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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 09 September 2014 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 1.00pm | Welcome |
| 1.10pm | Confirmation of minutes of meeting of 12 August 2014 |
| 1.30pm | New applications (see over for details) |
|  | i 14/NTA/131  ii 14/NTA/132  iii 14/NTA/134  iv 14/NTA/136  v 14/NTA/138  vi 14/NTA/139  vii 14/NTA/141 |
| 4.25pm | General business:   * Noting section of agenda |
| 4.45pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Brian Fergus | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Susan Buckland | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Apologies |
| Ms Shamim Chagani | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Mr Kerry Hiini | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Michele Stanton | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 01/07/2013 | 01/07/2016 | Apologies |
| Dr Christine Crooks | Non-lay (intervention studies) | 01/07/2013 | 01/07/2015 | Present |
| Dr Mark Smith |  |  |  | Present |

## Welcome

The Chair opened the meeting at 1.03pm and welcomed Committee members, noting that apologies had been received from Dr Karen Bartholomew and Ms Susan Buckland.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

The Chair welcomed Dr Mark Smith to the Committee.

The Committee noted that the Middlemore Hospital tissue bank was in the process of transferring ownership to University of Auckland. They agreed that the HDEC Secretariat will ask the new owners to provide documentation around the governance structure and operations.

## Confirmation of previous minutes

The minutes of the meeting of 12 August 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTA/131** |
|  | Title: | A Study to Evaluate Ledipasvir/Sofosbuvir Fixed Dose Combination in Adolescents and Children with Chronic HCV-Infection |
|  | Principal Investigator: | Dr Helen Evans |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 28 August 2014 |

Dr Helen Evans and Ms Kerry Walker were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

* The Committee asked why the researchers felt it was important to do this study in these age groups. Dr Evans explained that a similar study has been approved by the Northern B HDEC which is investigating sofosbuvir and ribavirin in a paediatric population with genotypes 2 and 3 HCV. This study will open up access to all types of genotype of HCV, which is important given that there is more genotype 1 in the paediatric population.
* The Committee noted that there are not a lot of treatment options for children with HCV. Dr Evans advised that the current PHARMAC recommendation is interferon and ribavirin which is badly tolerated by children. She explained that because of this, they do not usually treat children unless they have poor liver function. She said that there is evidence that treating patients earlier is better as there is less risk of developing liver cancer later in life.
* Ms Walker explained that ACS ran a similar study in adults with genotype 1 HCV, with some participants weighing as low as 40kg. This study has seen a 95% cure rate with 12 weeks of treatment.
* The Committee asked why it was preferable to study children. Dr Evans explained that sofosbuvir is being made available for the paediatric population as it has been so successful in adults.
* The Committee asked if the aim of the study was to determine tolerability. Ms Walker explained that the optional PK lead-in will determine the tolerability of the drug. This will be done in 12 to 18 year olds, who have to be over 45kg and will be followed by 12 weeks of treatment.
* The Committee asked if the researchers will wait for the results of the treatment for 12 to 18 year olds before deciding on the doses for the younger age groups. Ms Walker advised that the PK lead in for 7 to 12 year olds will not start until the data for 12 to 18 year olds has been analysed by the DSMB.
* Dr Evans advised that at the moment, there are four potential participants that they know about. None of these are in the 12 to 18 year old age group.
* The Committee asked why, given the vulnerability of the participants, the study had not been split into three separate studies of various age groups. Dr Evans advised that she thinks it is for logistical reasons and that the time between starting treatment for each age group alleviates this. She said other than the difference in doses for age groups, the study design is the same.
* Ms Walker explained that they would not enrol patients if they did not give their assent.
* The Committee asked if New Zealand would be the first country to give ethical approval. Ms Walker advised that ethical approval has been applied for in other countries but has not yet been received. She said that there may be a delay before the lead in group is established as it will depend on ethical approval in other countries.
* The Committee asked if a progress report could be provided for each age group at the end of each treatment. Ms Walker agreed that it could.
* The Committee asked what extra monitoring will be put in place given children may be affected differently. Dr Evans advised that they will monitor growth and pubertal status and a quality of life questionnaire will be administered.
* The Committee asked if the DSMB was independent from the sponsor. Ms Walker advised that it was and while she did not have a list of names, she could provide it to the Committee if required.
* Ms Walker advised that SCOTT approval had been applied for but not yet received.
* The Committee noted that health information needs to be retained for 10 years after a participant reaches the age of 16.
* The Committee asked who will be seeing medical information. Ms Walker advised that Dr Evans will see the participant’s hospital records. Any hospital information that Dr Evans deems relevant will put in the study files and made available for the study doctors, nurses and monitors.
* The Committee requested the following changes to the PIS and consent form for participants over 16 years of age and older:
  + Please include a short lay title.
  + Please include a statement advising that the study is voluntary.
  + Please review language as it is currently not very inviting.
  + Please review for too much repetition, for example signing this consent form.
  + Please remove statement on page 18 that confidentiality of records cannot be guaranteed.
  + Please clarify where samples will be stored.
  + The length of the main PIS is too long at 21 pages. Please reduce.
* The Committee requested the following changes to PIS and consent form:
  + Please simplify language for all PIS but particularly all of the main study PIS for all age groups.
  + Please shorten paragraph on RMI Guidelines (page 17 of parent/legal guardian PIS for participants under 16).
  + Please be consistent with titles for all PIS and consent forms.

Decision

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

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

This information will be reviewed, and a final decision made on the application, by Dr Christine Crooks and Dr Brian Fergus.

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| **2** | **Ethics ref:** | **14/NTA/132** |
|  | Title: | TR-701 FA vs linezolid for the treatment of bacterial pneumonia (TR701-132) |
|  | Principal Investigator: | Dr Shay McGuinness |
|  | Sponsor: | Trius Therapeutics Inc, a wholly-owned subsidiary |
|  | Clock Start Date: | 28 August 2014 |

Dr Shay McGuinness and Dr Rachael Parke 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 ethical issues

The main ethical issues considered by the Committee were as follows.

* The Committee asked for clarification on the consent process. Dr Mc Guinness explained that when a diagnosis of ventilator-associated bacterial pneumonia (VABP) or hospital-acquired bacterial pneumonia (HABP) is made, patients will be treated with standard care for the first 24 hours. The study design allows for a 24 hour window in which the researchers can talk to family, friends and whanau to gain written assent. When a patient recovers, the researchers will seek verbal consent to continue, followed by written consent. As there will be a follow up visit 28 days after beginning the study, it is likely that participants will be from the Auckland region.
* The Committee asked whether patients would have a pregnancy test as part of standard treatment. Dr McGuinness advised that participants will receive a pregnancy test as part of the study protocol but they would not normally as standard treatment.
* The Committee noted that it would be helpful to include further information in the PIS on why new antibacterial drugs are urgently required.
* Dr McGuinness explained that the FDA and EMA developed new guidelines in 2011 and 2012, around non-inferiority trials with antibiotics. Rather than demonstrating absolute superiority, trials are now designed around proving non-inferiority. The FDA has chosen to focus on mortality as an outcome, while the EMA has clinical cure as an outcome. This study will focus on both of these outcomes.
* The Committee asked why treatment group 1 started with the study drug and then placebo and treatment group 2 started with placebo then linezolid. Dr McGuinness explained that this was because they did not want any interactions between the two lines and to match the placebo with the comparator. As participants are already being treated with standard care, there is no delay in starting the treatment.
* Dr McGuinness confirmed that patients will not be enrolled if they cannot speak English as it will be difficult to complete the follow up.
* The Committee asked what was the likelihood of an allergic reaction to the study drug. Dr McGuinness advised that on the data to date, there were no more than linezolid and that it looks like it is a safer drug than linezolid.
* The Committee requested the following changes to the PIS and consent form:
  + Please include the pregnancy related risks in the PIS/CF for relative/whanau/friend.
  + Please clarify what data is de-identified (page 11 of the PIS/CF for relative/whanau/friend).
  + Please include in both PIS/CFs that there will be more follow up than standard care.
  + Please include details of the labs in the PIS.
  + Please include in the PIS whether patients will receive results back.

Decision

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

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

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| **3** | **Ethics ref:** | **14/NTA/134** |
|  | Title: | Perioperative care in chronic sinusitis |
|  | Principal Investigator: | Associate Professor Richard Douglas |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 28 August 2014 |

Dr Ravi Jain 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 ethical issues

The main ethical issues considered by the Committee were as follows.

* Dr Jain explained that chronic sinusitis affects around 8% of the New Zealand and Australian population and is associated with significant morbidity. This study aims to find out the effects of the current medications which are antibiotics and steroids.
* Dr Jain advised that the participants will be recruited from clinics at Gillies Hospital, Auckland City Hospital and North Shore Hospital. Participants will have been referred to these clinics by their GPs and at this stage will not have been diagnosed with sinusitis. When a patient is first enrolled at the clinic, a swab will be taken and they will then be randomised to either antibiotics or steroids.
* Dr Jain advised that the majority of patients go on to have surgery and the administration of drugs will not affect the decision on whether to operate.
* The Committee asked why the data generated was considered potentially identifiable. Dr Jain advised that while this highly unlikely given that it is held in a secure database, there is always a small possibility.
* The Committee noted the good feedback in the scientific peer review.
* The Committee asked how the randomisation will work. Dr Jain advised that the database provides random number generation, which will assign them to either antibiotics or steroids. These drugs are considered standard care. If patients are unwell, they will be given antibiotics.
* The Committee queried the reference to saline sinus rinses in B.1.4.1. Dr Jain advised that this was an error in the application and that at one stage it was thought that this would be another variable.
* Dr Jain confirmed that the researchers will seek HDEC approval for future use of tissue samples.
* Dr Jain advised that this is a bacteria genetics study and not a human genetics study.
* The Committee asked whether power calculations would be done at the end of the study. Dr Jain advised that they would to see whether a larger study needed to be done.
* Dr Jain advised that patients will be identified by a study ID and that only the research nurse will have access to the patient identifiers.

Decision

This application was *approved* by consensus

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| **4** | **Ethics ref:** | **14/NTA/136** |
|  | Title: | Aspirin4VLU: a randomised trial |
|  | Principal Investigator: | Dr Andrew Jull |
|  | Sponsor: |  |
|  | Clock Start Date: | 28 August 2014 |

Dr Andrew Jull and Ms Angela Wadham 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 ethical issues

The main ethical issues considered by the Committee were as follows.

* The Committee asked what the researcher thought were the main ethical issues for this study. Dr Jull explained that these were protection of patient information, maintenance of patient autonomy, integrity of data and protection of patients with regard to adverse events.
* Dr Jull explained that the safety profile of aspirin is well characterised, with the rate of major bleeds in the population around 7 to 10 per 10,000 patients. This study will investigate the rate of serious adverse events.
* Dr Jull explained that evidence suggests that if patients take 300mg of aspirin in addition to compression, at 16 weeks, there is a 62% increase in healing rates. As this is a large dose for older people, this study will look at a reduced 150mg dose.
* Dr Jull explained that the standard treatment for venous leg ulcers is compression bandages.
* Dr Jull advised that the study will take place in Auckland, South Auckland, Waikato and Christchurch and Dunedin.
* Dr Jull explained that the research nurses will be seconded from DHBs but they are district nurses so will have the necessary skills to treat patients. He advised that the research nurses will phone the participants and have three face to face visits at the venue of the patients’ choice.
* Dr Jull advised that the participants will not be required to see their GP. The study team will be in contact with the participant’s GPs to ensure that they can tolerate aspirin and do not have a condition that requires aspirin, which would mean they could not take the placebo.
* Dr Jull noted that a senior biostatistician has agreed to chair the DSMB, along with an international pharmacist who is an expert in pharmacovigilance and a public health doctor. The DSMB will write their own charter and decide on how many times to meet, although Dr Jull has recommended meeting at least three times.
* The Committee asked what the early stopping guidelines would be. Dr Jull advised that the researchers will be providing blinded and unblinded reports to the DSMB. The early stopping points will be for adverse events and not efficacy. The DSMB will provide recommendations to the trial steering committee which will be chaired by Dr Jull.
* The Committee asked whether the follow up on patients could be extended until the end of the two year recruitment period. Dr Jull advised that they only have sufficient funding to pay for six months of treatment and while they could follow up, as participants would be receiving no treatment, it would be a questionable use of resources and patient time.
* Dr Jull advised that they will inform patients at the study conclusion of the study results and what treatment they received. It will then be suggested that they contact their GP for further treatment options.
* The Committee asked if the researchers anticipated any recruitment problems. Dr Jull explained that they have previously done an 18 month trial with 370 participants and that there are already large numbers of patients with venous leg ulcers.

Decision

This application was *approved* by consensus.

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| **5** | **Ethics ref:** | **14/NTA/138** |
|  | Title: | Non-invasive markers for Neuroendocrine tumours |
|  | Principal Investigator: | Dr B Lawrence |
|  | Sponsor: |  |
|  | Clock Start Date: | 28 August 2014 |

Dr Cherie Blenkiron and Ms Kate Park 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.

Dr Christine Crooks declared a potential conflict of interest, and the Committee decided that she would not take part in the discussions.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

* The Committee noted that separate consent is required to collect samples, use the samples for specified research and use the samples for future unspecified research. Please refer to the Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes for further information <https://www.health.govt.nz/system/files/documents/publications/guidelines-use-of-human-tissue-may07.pdf>
* The Committee noted that for future specified research, the PIS should include information on:
  + the tissue banks
  + the governance in place for destruction and storage
  + whether appropriate New Zealand ethical approval will be in place when the tissue is sent overseas or if it will be subject to international ethical guidelines which New Zealand has no say in
  + that samples need to be kept identified for five years.
* The Committee noted that for future unspecified research, the PIS should include information on:
  + that the tissue sample could be transferred to another tissue bank
  + whether they have the ability to withdraw those samples at a later date
  + whether they will be contacted for future studies or if the researchers will apply for HDEC approval.
* Dr Blenkiron explained that the Middlemore Hospital tissue bank consent form had been submitted with the HDEC application. She said that while participant’s samples were in the University of Auckland study their rules would apply and when the samples were transferred to Middlemore their rules would apply.
* Dr Blenkiron advised that the Middlemore Hospital tissue bank consent form would be completed at the same time as the consent process for this study. She noted that Middlemore Hospital will not accept any tissue samples that were not signed off at the same time as the initial consent. The Committee advised that the researchers will need to ensure that the Middlemore consent form is consistent with the information for this study.
* The Committee asked what was the likelihood of clinically actionable findings (R.4.1.1). Dr Blenkiron explained that this was very unlikely but when looking at DNA, clinicians have a responsibility to report back findings if required. She advised that there is an advisory committee who will look at the findings and make a decision on what is actionable.
* The Committee requested the following changes to the PIS and consent form:
  + Please add date and version numbers to the PIS/CF.
  + Please add the ACC compensation clause to the PIS. Suggested wording can be found on the participant information sheet and consent form template at http://ethics.health.govt.nz/

Decision

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

* Please amend the participant information sheet and consent form, taking into account the suggestions 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 Ms Michele Stanton and Mr Kerry Hiini.

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| **6** | **Ethics ref:** | **14/NTA/139** |
|  | Title: | Nortriptyline In Knee Arthritis (NortIKA) |
|  | Principal Investigator: | Dr Ben Hudson |
|  | Sponsor: |  |
|  | Clock Start Date: | 28 August 2014 |

Professor Les Toop 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

The main ethical issues considered by the Committee were as follows.

* Professor Toop advised that this study is a double blind, randomised, controlled trial of nortriptyline to reduce pain in knee arthritis. He explained that current medications are either not effective or have dangerous side effects.
* Professor Toop noted that nortriptyline was originally an anti-depressant but has largely been replaced by SSRIs.
* Professor Toop explained that in the first eight weeks of the study, participants will be rung every two weeks by a research nurse. If their pain is not controlled, the dose will be escalated and if they are getting unacceptable side effects, the dose will be reduced. After the first eight weeks, participants will then receive a stable dose for six weeks. At the end of this time, the researchers will assess whether or not nortriptyline is better than the placebo.
* Professor Toop advised that participants will be recruited through DHBs and will be people who did not make the waiting list for knee replacement surgery as they did not have enough points. GPs who have patients who are eligible will also recruit and if there are not enough participants, the researchers will advertise.
* The Committee noted that the HRC reviewer had raised concern around the SF36 only being used at the end of the study and not the baseline. They asked how the researchers will know if there is an improvement in quality of life if it is not measured at baseline. After the meeting, Professor Toop confirmed that the SF36 is planned at baseline.
* The Committee noted that HRC reviewer had concerns about the use of other analgesics concomitantly. Professor Toop explained that this would mimic real life as people would be taking other drugs and as long as this was documented, he did not see an issue with it.
* The Committee asked if the researchers were concerned that the study could be underpowered. Professor Toop advised that it is unknown how many participants will withdraw in the first eight weeks. If significant numbers are dropping out, this could be an issue. The Committee asked if the sample size would be increased if too many people were withdrawing. Professor Toop advised that they could as there are large numbers of potential participants.
* The Committee asked if the researchers anticipated any problems with recruitment given that some of the participants would be taking a placebo. Professor Toop did not see this as being an issue as participants can use their usual pain relief.
* Professor Toop advised that withdrawal procedures will depend on whether participants are taking one, two or four capsules. After withdrawal, they will be passed over to their GP. The Committee noted that the PIS and protocol need to be amended as the study will take place over more than 14 weeks if withdrawal time is included.
* The Committee requested the following changes to the PIS and consent form:
  + Please include in the consent forms, that no interpreter will be available.
  + Please include information on how the withdrawal will be managed.
  + Please include a sentence in the PIS on the risks associated with treatment if a participant gets pregnant.

Decision

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

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

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| **7** | **Ethics ref:** | **14/NTA/141** |
|  | Title: | NHTP |
|  | Principal Investigator: | Dr Lyndie Foster Page |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 28 August 2014 |

Mrs Dorothy Boyd 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

The main ethical issues considered by the Committee were as follows.

* The Committee asked for clarification on filming of the treatment. Mrs Boyd explained that a feasibility study of the Hall Technique found that children enjoyed their visit more than using conventional techniques. As the Hall Technique does not involve drilling, the aim of the camera is to assess levels of relaxation for both child and dental therapists. The video camera is fixed to the pole attaching the dental light to the dental chair and can be turned on and off remotely. The camera can only see the child and the dental therapist but there will be audio so parents can be heard. The Committee advised that the researchers will need consent from anyone in the video, including the dental therapists and the parents.
* Mrs Boyd explained that this is both a treatment and psychological study. The Committee advised that it needs to clearer in the PIS that another purpose of the study is to determine discomfort levels for the Hall Technique. They noted that the researchers will need to be careful to ensure that the wording is not leading.
* Mrs Boyd advised that the researchers are planning to analyse the videos in conjunction with Dr Barry Gibson, a sociologist. The videos will not be used for training purposes.
* The Committee asked how the child would know which technique was used. Mrs Boyd explained that the treatments are delivered differently. With the conventional technique, there is drilling and children lie down, while with the Hall Technique they will sit upright. She said that the techniques will be randomised as the order of treatment may affect the outcome.
* Mrs Boyd explained that the techniques will not be done on the same day. This needs to be clarified in the PIS.
* The Committee commended the pictorial children’s assent form.
* The Committee asked if there would be any problems with recruitment. Mrs Boyd advised that it may be difficult to recruit children with decay in two back teeth.
* The Committee asked how long the Hall Technique lasted. Mrs Boyd advised that it is for the life of the tooth, with children usually losing their molars between 10 and 12. She said that compared with fillings, they last well.
* The Committee asked if the researchers would follow up with participants until the tooth falls out. Mrs Boyd advised that while this would be ideal, they were only funded for two years. She noted that in a Hawke’s Bay study which was only funded for six months, the DHB and dentists had sent data after two years so it may be possible in this study for the data to be sent to researchers after the funding has ended.
* The Committee felt that the explanation of focus groups was not explained well in the PIS. Mrs Boyd advised that they are still working through the process and when this is confirmed she will put it through as an amendment.
* The Committee noted that data needs to be kept for 10 years after children reach the age of 16.
* The Committee requested the following changes to the PIS and consent form:
  + Please amend from Northern B to Northern A Health and Disability Ethics Committee (page 3).
  + Please include in PIS that parents will be given a copy of the signed PIS to keep (page 1).
  + Please include in the PIS that there will be video and audio.
  + Please move the first paragraph on page 3 to the beginning of the PIS.
  + Please include the ACC compensation clause in the PIS. Suggested text can be found in the participant information sheet and consent form template at http://ethics.health.govt.nz/

Decision

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

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

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 07 October 2014, 01:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

The following members tendered apologies for this meeting.

Dr Brian Fergus

Ms Susan Buckland

The meeting closed at 4.37pm.