Information Sheet to more clearly indicate the voluntary nature of participation, for example ‘this is what the study involves’ or ‘this is what we would like you to do’.
3. The section about study procedures mentions bringing a support person and withdrawing from the study, although this is important please move this information elsewhere in the Participant Information Sheet.
4. Please offer a chaperone in the Participant Information Sheet for people who do not have a support person available.
5. Please clarify in the Participant Information Sheet that participants’ data may be used even if they withdraw from the study if this is acceptable to the participants.
6. Please remove the yes/no tick boxes from the consent form for all statements that are not truly optional, meaning that a participant could answer ‘no’ and still participate in the study.
7. Please put a picture of the device with size scale in the Participant Information Sheet.
8. Please make it clear in the Participant Information Sheet that the study involves testing a brand new device.

Decision

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

* 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)*

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| **5** | **Ethics ref:** | **16/NTB/197** |
|  | Title: | A study to examine the safety and tolerability of the trial drug Brincidofovir in healthy adults and in adults. |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 October 2016 |

Dr Chris Wynne 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 an antiviral that is showing good results in patients but when given orally it has poor bowel side effects. This study will investigate giving it intravenously to see if the same dose can be given without the same side effects.
2. 40 healthy participants, across 4 cohorts, will be given a single dose of the study drug, the dose level of the drug will be increased between cohorts after the safety data from each cohort is confirmed by an unblinded committee.

Summary of ethical issues (resolved)

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

1. The Committee questioned the restriction of study enrolment to surgically sterile or post-menopausal women, excluding women who practice abstinence for example. The Researcher explained that it is essential that participants do not get pregnant on this study and their experience with women who are able to get pregnant is that sometimes they do in studies even if they agree to prevent this. For this particular study the risk is too high and it is not acceptable to include any women who could physically become pregnant. The Committee agreed.

Summary of ethical issues (outstanding)

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

1. In the Participant Information Sheet please do not switch between terms interchangeable, such as cohort and group, one term should be used for each concept throughout. Clarify what is meant by ‘dose escalation’.
2. 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.”*
3. The Participant Information Sheet indicates that the study doctor will refer a participant whose partner becomes pregnant for obstetric care. The Committee noted that this implied that a formal reference would be given, however, the study doctor will only be informing the participant that their partner should seek obstetric care. Please revise for clarity.
4. The ACC compensation statement included in the Participant Information Sheet for this study refers to the Medicines New Zealand industry guidelines, however, these guidelines are not ACC equivalent. Please revise this statement to remove the reference to the Medicines New Zealand industry guidelines.
5. Please add to the Participant Information Sheet that participants will need to fast for 16 hours.
6. One of the advertisements provided does not apply to this study as it talks about a different study drug. Please revise this for accuracy.
7. Please revise the Participant Information Sheet to remove typographical errors, for example an incorrectly placed decimal point in the payment section makes it appear that participants will get 28cents for participation.
8. In the Participant Information Sheet please confirm how identifiable data will be when sent to other companies.
9. Please explain all acronyms in the Participant Information Sheet, such as CMV.
10. Please provide the position of the Māori cultural support person.

Decision

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

* 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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| **6** | **Ethics ref:** | **16/NTB/199** |
|  | Title: | A study to examine the safety and tolerability of the trial drugs REGN2477 alone and in combination with REGN1033 in healthy postmenopausal women. |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 October 2016 |

Dr Chris Wynne 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 involves healthy post-menopausal women in 4 cohorts.

Summary of ethical issues (outstanding)

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

1. The Committee questioned the safety of the study drug REGN2477, based on the limited previous trials with this drugs. The Researcher explained that they are satisfied that the drugs are suitably safe for this phase of trial due to other studies that have recently met primary safety points. The Committee requested further information on the safety of the study drug is provided.
2. The Committee noted that the application form provided information on Māori cancer rates in response to p.4.1 but this does not apply to this study. Please provide a correct answer to this question.
3. The Committee noted that a reading score had not been provided for the Participant Information Sheet and requested this is provided as stated in the application form.

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

1. The main Participant Information Sheet states that some people may be screened for study participation but then not able to enrol in the study and receive payment as the study may be full. However, the Committee expect that as this is a small New Zealand only study no participant should make it to screening if there is not sufficient space for them on the trial. The Researcher clarified that they would be a reserve participant and would receive some compensation. The Committee requested this is clarified in the Participant Information Sheet.
2. The optional Participant Information Sheet is labelled as pharmacogenomics, but called genetics in the protocol. Please revise these terms to be consistent across all documents.
3. Please revise the approving ethics committee in the Participant Information Sheet to be Northern B.
4. Please clarify in the Participant Information Sheet that participants can withdraw verbally at any time and do not need to withdraw in writing.
5. Please revise the advertisements to ensure they state the same number of follow up visits.
6. Please state the position of the Māori cultural support person in the Participant Information Sheet.
7. The ACC compensation statement included in the Participant Information Sheet for this study refers to the Medicines New Zealand industry guidelines, however, these guidelines are not ACC equivalent. Please revise this statement to remove the reference to the Medicines New Zealand industry guidelines.
8. Please remove all reference to the FDA from the Participant Information Sheet as this does not apply in New Zealand.
9. Please remove the pregnancy statement from the Participant Information Sheet as this study is for post-menopausal women.

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 respond to the Committee’s outstanding ethical concerns detailed above.

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

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| **7** | **Ethics ref:** | **16/NTB/201** |
|  | Title: | The value of periwound LA for post-operative anaelgesia of patients undergoing total hip joint replacement |
|  | Principal Investigator: | Dr David Kieser |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 October 2016 |

Dr David Kieser and Dr Lloyd Roffe were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

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

1. The Committee questioned whether having the wound catheter placed during the surgery would extend surgery time or increase the risk of infection. The Researcher confirmed that it would not extend surgery time significantly or increase infection risk.
2. The Committee questioned how much risk of infection there is as the Participant Information Sheet states that it is very low. The Researcher stated that it is virtually 0, but possible.
3. The Committee questioned whether the removal of the catheter would be painful. The Researcher confirmed that it should be similar to taking out stitches and not uncomfortable.
4. The Committee noted that consent will be obtained approximately a week before surgery, they questioned whether someone would re-affirm consent at time of surgery. The Researcher explained that the same person would be present at initial assessment, time of giving consent, and at surgery and would be able to re-affirm consent.
5. The Committee questioned who the sponsor of the study is. The Researcher explained that the University of Otago is responsible for the overall governance of the study.
6. The Committee questioned whether data from the study would be available for future research. The Researcher confirmed that it would be, although they have no current plans of what this might be they feel the data may be useful to someone.
7. The Committee questioned the data safety monitoring arrangements for this study. The Researcher explained that they will be monitoring data safety in real time and maintaining an ongoing understanding of the data. The Committee questioned what would be monitored. The Researcher explained that they will mainly be monitoring pain scores and complication rates. The Committee felt that this was a lot of work and responsibility for one person and emphasized that this person must be adequately supported to perform this role.
8. The Committee questioned whether Māori cultural consultation was being sought as the answers in the application form were inconsistent regarding this. The researcher explained that they are obtaining it and the answer in their application was meant to indicate that they felt there were no specific cultural concerns for this study.
9. The Committee questioned whether the NZ census ethnicity question will be used. The Researcher confirmed it will.

Summary of ethical issues (outstanding)

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

1. The Committee questioned the role of the person who provided peer review for this study. The researcher explained that the reviewer is a doctor with extensive research background. The Committee questioned whether any others reviewed the study. The Researcher explained that 3 independent people reviewed the study but did not provide written reports, although they stated that they felt the study was good. A biostatistician also reviewed the study. The Committee requested further evidence of this peer review process, including who reviewed it and their independence from the study.
2. The Committee questioned whether the same surgeon does all surgeries in the study. The Researcher confirmed this is the case as they are trying to control for as many variables as possible. The Committee suggested discussing this with a statistician to see if any other variables can be controlled for.

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

1. The Participant Information Sheet states that the researcher will be blinded to group allocation, however, it is unclear what this means as the participant and the surgeon will not be blinded. Please clarify who will be blinded or remove this statement as it may not be relevant to the participant if only the people reviewing results are blinded.
2. The Committee noted that the Participant Information Sheet indicates that participants will be directed to study publications, however, a lay summary of results should be offered instead.
3. Acronyms are used in the Participant Information Sheet without it being clearly stated what they mean, please ensure all acronyms are defined the first time they are used.
4. Please clarify when and how frequently participants need to do study procedures.
5. Please add a Māori cultural support contact person to the Participant Information Sheet.
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 have a space on the consent form for the researcher obtaining consent to sign, please see the HDEC template for more guidance.
8. Please remove the identifiers from the questionnaires and replace with a study number.

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 respond to the outstanding ethical concerns detailed above, including providing further evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).

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

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| **8** | **Ethics ref:** | **16/NTB/202** |
|  | Title: | Local anesthetic administration in NOF# closed reduction and internal fixation |
|  | Principal Investigator: | Dr David Kieser |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 October 2016 |

Dr David Kieser and Dr Lloyd Roffe 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 Researcher indicated that the study is now a bit different than what was applied for as they have recently realised they will require a small amount of funding and this should be provided by the University of Otago. The Committee stated that this was acceptable.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether either of the modes of administration in this study are standard of care. The Researchers explained that there is not a standard internationally or in New Zealand, care varies a lot between locations and between individual physicians.
2. The Committee questioned whether study participation is expected to increase surgery time significantly. The Researcher explained that it will not, except slightly for participants who would normally get no pain relief at all.
3. The Committee questioned the consent process for the study. The researcher explained that participants will be in pain and awaiting surgery, but all will be able to provide informed consent as dementia patients must be excluded as they cannot provide reliable pain scores. The Researcher went on to explain that participants would have some time to think about their participation as they are expected to arrive in the afternoon and most would not have surgery until the next day, although some would have surgery the same day. Participants would be offered study enrolment when first seen by the surgeon and then have some time to think about participation and provide consent.
4. The Committee questioned whether participants would be in a diminished state of competence due to sedation, pain, or anxiety. The Researcher explained that they have ways to assess competency to consent for treatment and will follow these to help ensure participants are able to provide consent freely, however due to the nature of the study participants will not be fully comfortable.
5. The Committee questioned the status of Māori consultation. The Researcher explained that it is currently underway.
6. The Committee noted that one of the goals for the study was to assess ethnic differences and questioned whether they are really able to do this. The Researcher agreed that they are unlikely to make any significant claims about ethnicity differences due to their study design, but will still record ethnicity.

Summary of ethical issues (outstanding)

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

1. The Committee questioned who the study sponsor is. The Researcher indicated that they will confirm who has overall responsibility for the study, either the DHB or the University.

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

1. Please state in the Participant Information Sheet what the alternative to study participation is, including what kind of care people not in the study can expect to receive.
2. The Committee noted that the Participant Information Sheet lists the wrong number of participants, please revise this for accuracy.
3. Please include the name and position of the Māori cultural support person.
4. Please simplify the aims section of the Participant Information Sheet.
5. Please use a larger font on the Participant Information Sheet and Consent Form to improve readability.
6. Please revise the Consent Form to ensure all statements are relevant and suitable.
7. Please do not collect identifying information on questionnaires, study numbers should be used to identify participants instead.
8. Please state in Participant Information Sheet clearly that the catheter will be left in a wound for 3 days, and be clear about any limits there will be for patients in movement.

Decision

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

* Please respond to the outstanding ethical concern detailed above.
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

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| **9** | **Ethics ref:** | **16/NTB/208** |
|  | Title: | CHYLD Study at 9 years |
|  | Principal Investigator: | Professor Jane Harding |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 27 October 2016 |

Professor Jane Harding and a co-investigator were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study is a follow up of children who were seen at birth, 2 years, 4.5 years, and are now 9 years old.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether the follow up at 4.5 was done at home and why the assessments at 9 would be done at school. The Researcher explained that at 4.5 a lot of assessments were done at a clinic and some were done at home. The reason for doing the 9year old follow up at school is to make it easy for the parents but at the request of the parents it could be done elsewhere.
2. The Committee questioned whether parents would be present when the children are being assessed. The Researcher explained that although parents are welcome they do not need to attend. The Committee expressed concern that parents may wish to attend but be unable to due to work commitments. The Researcher stated that parents are welcome to request the assessments are done at a different place or time.
3. The Committee questioned whether data generated in this study will be available to other researchers in a potentially identifiable format. The Researcher explained that the data would be provided with the participants’ study number attached but the other researchers would not be given the link to re-identify the participants.
4. The Committee commended the quality of the peer review provided, noting that the peer review questioned whether they would get follow up successfully. The Researcher explained that at last follow up they got 78% and told parents at this point that there may be further follow up so they expect to get good rates of follow up.
5. The Committee questioned how the feeling of ‘what’s wrong with me’ would be managed for the children, and how stigmatisation at school would be managed. The Researcher explained that the family involvement is key to the child understanding and that also the researchers would work hard at help make the children feel special for their involvement.

Summary of ethical issues (outstanding)

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

1. The Committee stated that they would prefer it was clearer in the adult and child Participant Information Sheet that study assessments didn’t need to be done at school if they would prefer they were done elsewhere, such as at home.
2. The Committee questioned why the children are not being told that they were in the study when they were younger. The Researcher stated that they didn’t feel the children would remember. The Committee stated that they believe they would and have a right to know, especially if they may be approached again in the future for further follow up. Please add this to the child information sheet.
3. The child information sheet needs to include an assent form also where the child can give written assent to their participation.
4. Please replace the interpreter box from the consent form with a statement regarding the availability of interpreters if required.
5. Please see the HDEC Participant Information Sheet template for section headings suggestions to improve the readability of the Participant Information Sheet.
6. Please update the Participant Information Sheet version number and dates for accuracy.
7. Please provide more information about brain scans, including how it is determined which children will have brain scans. The Researcher stated that most of this is in a separate information sheet and consent form. Please provide these forms and ensure the main Participant Information Sheet explains how it is determined which children are offered brain scans.
8. Please explain in the child information sheet that if the assessments are done at school that the school will know and if the child wants to do it somewhere else they can.
9. Please clarify in the Participant Information Sheet how long data will be stored for, the Committee noted that it should be for 10 years after the participant turns 16.
10. Please add the name and position of the Māori cultural support person in the Participant Information Sheet.
11. Please reference the Northern B HDEC as the committee that approved this study.
12. The Committee questioned the role of teachers in the study as it appears that they are asked to give subjective information on the child and this makes them participants in the study. The Researcher explained that they didn’t feel the teachers are participants. The Committee stated that the teachers are participants and need to provide informed consent for their participation, please provide an information sheet and consent form for this. This can be posted to the teachers with the questionnaire and returned by post with the questionnaire.
13. Please provide more information for parents about what happens if the brain scan shows something unexpected.

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)*

This following information will be reviewed, and a final decision made on the application, by Mrs Leesa Russell and Mr John Hancock.

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| **10** | **Ethics ref:** | **16/NTB/205** |
|  | Title: | XPEDITE |
|  | Principal Investigator: | Associate Professor Andrew Holden |
|  | Sponsor: | Cook Medical |
|  | Clock Start Date: | 27 October 2016 |

Helen Knight 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. Participant in this study are having artery surgery and this study is investigating a different stent.
2. Some people having a stent inserted have re-narrowing after the surgery which is not desirable and this study involves seeing if a different way of releasing medication from the stent reduces re-narrowing.
3. The control stent is currently commercially available but the manufacturer sees that there is room for improvement.
4. The follow up periods during this study are the same as standard care, with an extra angiogram at 6 months.
5. The Committee commended the researchers on a well put together application and a clear Participant Information Sheet.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether the anti-coagulant for 6 months post-surgery is standard. The Researcher explained that it is standard of care, but some people come off it at 3 months if they are not tolerating it well. The Committee asked whether participants in the study can come off it at 3 months if they aren’t tolerating it or if this would cause them to be withdrawn from the study. The Researcher confirmed that they would be able to come off it at 3 months and remain in the study.
2. The Committee questioned whether the surgeons need any specific training for the stent. The Researcher confirmed it is the same to use as the standard stent and no extra training is required.
3. The Committee questioned whether the prevalence is similar between Māori and other ethnicities. The Researcher stated that rates are similar but slightly higher in Māori than NZ European.

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 further information on the data safety monitoring committee. The Researcher stated that they expect it will be independent but it is not yet confirmed. The Committee requested some general information is provided, such as whether it is independent and what the makeup will be.
2. The Committee noted that the Participant Information Sheet talks about risks a lot but bloods are not being monitored for safety. Please confirm whether this is appropriate.

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

1. Please remove the information from the Participant Information Sheet on all aspects that are standard of care and not changed by study participation, such as anti-coagulant use.
2. Please remove the reference to the US law in the Participant Information Sheet.
3. Please change the reference to the approving committee to Northern B.
4. Please consider adding a lay title to the Participant Information Sheet that explains what the study is about.

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*).
* Provide details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies para 6.50).*

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

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| **11** | **Ethics ref:** | **16/NTB/209** |
|  | Title: | A study to evaluate safety and tolerability of GS-9688 in healthy subjects |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 27 October 2016 |

Prof Edward Gane was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The Committee commended the high quality of the application and noted that they were pleased to see information provided about the data safety monitoring arrangements for the 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 noted that participation involves quite long periods of confinement, up to 14 days. The Committee questioned what participants do while confined. The Researcher explained that they are taken for walks, attend music or yoga classes, and other activities.
2. The Committee noted a large number of blood draws in the study and questioned whether the participants would have a line put in. The Researcher stated a line would be put in during the intensive parts but not for the whole time.
3. The Committee questioned whether participants who withdraw from the study will be monitored for safety. The Researcher confirmed they would be and are always encouraged to continue with the safety monitoring aspects of 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 noted that the study involves dilating the pupils of participants and questioned whether participants with a history of acute narrow angle glaucoma would be excluded from the study. The Researcher stated that they assume this would be the case but need to confirm.

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

1. The Participant Information Sheet for cohort 6 explains randomisation and states that participants have a 5 out of 5 chance of getting the drug. Please revise this to remove the explanation of randomisation and simply say all participants will receive the study drug.
2. Please revise the information sheets to remove typographical errors.
3. Please add to the Participant Information Sheet that interpreters are available as required.
4. Please bold or otherwise emphasize that this is the first time the study drug has been tested in humans.
5. Please clarify in the Participant Information Sheet that tissue samples will be stored in California, USA.

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 respond to the outstanding ethical concern detailed above.

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

## 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:** | TBD |
| **Meeting venue:** | TBD |

1. **Problem with Last Minutes**

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

The meeting closed at 5:45pm.