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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 03 November 2015 |
| **Meeting venue:** | Novotel Ellerslie |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 06 October 2015 |
| 12:30pm | New applications (see over for details) |
|  | i 15/NTB/209  ii 15/NTB/204  iii 15/NTB/205  iv 15/NTB/206  v 15/NTB/198  vi 15/NTB/200  vii 15/NTB/201  viii 15/NTB/202  ix 15/NTB/203  x 15/NTB/207  xi 15/NTB/206  xii 15/NTB/211 |
| 5:00pm | General business:   * Noting section of agenda |
| 5:30pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Raewyn Sporle | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Apologies |
| 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 | Non-lay (other) | 01/07/2012 | 01/07/2015 | Present |
| Ms Shamim Chagani | Non-lay member in the provision of health and disability services | Co-Opt NTA | Co-Opt NTA | Present |
| Dr Nora Lynch | Non-lay (health/disability service provision) | 01/07/2015 | 01/07/2018 | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Mrs Stephanie Pollard.

The Chair noted that fewer than five appointed members of the Committee were present, and that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Ms Shamim Chagani confirmed their eligibility, and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 06 October 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/NTB/209** |
|  | Title: | HCV in Renally-Impaired Adults (EXPEDITION-4) |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | AbbVie |
|  | Clock Start Date: | 22 October 2015 |

Prof. Ed Gane and Ms Angelle Lockie 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 will consider a new treatment regime for patients with Hepatitis C and renal failure. The current treatments are unsuitable for these patients as they cause severe anemia and patients with renal failure will already have anemia.
2. The new treatment regime involves a combination of two drugs. This combination has been tested in participants with normal renal function and it has shown good tolerability, this study aims to test this treatment in patients with renal failure.
3. The Committee noted that this is an interesting study and that the application was well written and easy to understand.

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 number of blood samples needed to be taken from participants in the study. The Researcher explained that although the total volume of blood taken from participants would be approximately 500mls this would be taken over the course of 12-13 blood samples of approximately 30-40mls throughout the study. Further, the Researcher assured the committee by explaining that these blood samples would ideally be taken from the participant’s dialysis line and that the participants are unlikely to notice any change from their blood samples being taken.
2. The Committee noted that although participants may have increased rates of anemia, and this could increase the risks associated with taking blood samples, this did not pose a serious concern for this study due to the blood samples being spread over a number of visits.
3. The Committee questioned the statement on page 14 of the Participant Information Sheet regarding who needs to pay for the study costs as it states that participants will not need to pay for the investigational product but may need to pay for some medications as per hospital policy. The Researcher explained that this was meant to refer to medications participants will currently be taking and would continue to take throughout the study, consequently they would need to continue to pay for these throughout the study. The Committee requested that this was made clearer in the Participant Information Sheet as it currently sounded like participants would need to pay for medications required specifically for the study.
4. The Committee questioned the status of Māori consultation. The Researcher assured the committee that it had been submitted and they expected to receive a response shortly.
5. The Committee noted that the Participant Information Sheet statements regarding what happens if a participant becomes pregnant during the study are quite harshly worded and state that the outcomes of pregnancy will be followed up. The Committee requested that this was softened to make it clear that the outcomes of pregnancy would only be followed up with the participant’s consent.
6. The Committee questioned if the researchers would also need to follow up on the outcomes of pregnancy if the participant’s partner were to become pregnant, rather than the participant themselves. The Researcher explained that in this case it would not be necessary to follow up if the partner became pregnant as they had no reason to believe that there was any risk from a partner becoming pregnant.
7. The Committee questioned if the number on the Participant Card was available 24/7. The Researcher agreed to alter the number to ensure it was available 24/7.
8. The Committee questioned the lack of arrangements for formal data safety monitoring. The Researcher explained that a committee will monitor the data safety in real time as it is collected. The Committee requested that this is clarified in writing to the Committee.
9. The Committee questioned the response to the question regarding reducing inequalities in the application form. The Researcher explained that the study hoped to reduce inequalities as Māori had much higher rates of renal failure and use of dialysis, therefore the results of this study may disproportionately provide benefits for Māori. The Committee stated that in future it would be beneficial to explain this more clearly in the application as this was an important benefit of the study.
10. The Committee questioned the statement in the Participant Information Sheet that participants may wish to consult with a kaumatua, they suggest that it may be more appropriate to have a more general statement suggesting that participants consult with someone they trust.

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

1. Please ensure that the Māori Support Contact Details are more clearly included in the Participant Information Sheet.
2. Please ensure it is clear in the Participant Information Sheet that participants will need to continue paying for medication unrelated to the study but that all study medication will be provided free of charge.
3. Please ensure that any American spelling in the Participant Information Sheet is modified to the appropriate New Zealand spelling.
4. Please ensure a 24/7 contact number is provided on the Participant Card.
5. Please soften the statements regarding follow up of pregnancy outcomes.
6. Please alter the statements regarding the suggestion to consult with a kaumatua.

Decision

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

1. Provide details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies para 6.50).*
2. Please amend the information sheet and consent forms, 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 the secretariat.

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| **2** | **Ethics ref:** | **15/NTB/204** |
|  | Title: | GS-US-367-1171: A study of Sofosbuvir/Velpatasvir/GS-9857 chronic hepatitis C patients previously treated with a direct acting antiviral |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 22 October 2015 |

Prof. Ed Gane and Mrs Carolyn Harris 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 follows a successful phase 2 trial completed earlier this year.
2. The study medication combines two new drugs with a current treatment in a single tablet to create an effective and robust triple therapy.
3. The study drug hopes to provide an effective therapy for patients who have failed treatment with standard care as there is not currently any treatment options for these patients as they have failed all other treatment regiments.
4. The Study drug will be taken once daily for 12 weeks by participants.
5. The Committee thanked the researchers for the high standard of their 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 questioned the likelihood of participants requiring a liver biopsy if their fibro scan is indeterminate. The Researcher explained that they do not expect to need to do any liver biopsies on participants in this study as they have not needed to do any for the previous few years.
2. The Committee noted participants will undergo a urinary drug screen and the Committee questioned the process undertaken if illicit drugs are detected. The Researcher explained that although detecting cannabinoids does not pose an issue, the presence of methamphetamine or narcotics would cause a participant to be unable to participate in the study as these drugs may interact poorly with the study drug. The Researcher explained that participants will be told that they will be tested for drugs and that if certain drugs are found they will not be allowed to participate. If the drug test returns a positive result these individuals will be referred to the CADS service, although this is a self-referred service and they may not wish to follow this up.
3. The Committee questioned the reasons for including participants’ date of birth on their tissue samples, rather than just their participant number. The Researcher explained that this was common across many of their studies and used as a second form of identification to track participants’ samples and reduce the chance of errors.
4. The Committee noted that the main Participant Information Sheet states that some leftover blood samples will be frozen and stored in Singapore, the Committee questioned if this only applied to participants who consented to their tissue being used for unspecified future research. The Researcher explained that they have a separate consent form for future unspecified use of tissue and that this statement only applied to participants who consented to this. The Committee requested that this is rephrased in the main Participant Information Sheet to make it clear that having their leftover blood frozen and stored in Singapore was optional and would only occur with their consent.
5. The Committee noted that in the Future Unspecified Use of Tissue form participants are consenting to three things, extra blood being taken, blood being stored for future research (non-genetic), and blood being used for future (genetic) studies. The Committee noted that the tests consented to under the primary consent form are only non-genetic testing and they suggest that it would be valuable to make this distinction clearer in the main consent form.
6. The Committee questioned whether the study was registered in a clinical trial registry. The Researcher confirmed that the registration with trials.govt is currently pending.
7. The Committee questioned what happens after the end of the study, for example if the study drug would continue to be available to participants or if they would revert back to standard of care. The Researcher explained that this drug is a short term curative treatment and if successful participants should not need to continue treatment with it.
8. The Committee questioned the Māori Consultation process. The Researcher confirmed that it is underway and going well and that they have already identified someone to be listed as the Māori Support Contact on the Participant Information Sheet.

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

1. Please ensure it is clear in the main consent form and information sheet that testing done for the main study is only non-genetic.
2. Currently the Participant Information Sheet states that participants will be reimbursed for child care, missed work etc, however, the Committee noted that this sounds like income rather than simply reimbursement of study expenses. The Researcher explained that $250 would be offered to participants in the optional sub-study to reimburse them for their time as they would be required to stay overnight. Please ensure this is clearly explained in the Participant Information Sheet.
3. Please clarify in the Participant Information Sheet how much reimbursement for travel is available for participants.
4. Please ensure Māori contact details are included in the Participant Information Sheet.
5. Please ensure it is clear in the Participant Information Sheet that pregnancy outcomes will only be followed with permission from the participant.
6. The Committee questioned the statement in the Participant Information Sheet that no treatment options are available for participants, they suggest that the wording of this statement could be softened slightly as although this may be factual wording it this strongly may be distressing for participants. The Researcher agreed to soften the statement and explained that this study is specifically aimed at patients who have no other treatment options available.
7. The Committee requested that it is clear in the Participant Information Sheet that the study drug will not be available after the end of the study.
8. The Committee questioned the risks from the study drug causing pregnancy issues or birth defects. The Researcher explained that this was not a specific concern with this study. The Committee suggested that the statement in the Participant Information Sheet regarding the risks of becoming pregnant is softened slightly to reflect this.
9. The Committee suggests that the statement in the Participant Information Sheet regarding men not donating sperm is reworded to make it clearer.

Decision

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

1. Please amend the information sheet and consent forms, 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 the secretariat.

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| **3** | **Ethics ref:** | **15/NTB/205** |
|  | Title: | GS-US-367-1172: A study of Sofosbuvir/Velpatasvir/GS-9857 chronic hepatitis C patients naive to direct acting antiviral treatment |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 22 October 2015 |

Prof. Ed Gane and Mrs Carolyn Harris 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 Committee discussed this application alongside 15/NTB/204 as the studies are closely related.
2. The Committee thanked the researchers for the high standard of their application.
3. This study is considering an alternative treatment with a shorter treatment time. The current treatment is a pill containing 2 drugs that is taken daily for 12 weeks, the treatment in this study combines 3 drugs into a pill that is taken daily for only 8 weeks.

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 likelihood of participants requiring a liver biopsy if their fibro scan is indeterminate. The Researcher explained that they do not expect to need to do any liver biopsies on participants in this study as they have not needed to do any for the previous few years.
2. The Committee noted participants will undergo a urinary drug screen and the Committee questioned the process undertaken if illicit drugs are detected. The Researcher explained that although detecting cannabinoids does not pose an issue, the presence of methamphetamine or narcotics would cause a participant to be unable to participate in the study as these drugs may interact poorly with the study drug. The Researcher explained that participants will be told that they will be tested for drugs and that if certain drugs are found they will not be allowed to participate. If the drug test returns a positive result these individuals will be referred to the CADS service, although this is a self-referred service and they may not wish to follow this up.
3. The Committee questioned the reasons for including participants’ date of birth on their tissue samples, rather than just their participant number. The Researcher explained that this was common across many of their studies and used as a second form of identification to track participants’ samples and reduce the chance of errors.
4. The Committee noted that the main Participant Information Sheet states that some leftover blood samples will be frozen and stored in Singapore, the Committee questioned if this only applied to participants who consented to their tissue being used for unspecified future research. The Researcher explained that they have a separate consent form for future unspecified use of tissue and that this statement only applied to participants who consented to this. The Committee requested that this is rephrased in the main Participant Information Sheet to make it clear that having their leftover blood frozen and stored in Singapore was optional and would only occur with their consent.
5. The Committee noted that in the Future Unspecified Use of Tissue form participants are consenting to three things, extra blood being taken, blood being stored for future research (non-genetic), and blood being used for future (genetic) studies. The Committee noted that the tests consented to under the primary consent form are only non-genetic testing and they suggest that it would be valuable to make this distinction clearer in the main consent form.
6. The Committee questioned whether the study was registered in a clinical trial registry. The Researcher confirmed that the registration with trials.govt is currently pending.
7. The Committee questioned what happens after the end of the study, for example if the study drug would continue to be available to participants or if they would revert back to standard of care. The Researcher explained that this drug is a short term curative treatment and if successful participants should not need to continue treatment with it.
8. The Committee questioned the Māori Consultation process. The Researcher confirmed that it is underway and going well and that they have already identified someone to be listed as the Māori Support Contact on the Participant Information Sheet.
9. The Committee questioned the appropriateness of the study design, specifically as an open label rather than blinded study. The Researcher explained that the Open Label design was suggested by the FDA and they did not believe it would impact results as they were not treating symptoms in this study. Further, the Researcher explained that they believe it would be overly difficult, compared to the benefits, to blind this trial as a placebo would need to be developed for the study arm that only lasts 8 weeks.

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

1. Please ensure it is clear in the main consent form and information sheet that testing done for the main study is only non-genetic.
2. Currently the Participant Information Sheet states that participants will be reimbursed for child care, missed work etc, however, the Committee noted that this sounds like income rather than simply reimbursement of study expenses. The Researcher explained that $250 would be offered to participants in the optional sub-study to reimburse them for their time as they would be required to stay overnight.
3. Please clarify in the Participant Information Sheet how much reimbursement for travel is available for participants.
4. Please ensure Māori contact details are included in the Participant Information Sheet.
5. Please ensure it is clear in the Participant Information Sheet that pregnancy outcomes will only be followed with permission from the participant.
6. The Committee questioned the statement in the Participant Information Sheet that no treatment options are available for participants, they suggest that the wording of this statement could be softened slightly as although this may be factual wording it this strongly may be distressing for participants. The Researcher agreed to soften the statement and explained that this study is specifically aimed at patients who have no other treatment options available.
7. The Committee requested that it is clear in the Participant Information Sheet that the study drug will not be available after the end of the study.
8. The Committee questioned the risks from the study drug causing pregnancy issues or birth defects. The Researcher explained that this was not a specific concern with this study. The Committee suggested that the statement in the Participant Information Sheet regarding the risks of becoming pregnant is softened slightly to reflect this.
9. The Committee suggests that the statement in the Participant Information Sheet regarding men not donating sperm is reworded to make it clearer.

Decision

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

1. Please amend the information sheet and consent forms, 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 the secretariat.

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| **4** | **Ethics ref:** | **15/NTB/206** |
|  | Title: | A natural environment versus medication in children with ADHD |
|  | Principal Investigator: | Dr. Dione Healey |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 October 2015 |

Mr Matt Stevenson 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 aims to extend research that demonstrated improved attention abilities after a short exposure to a natural environment.
2. This study will compare the effects of a short walk in a natural environment to a short walk in an urban environment in children with ADHD.
3. Participants will either receive their normal dose of Ritalin or a Placebo prior to the walk. Participants who receive the Placebo will be given their regular dose of Ritalin after they complete the study tasks.

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 if there was a risk posed by removing the child’s dose of Ritalin. The Researcher assured the Committee by stating that the child’s Ritalin would only be slightly delayed, rather than removed completely.
2. The Committee questioned who wrote the Peer Review as it does not provide their name. The Researcher explained that the Peer Review process was international and they are unsure of the reviewer’s name, although they can assure the Committee that the Peer Reviewer is independent from the study.
3. The Committee questioned if the researchers intended to collect Ethnicity Data. The Researcher stated that they did not currently intend to. The Committee requested that Ethnicity Data is collected and suggested that the New Zealand Census question is used.
4. The Committee questioned if a 24 hour Washout period was long enough for the study. The Researcher stated that they had questioned this and could not remember the answer to the question at the time, however, they believed that a 24 hour washout was suitable in this case and would confirm with their supervisor.
5. The Committee questioned the amount of time that children would need to commit to participation in the study, especially as this would require them to not attend school. The Committee suggested that it may be beneficial to consider holding the study sessions in school holidays to ensure participants do not need to miss school. The Researcher stated that they would look into this possibility, and that they expected that they may have some participants drop out of the study as they needed to attend 4 study sessions.
6. The Committee questioned who the study sponsor is, in terms of who is responsible for the study. The Committee suggested that it may be the Head of Department from the University may be comfortable being listed as the study sponsor as it is generally the student’s institution. The Researcher stated that they will follow up with their Institution to determine who should be listed as the sponsor.
7. The Committee questioned the statement in the Peer Review that talked about a study in children without ADHD. The Researcher explained that his study was conducted in Denmark so had not come though HDEC review.
8. The Committee questioned what happens if it rains during the study period, will the children still go for a walk outside. The Researcher explained that in poor weather the study period will be postponed to a different day.
9. The Committee questioned parents would be reimbursed for their travel costs. The Researcher explained that they would be providing a petrol voucher to parents.
10. The Committee questioned what happens if something goes wrong during the study. The Researcher explained that someone from the department of medicine will administer the Placebo and a Psychiatrist will be available if necessary.
11. The Committee questioned the recruitment processes and asked if participants would be recruited through CAMP services. The Researcher explained that they have the support of the ADHD clinic at the University with a database of participants that they will recruit from, they do not intend to contact CAMP services.

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

1. The Committee requested that tick boxes are only included in the Consent Form for sections that are truly optional.
2. Please add page numbers to the Participant Information Sheet.
3. Please include the Māori Support contact detail in the Participant Information Sheet.
4. Please adjust the study contact details in the Participant Information Sheet to New Zealand phone numbers.
5. The Committee suggested that having the Participant Information Sheet proof read for spelling and grammatical errors would be beneficial.
6. Please add the availability of a petrol voucher to the Participant Information Sheet.
7. The Committee requested that the Child Participant Information Sheet and Consent Form may not be age appropriate. Please adjust these forms to ensure they are suitable for the age group.
8. Please clarify in the Participant Information Sheet who will be going for the walk.
9. Please make it clear in the Participant Information Sheet if the children will need to miss any school for the study.

Decision

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

1. Please confirm that a 24 hour washout period is suitable for the purposes of this study.
2. The Committee requested that the name of the Peer Reviewer is provided if possible for completeness.
3. Please provide the name of the study sponsor, who will be responsible for the study.
4. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Intervention Studies para 6.22)*

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| **5** | **Ethics ref:** | **15/NTB/198** |
|  | Title: | Can ultrasound scanning be utilised in the assessment of paediatric airway pathology? A pilot study |
|  | Principal Investigator: | Dr Jean Murdoch |
|  | Sponsor: | Capital and Coast District Health Board |
|  | Clock Start Date: | 22 October 2015 |

Dr Jean Murdock 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. The Committee noted that this was a very interesting application and the proposal seemed to be a beneficial and innovative idea.
2. The Committee requested that in future applications documents are submitted without track changes and with a larger font size to improve readability.

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 status of Māori Consultation. The Researcher explained that it has not yet been submitted as they were waiting for the ethics approval. The Committee noted that this could be submitted at the same time in future.
2. The Committee questioned whether the researchers were comfortable with the data safety monitoring arrangements for this study. The Researcher confirmed that they are comfortable with the arrangements.
3. The Committee questioned how the researchers would determine it was appropriate to stop recruiting participants. The Researchers explained that all study doctors would be in close contact and recruitment would stop once they had recruited 20 study participants and 100 control participants.
4. The Committee questioned the statement that there are no Māori Cultural issues, however as the researchers will be touching the children’s head and neck this raises cultural issues that will need to be addressed for their Māori consultation. The Researcher agreed to look into this for their Māori consultation.
5. The Committee questioned how the ultrasounds would be performed on young babies who have short necks. The Researcher explained that they have a special ultrasound bed and will use a pillow under the infants shoulder or neck to extend the neck to improve access.

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

1. The Committee requested that the Participant Information Sheet was reconsidered to make it easier to understand for lay participants, for example please ensure all technical terms are explained clearly.
2. Please ensure accurate compensation wording regarding ACC is included in the Participant Information Sheet. The Committee suggested the wording from the HDEC template: *“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 questioned the statement in the Participant Information Sheet regarding access to study data. It is stated that only the researchers will have access to the data, however it appears that study data will be entered into a regular treatment electronic database that would allow other clinicians, not in the research team, access to this data. Please clarify this in the Participant Information Sheet.
4. Please include the HDEC Contact details in the Participant Information Sheet.
5. The Committee noted an inconsistency between the control and main Participant Information Sheet, one refers to participants between 0-10 years and the other states 0-12 years, please ensure these are made consistent.
6. The Consent Form states that information may be used for future trials. Please remove this or add more information regarding the kinds of trials and how they will be conducted.
7. Although the Committee encourages the collection of ethnicity data, they request that this is not collected on the Consent Form as this is not a data collection form.
8. Please ensure it is clear in the Participant Information Sheet that study data will be kept long term, and is potentially identifiable as it is linked with their NHI number.
9. The Committee questioned the lack of information sheets and assent forms for child participants. They requested that these are developed for the 7-12 year old participants.
10. Please ensure correct spelling of Tokelauan.

Decision

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

1. Please develop child assent forms and information sheets for the 7-12 year old participants.
2. Please amend the information sheet and consent forms, 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 Maliaga Erick.

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| **6** | **Ethics ref:** | **15/NTB/200** |
|  | Title: | Respiratory Virus Whole Genome Sequencing |
|  | Principal Investigator: | Assoc Prof Lance Jennings |
|  | Sponsor: | Canterbury District Health Board |
|  | Clock Start Date: | 22 October 2015 |

Dr Jo Mitchell 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 ethical issues (resolved)

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

1. The Committee questioned the status of Māori Consultation. The Researcher explained that it is currently in progress.
2. The Committee questioned if all of the study information will be fully de-identified. The Researcher explained that samples will have a participant number that cannot be linked to a person in New Zealand by the overseas researchers.
3. The Committee questioned if ethnicity data would be collected from the donors. The Researchers explained that they only have access to very limited information regarding the individual the samples were obtained from, and this does not include ethnicity data so they cannot collect it.
4. The Committee questioned how the use of tissue without consent is ethical in this study. The Researcher explained that the samples were collected with the purpose of being diagnosed with a virus and this study continues to use these samples for a very similar purpose of looking more closely at this virus.
5. The Committee explained that under the Human Tissue Act 2008 these samples are considered Human Tissue and, therefore, cannot be used without the consent of the individual unless approved by an ethics committee under Right 7(10)(b) of the HDC Code of Rights.
6. The Committee determined that due to the potential benefits of this research, and as the use of the tissue for this study is closely related to the purpose for which it was originally collected, it was appropriate to approve the use of tissue without consent under Right 7(10)(b) of the HDC Code of Rights.

Decision

This application was *approved* by consensus.

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| **7** | **Ethics ref:** | **15/NTB/201** |
|  | Title: | Investigating the feasibility of a Mindfulness Based Cognitive Therapy text package for young adults who have experienced psychosis symptoms. |
|  | Principal Investigator: | Mrs Mary Miller |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 22 October 2015 |

Mrs Mary Miller 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 MINT text message system being trialed in this study is aimed at providing further support to patients receiving mental health care.
2. Participants’ will receive reminder texts twice daily, once in the morning and once in the evening. The Morning message reminds participants why it is important to practice their mindfulness exercises. The Afternoon message will provide more practical suggestions to participants on exercises they can do.
3. Participants will receive standard care as well as the MINT message system.
4. Participants are able to text the word ‘Crisis’ back to the system to receive contact details if they need urgent or further support.
5. The Committee noted that this is an innovative and on-trend study.
6. The Committee noted the high quality of the peer review and the good data safety monitoring process, the committee noted that they are also happy with the quality of the Māori Consultation.

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 ethnicity data was not being collected in this study. The Researcher explained it is due to the small sample side. The Committee responded that they did not feel that this was sufficient reason to not collect ethnicity data and suggested that it is important to collect this information if possible. The Committee suggested that it may be possible in future to customize the system with Te reo Maori messages, for example, and collecting ethnicity data would be important for this.
2. The Committee questioned if health information, or baseline data was being collected for this study. The Researcher explained that they would not access participants’ notes and the data would be self-disclosed from participants.
3. The Committee questioned if an interpreter would be available. The Researcher explained that understanding of English is essential for this study as the text messages would be only sent in English.

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

1. The Committee noted an inconsistency between the compensation specified in the advertisement and the Participant Information Sheet, please modify this to ensure accuracy.
2. Please ensure the Participant Information Sheet include Māori Support Contact Details.
3. The Participant Information Sheet seems to suggest that participant’s health information will be accessed, please clarify that the researchers will only access information that participant’s give researchers directly.

Decision

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

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

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| **8** | **Ethics ref:** | **15/NTB/202** |
|  | Title: | Dementia Research Clinic: Identifying biomarkers and factors that affect Mild Cognitive Impairment and dementia |
|  | Principal Investigator: | Associate-Professor Lynette J. Tippett |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 22 October 2015 |

Ass. Prof. Lynette Tippett and five co-investigators were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The Committee noted that this was a thorough and well put together application.
2. The Committee noted that the overview flow chart was an excellent idea and they found it to be beneficial.
3. The Committee noted that the Tissue Bank application and management system was well documented and presented.

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 recruitment and referral process. The Researcher explained that participants would either be referred by their primary or secondary clinician, although they also wanted the option to allow individuals to self-refer if they had a strong family history. The Researchers have flyer that will be available for GP offices and Memory Clinics. The Researcher explained that one reason they are primarily looking to recruit through physicians is because they do not know how many potential participants they will have access to and are not equipped to cope with very large numbers of participants, therefore the involvement of physicians in the referral process will help ensure potential participants meet the inclusion criteria before they are referred to the study.
2. The Committee questioned the process for recruiting the participant’s ‘study partner’. The Researcher explained that the ‘study partner’ is almost essential to the study, however if the participant did not want to involve their family or friends they may still be able to participate. The Researcher did not expect recruiting ‘study partners’ to be a significant issue as most patients had a close family member or friend who would be willing to participate. The study partner would be suggested by the participant and then approached by the researchers and asked to complete an informed consent process.
3. The Committee questioned whether participants would be able to access information collected about them, noting that the information collected may be difficult to understand and very technical. The Researcher explained that it was important that participants could access information collected about them if they wanted to, however they would only routinely be provided with a feedback meeting that explained their results in lay language by an experienced professional.
4. The Committee questioned the need for participants to be fluent in English. The Researchers explained that it was important that participants had a good understanding of English and that participants’ referring clinician would be able to help determine this. The Committee noted that certain ethnicities have higher rates of dementia and that dementia patients may revert back to their first language, they are concerned that these factors could result in some minorities being excluded from the study. The Researcher explained that although they do not wish to exclude people who are not fluent in English they do not have access to interpreters for this study and this has imposed some constraints on their inclusion criteria.
5. The Committee questioned if participants will be reimbursed for their travel costs. The Researcher explained that although they would like to provide petrol vouchers or similar, and their locality has also requested this, they do not have the available funding to cover this cost.
6. The Committee questioned how long participants will be followed for, and under what circumstances the research team would stop following them, for example if they moved into managed care. The Researcher explained that they would ideally follow participants until they expressed a desire to stop participating, or if participation became outside of their abilities.
7. The Committee noted some inconsistency regarding whether participants would be asked for their permission to involve their doctor. The Researcher explained that the participant agreeing to the researchers forwarding any results to their doctor was a requirement of participation, and if they did not want their results shared they would be prevented from participation in the study.
8. The Committee questioned if all participant would be competent to consent for themselves and who would determine this. The Researcher explained that the research team was experienced with this patient population and they did not expect to encounter a problem as they were only including participants with mild dementia and any participant who expressed a desire to stop participating in the study would be removed from the study. Further, participant’s referring clinician would have a good understanding of their competencies and could advise whether participants are capable of providing informed consent.

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

1. The Committee noted some Australian references and American spelling in the Participant Information Sheet and requested that it was modified to make it more suitable for the New Zealand population.
2. Please ensure all technical terms are explained in the Participant Information Sheet.
3. Please ensure the Participant Information Sheet includes information regarding all the processes participants will be involved in or expected to do and how often they will be conducted.

Decision

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

1. 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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| **9** | **Ethics ref:** | **15/NTB/203** |
|  | Title: | Apama RF Balloon Catheter System |
|  | Principal Investigator: | Dr Ian Crozier |
|  | Sponsor: | Apama Medical |
|  | Clock Start Date: | 22 October 2015 |

Dr Ian Crozier 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 noted that this was an interesting first in human study.

Summary of ethical issues (resolved)

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

1. The Committee questioned what kind of preclinical training the sponsor was providing. The Researcher explained that they had required the sponsor to provide training in animals for the researchers and they had begun the application process to do this training in animals.
2. The Committee questioned the data safety monitoring arrangements. The Researcher explained that an independent, external, monitoring company based in Australia would monitor the study and that there would also be internal monitoring.
3. The Committee questioned if this study would involve participants from other countries. The Researcher explained that New Zealand is the main site for the study and that sites in other countries would only be established if enough participants could not be recruited in New Zealand. The Researcher estimated that there would be 30 total participants, with 20 participants in New Zealand.
4. The Researcher explained that they would like to do all of the study procedures in New Zealand if recruitment numbers allow. The Committee questioned how difficult it would be to recruit 30 participants in New Zealand. The Researcher stated that they expect to see 80 potential participants per year at each of the two New Zealand study sites, a total of 160 possible participants, however, it was unknown how easily they would be able to recruit participants from these patients.
5. The Committee requested that the details of the co-investigators is provided as this was mistakenly omitted from the original application.

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

1. Please ensure it is clear in the Participant Information Sheet that although participants are likely to receive a smaller dose of radiation in this study they may end up receiving a similar dose if their physician believes they need a CT scan at the end of the study.

Decision

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

1. Please ensure the Participant Information Sheet is clear regarding the expected dose of radiation participants are likely to receive in relation to the amount they would likely receive if they are not in the study.

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| **10** | **Ethics ref:** | **15/NTB/207** |
|  | Title: | Australasian phase II haplo study |
|  | Principal Investigator: | Dr Nigel Patton |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 October 2015 |

Dr Nigel Patton 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. Patients with certain malignant blood conditions often require a Haemopoietic stem cell transplantation from a HLA-identical donor, however such well-matched donors are very difficult to find. 20% of patients do not have such a donor and until recently did not have the option of a cure by transplantation.
2. Until recently it was considered very dangerous to attempt a transplant from a half-matched family member as the risk of rejection was high. However, recent research has shown that use of a drug, cyclophosphamide, after the stem cells have been infused can allow this kind of transplant to be performed.
3. This kind of transplant, from half-matched family and with the use of cyclophosphamide, has already been performed in some Australian and New Zealand clinics and this trial aims to verify and formalize the results of this form of transplantation.
4. The chances of locating a fully matched donor are much higher for Caucasian individuals, consequently, minorities less likely to be cured by transplantation currently.
5. There are only approximately 1-2 patients per year that are suitable for this kind of transplant in each hospital, this study hopes to combine their data to generate more useful results.

Summary of ethical issues (resolved)

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

1. The Committee noted that participants are able to withdraw from the study verbally, however the forms provided suggested that participants would need with writing. The Researcher stated that this was an oversight on their part and would be removed.
2. The Committee questioned how the consent process would be conducted and whether participants would have the study verbally explained to them given the technical nature of the procedure. The Researcher explained that they will take significant time to explain the study and the procedure to the participants over a period of time.
3. The Committee questioned if the study had been registered. The Researcher assured the committee that it has been and that this was a mistake in the application form.

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

1. The Committee noted that the Participant Information Sheet is confusing. For example, the table listing medications in the Participant Information Sheet is confusing. The Researcher responds that this table reflects the transplant conditioning treatments that every patient receives as standard of care.
2. The Committee questioned the accuracy of the Participant Information Sheet, specifically regarding the matching of the drugs listed in the table and the drugs listed in the narrative. The Committee suggested that a closer reading of the Participant Information Sheet and some more detailed work on it would enable improved clarity for participants. The Researcher agreed to revise the Participant Information Sheet to make it more accessible to lay participants.
3. The Committee noted that 50% haploidentity genetic similarity, is not the same as 1 in 2 people, they suggested that this be revised.
4. The Committee recommended a thorough spelling and grammar check of the Participant Information Sheet to reduce errors.
5. The Committee suggests that a rearrangement of the side effects may provide more clarity, for example listing the side effects from most to least common may provide useful.

Decision

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

1. Please amend the information sheet and consent forms, 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 the full Northern B Committee at an online meeting.

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| **11** | **Ethics ref:** | **15/NTB/208** |
|  | Title: | Aldosterone levels in very preterm infants. |
|  | Principal Investigator: | Dr Roland Broadbent |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 October 2015 |

Dr Roland Broadbent 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. Increased levels of Aldosterone (a hormone) may be harmful for infants if its increased presence continues for over 1 month after birth, this study will consider how long Aldosterone continues to be present in preterm infants after birth.
2. Blood samples will be collected from the placenta and then regularly from the infant after birth until they are well enough to leave the hospital.

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 who is responsible for the study and can be listed as the sponsor, they suggested that it may be the School of Medicine. The Researcher agreed to follow this up and clarify this for the Committee.
2. The Committee raised concerns regarding the proposed deferred consent process for collecting blood from the placenta, especially given the cultural issues surrounding the use of the placenta.
3. The Committee was disappointed with the statement that they are no expected concerns regarding the taking of placenta blood prior to consent as this invalidates the feelings of individuals who may have concerns, especially regarding the use of the placenta. The Researcher explained that in their experience parents do not have objections regarding the taking of blood from the placenta to check the medical condition of the baby. The Committee explained that taking blood for medical testing aimed to benefit the individual is ethically different to taking blood for the purposes of research.
4. The Committee questioned what happens to the blood taken from the placenta if the parents do not want to their infant to participate. The Researcher explained that prior to obtaining consent the placenta blood would only be taken and stored in case they are able to use it for the study. If the parents did not wish for their infant to participate in the study the sample would then be disposed of according to hospital policy, with the option of disposal with Karakia.
5. The Committee explained that blood samples from the placenta cannot be taken or used for the purposes of research without the consent of the individual, unless approved by an ethics committee under Right 7(10)(b) of the HDC Code of Rights.
6. The Committee determined that due to the potential benefits of this research, the need to take blood from the placenta swiftly after birth, the difficulties surrounding obtaining consent prior to collection of the tissue, and because no tests would be conducted on the samples before consent is obtained, it was appropriate to approve the collection of tissue without consent under Right 7(10)(b) of the HDC Code of Rights.

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

1. Please clarify the statement in the Participant Information Sheet regarding the compensation arrangements.
2. The Committee noted that participants do not need to withdraw in writing, verbal withdrawal is binding in New Zealand. Please modify these in the participant facing forms.
3. Please remove the statement from the Participant Information Sheet regarding there being no expected concerns with taking placenta blood prior to consent.
4. Ensure all technical terms are clearly explained in the Participant Information Sheet.
5. Please revise or remove the statement from the Participant Information Sheet regarding the Ethics Committee checking health records.
6. Please include the HDEC contact details in the Participant Information Sheet.
7. Ensure the Participant Information Sheet clearly explains what happens to tissue during the study, including how it is stored and disposed of, and what tests may be conducted on these samples.
8. Please ensure accurate compensation wording regarding ACC is included in the Participant Information Sheet. The Committee suggested the wording from the HDEC template: *“If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.  
   If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover”*
9. Please ensure that every procedure done in the study is clearly explained in the Participant Information Sheet.

Decision

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

1. 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 the full committee in an online meeting.

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| **12** | **Ethics ref:** | **15/NTB/211** |
|  | Title: | BELLPIC |
|  | Principal Investigator: | Dr Stuart Dalziel |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 October 2015 |

Dr Stuart Dalziel 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 considers the efficacy of steroids as a treatment for Bell’s Palsy in children.
2. Bell’s Palsy causes facial palsy for varying lengths of time, and seems to act slightly differently in children compared to adults.
3. Bell’s Palsy in adults is routinely treated with steroids and there is evidence to support this, however due to the differences in treating children there is not an agreed standard of care. Some physicians treat children with steroids as they would an adult while others do not.
4. This study aims to recruit 10-15 participants who will be randomized into one of two double blind study arms. One study arm will receive steroids while the other receives a placebo. The Researchers believe that this study meets equipoise as each study arm is commonly used and would depend on the treating doctor’s preference.

Summary of ethical issues (resolved)

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

1. The Committee raised questions about the recruitment process as participants can only be recruited through the Emergency Department in the study design. The Researcher explained that this was the primary way to recruit participants, but that participants could be referred from their GP to the Emergency Department if they wanted to be involved in the study.
2. The Committee raised concerns regarding the extra burden this recruitment process would place on families. The Researcher explained that although they understood this they did not have another recruitment method available but would provide parents with a petrol voucher to reduce the burden on parents somewhat.
3. The Committee questioned who the study sponsor is, in terms of holding responsibility for the study. The Researcher explained that he holds the overall responsibility for the study.
4. The Committee questioned the status of Māori Consultation. The Researcher explained that it has been submitted but has not yet been considered at a meeting.
5. The Committee noted that no assent forms were provided for the children participants. The Committee explained that it was important to show respect for children as people by providing them with information and the ability to assent in a way that they are able to understand.
6. The Committee questioned who will be making and confirming the diagnosis before participants are enrolled in the study. The Researcher explained that the local clinician will make the diagnosis.
7. The Committee questioned the need to take photos and videos of participants. The Researcher explains that although this is optional, they have a strong preference to record these as they will help to ensure the study results are robust. However, they do not want to exclude participants who are strongly against having photos or videos taken.
8. The Committee questioned how these photos and videos would be recorded. The Researcher explained that they have an IPod that they have used for another study that is stored in the secure drug room to ensure security of this device and the photos recorded by it. The Researcher explained that the use of the IPod is well accepted by parents.
9. The Committee questioned how long the photos and videos would be stored for. The Researcher clarified that they would be stored until the end of the study, which they expected to be a few years after recruitment ends.
10. The Committee asked for clarification regarding how the follow up process differs from standard care. The Researcher explained that it is unclear from the literature how long it takes for patients to fully recover from Bell’s Palsy as patients are not routinely followed up. The researcher explained that this is a potential benefit to participants in the study as they will be followed up by a specialist.
11. The Committee questioned the Peer Reviewer’s comments and process. The Researcher explained that the study had undergone as vigorous review process for funding, this involved 3 or 4 independent reviewers and a panel of about 10 people reviewing the study, the study was also further reviewed for approval in Australia.

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

1. The Committee suggests reviewing the ‘flipping a coin’ reference in the Participant Information Sheet.
2. Please provide appropriate information sheets and assent forms for children participants, the Committee noted that it would be appropriate to provide one assent form for participants aged 7-12 and another for participants aged 12-15.
3. Please ensure it is clear in the Participant Information Sheet how long photos and videos will be stored for.
4. Please clarify in the Participant Information Sheet that petrol vouchers will be available as compensation for travel.

Decision

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

1. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Intervention Studies para 6.22)*
2. Please provide appropriate assent forms and information sheets for children participants.

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

## 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:** | Tuesday. 02 February 2016 |
| **Meeting venue:** | Novotel Ellerslie |

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 5:30pm