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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 04 April 2017 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:10pm | General business:  Noting section of agenda |
| 12:30pm | New applications (see over for details) |
|  | i 17/NTB/60  ii 17/NTB/45  iii 17/NTB/49  iv 17/NTB/58  v 17/NTB/53  vi 17/NTB/44  vii 17/NTB/59  viii 17/NTB/56  ix 17/NTB/57  x 17/NTB/50  xi 17/NTB/55  xii 17/NTB/54 |
| 5:30pm | Review of approved studies (see over for details) |
| 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 | Apologies |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Present |
| Dr Catherine Jackson | Non Lay(health/disability service provision) | 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 Ms Leesa Russell.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## New applications

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| **1** | **Ethics ref:** | **17/NTB/60** |
|  | Title: | A study to determine the safety, antiviral activity and pharmacokinetics of ARB-1740. |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Arbutus Biopharma |
|  | Clock Start Date: | 23 March 2017 |

Dr Ed 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 study investigates the safety, antiviral activity, and pharmacokinetics of the drug ARB-170
2. Globally this study is a phase I trial of the drug. The only groups in New Zealand are groups 2 and three.
3. Participants will be randomised to one of these two groups with an 80:20 ratio of study drug: placebo.

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 why a first in man medicine was being tested in a patient population and not healthy volunteers. The Researchers explained that the study uses a second generation medicine and that side effects have been reduced or eliminated.
2. The Committee queried if all participants will still receive standard care antivirals. The Researcher explained that they would and that the two arms involve placebo and antivirals or the study drug and antivirals.
3. The Committee queried if the level of reimbursement for the study was sufficient to cover participant’s costs associated with their participation. The Researchers agreed that reasonable travel expenses will be reimbursed.
4. The Committee noted that the insurance document for the study expires on 1 July 2017 and that they will need to be provided with the new certificate once it is available
5. The Committee queried if the number of participants recruited in New Zealand would be very high. The Researcher explained that the number of participants would not be quite low, with a target of 5.
6. The Committee queried the unblinding procedures for the study. The Researchers explained that the unblinding information is held onsite and can be provided in an emergency.

Summary of ethical issues (outstanding)

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

1. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. The Committee noted the dose of steroids in the study was very high and asked if this was necessary. The Researcher stated they will check with the sponsor about the need for this. Please inform the Committee to the outcome of this discussion.
3. The Committee asked if genetic testing will be performed either as part of Future Unspecified Research or main study as a whole. The Research explained that they will confirm that this will not occur with the study sponsor. Please advise the Committee if genetic testing will occur and provide updated PIS/CF documents if genetic testing is part of the study.
4. The Committee asked if participants will be safe to drive after taking a sedating antihistamine and the Researcher said they would not be safe. The Researcher stated that they will update the participant information sheet accordingly.
5. Please provide pregnant partner information forms.

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

1. Please add a lay-friendly title to the participant information sheet.
2. Please remove references to a flip of the coin from the randomisation explanation on p2 of the PIS. The Committee suggested explaining the 80:20 randomisation in this section.
3. Please add the word ‘blood’ to the sentence beginning ‘Some Māori’ in the tissue statement section.
4. Please add that this is a first in human or a rollover study to the PIS/CF.
5. Please state that the placebo is saline.
6. Please add a sentence explaining that once a certain number of participants have been enrolled that there will be no further enrolments and that patients may undergo screening and then not be able to participate.
7. Please explain that acute hepatitis C is a notifiable disease and what this means for patient’s information.
8. Please remove the final sentence from section 8.2 as HDECs do not support the termination of studies purely for commercial reasons.
9. Please include what will happen of participants request that their tissue sample for future unspecified research is destroyed after study procedures have finished.
10. Please include the information associated with risks and pregnancy in its’ own section of the PIS.

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 explain why such a high dose of steroids is necessary
* Please clarify if genetic testing is part of the main study, or optional future unspecified research. If so then please update the PIS/C documents accordingly.
* Please provide pregnant partner information forms.

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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| **2** | **Ethics ref:** | **17/NTB/45** |
|  | Title: | Anticoagulation in the Obese - Prospective Registry |
|  | Principal Investigator: | Dr Eileen Merriman |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 March 2017 |

Dr Eileen Merriman 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 the establishment of the New Zealand branch of a registry of significantly obese patients who are referred to the service for anticoagulation treatment.
2. The Researcher hopes to recruit approximately 45 people in New Zealand, to contribute to the worldwide number of 350.

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 there will be any additional procedures as part of study participation. The Researcher explained that there would not.
2. The Committee queried the need for such a registry. The Researcher explained that at this time there is no meaningful data on obese people who are receiving anti-coagulation medications. By creating such a registry then these data can be collected and more research can be done.
3. The Committee asked for the justification for opt-out consent. The Researcher explained that participants will have the registry explained for them.
4. The Committee asked if there was risk of stigmatisation by creating a registry of obese patients. The Researcher explained that in their experience patients are accepting of their obesity and how it contributes to their health.
5. The Committee were concerned about how effectively a multinational registry can be run with no funding. The Researcher explained that they have experience running projects with low to little funding.

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 if there was a participant information sheet for the registry. The Researcher explained that there is a letter and that participants will have the registry explained to them. The Committee suggested that suitable PIS/CF documents be provided and suggested using the pro forma forms found on the HDEC website. Please provide suitable participant information sheets and consent forms.
2. Please localise all information in the participant information letter and PIS/CF to be New Zealand relevant. This includes references to privacy or contact details.
3. The Committee asked if the DHB is considered the sponsor. The Researcher explained that they did not know Please clarify if the DHB is the sponsor for this project.
4. Please provide suitable peer review for this study. The Committee suggested the template found on the HDEC website.
5. 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).
6. The Committee noted that issues such as whakamā and takahi mana could occur for participants and that the outcome of cultural consultation had not occurred. Please provide the outcome of cultural consultation.
7. The Committee requested that they be provided with the governance documents for the database.
8. The committee noted that in p.4.1 of the application the Researcher had stated that Māori supposedly are underrepresented in the demographic of venous thrombosis, but in fact may be overrepresented within the obese population of thrombosis. The Committee suggested that wording be included in the PIS that could help limit whakamā for participants.
9. The Committee stated that sufficient justification for opt-out consent had not been provided. The Committee request that the Researchers provide information sheets and consent forms for opt-in consent for this project.

Decision

This application was *declined* by consensus, as the Committee did not consider that the study would meet the following ethical standards.

* The Committee stated that opt-out consent is not considered full informed consent. The Committee stated that they could not approve the study in its’ current form and request the Researcher resubmit the application with opt-in consent and the appropriate information and consent forms *(Ethical Guidelines for Observational Studies para 6.26)*
* The Committee stated that they could not approve the sending overseas of identifiable health information until they have reviewed the data safety and data governance arrangements for the study. Please provide details of the Data Safety Monitoring plans *(Ethical Guidelines for Observational Studies para 8.2)*
* Please provide suitable peer review for the study *(Ethical Guidelines for Observational Studies paras 5.7 & 5.8)*
* Please address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed (*Ethical Guidelines for Observational Studies* *para 4.4*).

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| **3** | **Ethics ref:** | **17/NTB/49** |
|  | Title: | Prophylactic early PN in HPT |
|  | Principal Investigator: | Dr Andrew Butler |
|  | Sponsor: | University of Sydney |
|  | Clock Start Date: | 23 March 2017 |

Dr Andrew Butler was not present for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates whether prophylactic parenteral nutrition helps with the conditioning treatment and grafting of bone marrow in patients receiving bone marrow transplants for haematologic malignancy.
2. 20 patients will be recruited in New Zealand, out of 408 worldwide.
3. Participants in this study will either receive prophylactic parenteral nutrition or standard nutritional care (as-needed basis).

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 donor mismatch can occur, but that this is not a risk associated with study procedures.
2. The Committee noted that parenteral nutrition presents a risk of infection in immunocompromised patients.
3. The Committee noted that data will be collected for 8 years. The first 4 years will be direct followup with patients with the latter 4 being from registries.

Summary of ethical issues (outstanding)

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

1. The Committee noted that the peer reviewer had queried if making participants more sensitive to the pre-conditioning regime will lead to increased toxicity. Please advise the Committee on how this concern was addressed.
2. The Committee noted that the protocol mentions parenteral nutrition being provided at home. The Committee assumed that this is not the case in New Zealand but requests clarification on if this will happen in New Zealand and how this will be managed.
3. The Committee noted that the PIS mentions bloods being sought for future analysis. The Committee were unclear about the consent for this procedure and if Future Unspecified Use of tissue was part of this study. Please clarify if Future Unspecified Research (FUR) of tissue is part of this study and if so, provide the required separate PIS/CF and advise where the tissue will be held. If tissue is being stored in New Zealand for FUR purposes, then please provide the details of the HDEC-registered tissue bank where this will be stored. The Committee recommended that the Researchers contact the Secretariat to seek advice on this issue.
4. The Committee noted that recruitment is being done by a treating clinician, and not a research nurse. The Committee ask if using a research nurse would this would be a better alternative to avoid coercion.
5. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee. The Committee suggested the Researchers use the HDEC template from the HDEC website. (*Ethical Guidelines for Intervention Studies* *para 6.22*).
6. The Committee noted that p3 of the sheet implies that family members may be obligated to either participate in the study, or provide health information about their family. HDECs do not support this. The Committee stated that in the event that Researchers are unable to reach family members then the Researchers must attempt to make contact at another time.
7. The Committee stated that withdrawal from a study does not have to be in writing.
8. Please explain how this study meets the equipoise standard.
9. Please explain why ethnicity data are not being collected yet the cultural questions mention how inequalities are faced by Māori.

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

1. Please remove abbreviations from the participant information sheet.
2. Please remove any references to seeking health information from family members from the family member phone conversation section on p3. The Researchers are to seek health information from participants only.
3. Please explain what is involved with the nutritional assessments, mentioned on page 3 of the PIS, in the PIS.
4. Please include infection information about the risks of parenteral lines and immunocompromised patients. These are not considered minor.
5. Please replace references to Australian guidelines and legislation with New Zealand relevant ones.
6. Please add contact details for Māori cultural support, the co-ordinating investigator, and the Health and Disability Commissioner.
7. Please amend the PIS to remove the sentence that withdrawal from the study has to be in writing.
8. Please amend the CF so that notifying of a participant’s GP is an optional aspect.

Decision

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

* Please address the questions raised as part of the peer review.
* Please provide suitable information and consent forms.
* Please address the Committee’s outstanding concerns.
* Please address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed (*Ethical Guidelines for Intervention Studies* *para 4.7*).
* 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 clarify if FUR is occurring as part of this study, and if so, provide the details of the HDEC registered tissue bank where tissue will be stored. Please provide a separate FUR PIS/CF.

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

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| **4** | **Ethics ref:** | **17/NTB/58** |
|  | Title: | PRONTO-T1D |
|  | Principal Investigator: | Dr John Baker |
|  | Sponsor: | Eli Lilly Australia Pty Ltd |
|  | Clock Start Date: | 23 March 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. The study investigates a new type of insulin for type 1 diabetes and whether or not the current standard of care drug provides the best outcome for patients.
2. Insulin has been shown to be more effective when it has a shorter window and is faster acting.
3. 24 participants will be recruited in New Zealand. Worldwide 27 countries will participate, with a total of 1005 participants.

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 about the handheld electronic diary and its’ purpose. The Researchers explained that the sponsors like to collect information about the use of insulin and the associated treatment.
2. The Committee asked if the Insulin Treatment Satisfaction Questionnaire and if this was part of the study questionnaire. The Researchers stated that it is.
3. The Committee were concerned that participants without wireless internet may not be able to use the tablet devices to complete the questionnaire. The Committee suggested that the sponsors consider pre-paying on the tablets to allow them to connect to the internet without the need for a wireless home connection.
4. The Committee noted that any future advertisements for this study will need review.

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 while there is no need for an independent data safety monitoring committee they were interested in knowing what safety and governance procedures were in place. Please advise the Committee about what procedures are in place in lieu of a data safety monitoring committee.
2. The Committee noted that the sponsor is updating their insurance and that New Zealand participants would not be covered to the extent that Australian participants would be. Please provide evidence of cover for New Zealand participants that is equal to what overseas participants are receiving.
3. The Committee noted the ambiguous statement about biomarker research. The Researchers explained that the sponsor would remove this aspect if it had to be optional. The Committee noted that if this was left in then it could exclude those who do not want to give genetic material. Please explain why this cannot be made optional.
4. Please advise the Committee if Māori consultation has occurred and the outcome of this consultation.
5. Please clarify if the data until withdrawal consent is optional.

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. The Committee suggested that the PIS also include the entitlements for compensation that were agreed to in the HDEC application form. These were:
   * rehabilitation (comprising treatment, social rehabilitation, and vocational rehabilitation)
   * first week compensation
   * weekly compensation
   * lump sum compensation for permanent impairment
   * funeral grants, survivors' grants, weekly compensation for the spouse or partner, children and other dependents of a deceased claimant, and child care payments
3. Please remove the statement about participants being unable to review their data until the experiment is completed.
4. Please amend the privacy statement to state that there will be no use of data or tissue for future unspecified research.
5. Please remove the impartial witness declaration from the consent form.
6. Please remove that withdrawal has to be in writing. Verbal withdrawal is acceptable in New Zealand.
7. Please move the paragraph beneath the Māori cultural statement to a more appropriate location. As the current placement is confusing.

Decision

This application was *provisionally approved* 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 Māori cultural consultation. (*Ethical Guidelines for Intervention Studies* *para 4.7*).
* Please clarify if the biomarker research can be optional and if not then explain why not.
* Please provide evidence that New Zealand participants will be insured to the same level as overseas participants.
* Please explain what safety procedures are in place in lieu of a data safety monitoring committee.

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Mr John Hancock.

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| **5** | **Ethics ref:** | **17/NTB/53** |
|  | Title: | A study on the effects of oral BEZ235 and/or RAD001 on respiratory tract infections in elderly subjects. |
|  | Principal Investigator: | Dr Dean Quinn |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 March 2017 |

Dr Dean Quinn 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 trial of drugs designed to help improve immune function in the elderly who have respiratory issues.
2. 168 participants will be recruited in New Zealand.
3. Participants will be randomised into a placebo or study drug arm. The two arms with the study drug will have 5 or 10 milligram doses.

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 what ethical issues can be identified with the project. The Researcher explained that there is tissue and blood collection as part of this study and that some patients could be considered vulnerable due to advanced age.
2. The Committee asked how vulnerable participants will be protected. The Researcher explained that they will only be enrolling patients who are healthy and can consent. Participants will be referred from services or be contacted through the sponsor’s database. People sign up to the database to be recruited for research.
3. The Committee asked if there are 12 sites in New Zealand. The Researcher confirmed this.
4. The Committee asked if recruitment procedures will be standardised across sites. The Researcher explained that recruitment will be based on referrals and so cannot be fully standardised.
5. The Researcher explained that a mini mental state assessment will be performed to ensure that participants are able to provide informed consent. In the event that someone is recruited directly then their GP will be contacted for their opinion on their suitability and consentability.
6. The Committee noted that any future advertisements would require HDEC review.
7. The Committee asked if the participant card will feature a 24 hour number. The Researcher explained that it does and that there are procedures in place to allow the un-blinding of patients in an emergency.
8. The Committee noted that the other trial sites have experience in running clinical trials.
9. The Committee noted that the PIS requires participants to stop their medications. The Researcher explained that this is very unlikely to happen and may only be for specific medicines. Participants would only stop their medicines following a discussion with their GP.

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 there is a $100 reimbursement for travel costs per visit and asked if anyone has greater travel costs if these will be met. The Researcher explained that they would meet these costs. The Committee asked that the PIS be updated to reflect this.
2. The Committee asked how the data safety monitoring committee is considered independent. The Researcher explained that they did not know at this stage but that they would contact the sponsor for an explanation.
3. The Committee asked about what Māori consultation had been sought for the study and the outcome. The Researcher explained that consultation had not finished but they would provide the outcome of this once it is available.

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

1. Please list the locations of the specialist labs mentioned in the PIS/CF.
2. 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.”*
3. The Committee suggested that the PIS also include the entitlements for compensation that were agreed to in the HDEC application form. These were:
   * rehabilitation (comprising treatment, social rehabilitation, and vocational rehabilitation)
   * first week compensation
   * weekly compensation
   * lump sum compensation for permanent impairment
   * funeral grants, survivors' grants, weekly compensation for the spouse or partner, children and other dependents of a deceased claimant, and child care payments
4. Please state that all reasonable travel expenses will be met.

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 cultural consultation (*Ethical Guidelines for Intervention Studies* *para 4.7*).

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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| **6** | **Ethics ref:** | **17/NTB/44** |
|  | Title: | Multi-dimensional Approach to Improve Exercise Compliance in Patients with Inflammatory Bowel Disease - A Pilot Study |
|  | Principal Investigator: | Miss Georgina Fagan |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 23 March 2017 |

Miss Georgina Fagan and Dr Hamish Osborne 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 whether or not a multi-dimensional approach of care helps improve exercise compliance in patients with inflammatory bowel disease.
2. 100 patients in the Dunedin area will be recruited and self-allocate themselves to one of the arms of the study. One arm involves group exercise with a trainer and the other involves independent exercise with an exercise planner.
3. The Committee noted that the Researcher had responded to the Committee’s concerns from the prior application.

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 previous study design was too large for an honours project and queried how this would be managed. The Researcher explained that the follow up will not be performed by the co-ordinating investigator and Dr Schulz will perform the final follow up.
2. The Committee queried the apparent lack of equipoise with the study and how a lack of randomisation will negatively impact the study. The Researcher explained that this study aims to help the participants achieve independence and does not seek to establish the superiority of one arm over the other.
3. The Committee had concerns over how self-selecting would lead to a bias in the two groups. The Researchers explained that previous research shows that self-selection has not been shown to predict or influence compliance.
4. The Committee queried why samples have to be sent overseas. The Researcher explained that there are specialist laboratories in Canada that they need to send samples to.

Summary of ethical issues (outstanding)

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

1. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. The Committee asked if Māori consultation had been completed. The Researchers explained that it had not. Please provide the outcome of Māori consultation.

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

1. Please ensure the PIS/CF is clear that there is no randomisation in this study.
2. Please add a specific Māori contact.
3. Please add the contact details for the Health and Disability Commissioner and Health and Disability Ethics Committees.
4. Please amend the pis/cf to clarify if pregnant people will be excluded or not
5. Please make it clear that this is student-led research.

Decision

This application was *provisionally approved* 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 4.7*).
* Please check the questionnaire for typographic errors.
* Please number the items that are referred to as items 1-3 in the questionnaire.

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

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| **7** | **Ethics ref:** | **17/NTB/59** |
|  | Title: | Staphylococcus capitis colonisation of neonates at Dunedin Hospital |
|  | Principal Investigator: | Miss Louise Thorn |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 March 2017 |

Ms Louise Thorn 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 seeks to identify the sources of staphylococcus capitis in Dunedin Hospital’s Neonatal Intensive Care Unit (NICU.)
2. Analysis of swab data, which is collected as part of standard care, will be used to identify cases and controls in the unit.
3. Approximately 75 neonates will be recruited as part of this 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 the high quality of the application.
2. The Committee noted that NICU staff will be recruiting and know the purpose of the research and asked if the staff would be aware that if an infection is identified it would be due to a failure to uphold handwashing protocols. The Researcher explained that data collected about staff will not be identifiable.
3. The Committee asked if the charge nurse will be allocating a de-identification code. The Researchers explained that this was the case, but all data would be immediately de-identified on receipt and that this de-identified will then be further de-identified in a code-to-code linking document. This means that data will be permanently anonymised and there is no risk of individual staff being targeted.
4. The Committee asked where the code-to-code document will be stored. The Researcher explained that it will be stored on a password protected computer.
5. The Committee asked if family members will need to be informed of test results. The Researcher explained that all tests are standard care and the parents will already be informed.

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 the information and consent forms for Future Unspecified Research (FUR) need to be separate from the main study information sheet and consent form. Please provide a separate information sheet and consent form for FUR and amend the main information sheet and consent form to remove references to FUR. The Committee recommended the Researcher use the template on the HDEC website and contact the Secretariat for assistance if necessary.
2. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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

1. Please add that this project is for a qualification and specify what the qualification is.
2. Please add page numbers.
3. Please include that parents have the right to look at their child’s health information.
4. Please make sure that the PIS states early on that this project is research.
5. Please remove the yes/no tickbox for making clinical staff aware of which children are participating, as this is non-optional.
6. Please remove that it is the parent’s responsibility to check for study eligibility. This lies with the Researcher.
7. Please ensure that the PIS reflects that both mother and babe are participants but that it may not always be the mother providing the consent for release of the infant’s health information.
8. Please make sure that Māori cultural support details are on the PIS.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please provide a separate PIS/CF for FUR.

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

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| **8** | **Ethics ref:** | **17/NTB/56** |
|  | Title: | LADAMO study |
|  | Principal Investigator: | Dr David Squirrell |
|  | Sponsor: | Save Sight Institute (SSI) |
|  | Clock Start Date: | 23 March 2017 |

Dr David Squirrel was not present for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study is a randomised controlled trial of laser therapy and the study drug, aflibercept, versus aflibercept only in patients who have diabetic macular odema.
2. 10 patients will be recruited in New Zealand, with a further 45 being recruited in the Australian arm of the study.
3. Randomisation to each arm of the study will be at a 1:1 ratio.

Summary of ethical issues (resolved)

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

1. The Committee recommended that the Researcher use the pro forma PIS/Cf found on the HDEC website (<http://ethics.health.govt.nz/>).

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 they are unsure if this study counts as a commercially sponsored trial and what this means for participant eligibility for ACC compensation. Please clarify if this study is a commercially sponsored clinical trial and use the appropriate compensation wording in the participant information sheet. If the trial is commercially sponsored please provide evidence of the sponsor’s insurance documentation.
2. Please provide an updated peer review from a New Zealand-based reviewer. Please note that if the study is sent to the Standing Committee on therapeutic Trials then this is sufficient.
3. The Committee queried if there was a data safety monitoring committee. Please explain if there is and what measures are being taken to ensure participant safety and study oversight.
4. Please explain when data will be anonymised.
5. Please explain why ethnicity data is not being collected
6. The Committee noted that the Researcher stated that they will not be reviewing medical records to recruit participants. Please explain the recruitment procedures for this study.
7. Please explain in greater detail how adverse events will be managed.
8. Please explain why there is only one pregnancy test as part of the study.
9. 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*).
10. The Committee were unclear if the study drug is registered in New Zealand but not funded. Please advise the Committee if this is the case and include this in the PIS. If the study drug is not registered in New Zealand then please provide evidence of review by the Standing Committee on Therapeutic Trials.

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

1. Please ensure that all PIS/Cf documents are localised to be New Zealand relevant.
2. Please add a lay title.
3. Please provide more detail on side effects.
4. Please update the HDEC contact details in the form for accuracy.
5. Please add Māori contact details.
6. Please add that participants should endeavour not to become pregnant.
7. Please remove the witness statement.
8. Please specify what contraception or other birth control should be used.
9. Please use lay terms in place of words such as fovia.
10. Please use the New Zealand complaints number, not an Australian-based one.
11. Please add a section to the start of the PIS/Cf about asking for an interpreter.

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 clarify if this study is a commercially sponsored clinical trial and use the appropriate wording in the participant information sheet. If the trial is commercially sponsored please provide evidence of the sponsor’s insurance documentation.
* Please provide an updated peer review from a New Zealand-based reviewer. Please note that if the study is sent to the Standing Committee on therapeutic Trials then this is sufficient.
* The Committee queried if there was a data safety monitoring committee. Please explain if there is and what measures are being taken to ensure participant safety and study oversight.
* Please explain when data will be anonymised.
* Please explain why ethnicity data is not being collected
* The Committee noted that the Researcher stated that they will not be reviewing medical records to recruit participants. Please explain the recruitment procedures for this study.
* Please explain in greater detail how adverse events will be managed.
* The Committee were unclear if the study drug is registered in New Zealand but not funded. Please advise the Committee if this is the case and include this in the PIS. If the study drug is not registered in New Zealand then please provide evidence of review by the Standing Committee on Therapeutic Trials.

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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| **9** | **Ethics ref:** | **17/NTB/57** |
|  | Title: | Community Pharmacists Educating to Reduce risk of Acute Kidney Injury |
|  | Principal Investigator: | Ms Di Vicary |
|  | Sponsor: | Hawke's Bay DHB |
|  | Clock Start Date: | 23 March 2017 |

Ms Di Vicary and Dr Colin Hutchinson 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 if community pharmacists educating about temporarily stopping certain groups of medication when people are unwell, helps reduce the risk of acute kidney injury.
2. 250 participants will be recruited in New Zealand in a cohort design.

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 the high quality of the application.
2. The Committee asked for the rationale for the project. The Researchers explained that minor kidney injury is associated with worse long term outcomes in patients who are on medications. Educating patients about risks may help improve outcomes.
3. The Committee queried the recruitment processes and if participants will have time to think about their participation. The Researchers explained that there is no need to decide about participation immediately.
4. The Committee asked about the privacy of the education setting. The Researchers explained that the conversation will occur in private if possible.
5. The Committee asked about use of terms such as ‘unwell’ in the information sheet and if these were appropriate. The Researchers explained that they had made these changes following Māori consultation to make the language more accessible to their community. The committee suggested the HDE template information sheet and consent forms may be helpful with any further revisions of study documents.
6. The Committee noted that sending identifiable health information via fax was not a secure method. The Researchers agreed that collecting the information from pharmacies in person would be more appropriate.
7. The Committee asked if the Researchers could seek expert peer review for advising participants to stop their medications for several days. The Researchers explained that they have gone through a local peer review process involving cardiologists, diabetes specialists, and nephrologists and that all these experts have assessed the protocol.
8. The Committee asked if the patient would be counselled to always notify their GP on the day of stopping medication and the Researcher agreed this would be part of the education package.
9. The Committee asked about the analysis plan for the study and if it used quantitative of qualitative methods. The Researchers explained that the study uses qualitative methods and investigates patient retention and recall of information whilst identifying what types of patients it proved beneficial for.

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 they be provided with copies of the intervention training manual and powerpoint slides.
2. The Committee requested that they be provided the 6 day guidance sheet for participants.
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.)

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

1. Please make sure that the information clearly instructs participants to discuss stopping their medications with their GP.
2. Please include how long the education talk will take.
3. Please clarify that health information collected during the study must be held for ten years, and that it will be stored in a secure location.
4. Please add Māori, HDC, and HDEC contact details to the information sheet.
5. Please separate the information sheet and questionnaire.
6. Please ensure that there is no data collection on the consent form, these questions should be moved to the questionnaire.
7. Please add that participants have the right to access their information and correct it.
8. Please move the statements about koha and informing participant’s GPs about their study participation to the information sheet and consent form.
9. Please check the information sheet and consent forms for typos.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please 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.
* Please provide the committee with copies of the six day guidance sheet, intervention training manual and slides.

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

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| **10** | **Ethics ref:** | **17/NTB/50** |
|  | Title: | Quantification of intranasal topical gadolinium distribution |
|  | Principal Investigator: | Dr James Johnston |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 23 March 2017 |

Dr James Johnston 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 uses intranasal gadolinium spray to investigate the distribution of nasal sprays in the noses of patients who have had surgery for sinusitis.
2. 10 potential participants will be identified from a database of people who have had sinusitis surgery and have indicated that they would like to be approached for research participation.
3. Participants who have not had sinus surgery do not respond well to sprays due to sinus blockage and thus are ineligible for study participation.
4. By performing the study the Researcher hopes to determine if the current modelling technique for spray distribution is useful and validate or amend the current model.

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 this seems to be a pilot study of a diagnostic test , not a study comparing different devices to administer nasal medication and asked if the Researcher had a plan to do a larger study. The Researcher explained that at this study is wholly a proof of concept project.
2. The Committee asked about the cut-off age for the project and why over 60 year olds were excluded. The Researcher explained this is the standard cut-off age in most sinus studies, that over 60s and have had sinusitis for a long time will likely have had changes to their sinuses. There is also a slight risk of nephrotoxicity from gadolinium.
3. The Committee asked how recruitment would occur. The Researcher explained that they have a database of patients who have been seen in the past and who have indicated that they are willing to be approached for research. The Committee suggested using the database first in all instances rather than cold calling.

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 outcome of Māori consultation. (*Ethical Guidelines for Intervention Studies* *para 4.7*).

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

1. Please explain that MRIs can be noisy and claustrophobic.
2. Please include contact details for Māori cultural support, the CI, and the HDC on the information sheet.
3. Please include that suitable travel costs will be reimbursed.
4. 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.”*
5. Please remove all tickboxes from the consent form apart from those items where saying no would not exclude someone from the study.
6. Please include that there will be a one week follow-up phonecall.
7. Please include that data will be held for 10 years, not for future research and that this data will be store in a de-identified form.
8. Please specify the storage arrangements for the MRI scans.

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 4.7*).

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

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| **11** | **Ethics ref:** | **17/NTB/55** |
|  | Title: | Comparison of the blood levels of two forms of acamprosate tablets in healthy male and female volunteers under fed conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 23 March 2017 |

Dr Noelyn Hung, Dr Tak Hung, and Ms Linda Folland 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 is a blinded, two-way, crossover bioequivalence trial of acamprosate tablets in healthy volunteers under fed conditions.
2. Approximately 26 healthy volunteers aged between 18 and 55 will be recruited from the sponsor database and advertisement for this project.
3. Participants will spend a 36 hour overnight stay at the study site on each of 2 separate weekends.

Summary of ethical issues (resolved)

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

1. The Committee queried the side effects associated with the study drug. The Researchers explained the drug is safe. Side effects would be limited to headache, back pain and minor flu-like symptoms.
2. The Committee asked if the Researchers have a specialist trained in the administration of the suicidal ideation scale. The Researchers stated that they do.
3. The Committee asked what would happen if any participant felt suicidal. The Researchers explained the specialist would intervene immediately.
4. The Committee noted that participants in this study are male and female and stated that requirements for contraception need to be from two weeks ahead of study procedures. The Researchers agreed that they would update the study protocol and information sheet.
5. The Committee noted that PIS clearly and thoroughly explained the effects of the study drug.

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*).

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

1. Please add that all participants need to check that their study participation will affect their health insurance, not just international participants.
2. Please amend the PIS regarding the requirements for contraception that were agreed at the meeting.
3. Please indicate that the pregnancy risk on the consent form, 4th from the bottom in the list, applies to all and not just the partner.
4. Please remove all technical language such as excipient.
5. Please add the Māori support contact phone number to the information sheet.
6. Please remove the statement on page 4 of the information sheet that states that participants must refrain from prescription meds as this is confusing.

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*).

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

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| **12** | **Ethics ref:** | **17/NTB/54** |
|  | Title: | Comparison of the blood levels of two forms of acamprosate tablets in healthy male and female volunteers under fasted conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 23 March 2017 |

Dr Noelyn Hung, Dr Tak Hung, and Ms Linda Folland 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 is a blinded, two-way, crossover bioequivalence trial of acamprosate tablets in healthy volunteers under fasted conditions.
2. Approximately 26 healthy volunteers aged between 18 and 55 will be recruited from the sponsor database and advertisement for this project.
3. Participants will spend a 36 hour weekend stay at the study site on each of 2 weekends.

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 asked about the side effects associated with the study drug. The Researchers explained the drug is safe. Side effects would be limited to headache, back pain and minor flu-like symptoms.
2. The Committee asked if the Researchers have a specialist trained in the administration of the suicidal ideation scale. The Researchers stated that they do.
3. The Committee asked what would happen if any participant felt suicidal. The Researchers explained the specialist would intervene immediately.
4. The Committee noted that participants in this study are male and female and stated that requirements for contraception need to be from two weeks ahead of study procedures. The Researchers agreed that they would update the study protocol and information sheet.
5. The Committee noted that PIS clearly and thoroughly explained the effects of the study drug.

Summary of ethical issues (outstanding)

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

1. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. The Committee requested that they were provided the outcome of Māori consultation. (*Ethical Guidelines for Intervention Studies* *para 4.7*).

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

1. Please add that all participants need to check that their study participation will affect their health insurance, not just international participants.
2. Please amend the PIS regarding the requirements for contraception that were agreed at the meeting.
3. Please indicate that the pregnancy risk, 4th from the bottom in the list, applies to all and not just the partner.
4. Please remove all technical language such as excipient.
5. Please add the Māori support contact phone number to the information sheet.
6. Please remove the statement on page 4 of the information sheet that states that participants must refrain from prescription meds as this is confusing.

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*).
* The Committee requested that they were provided the outcome of Māori consultation. (*Ethical Guidelines for Intervention Studies* *para 4.7*).

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

## 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:** | 02 May 2017, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

The meeting closed at 5:45pm.