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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 05 August 2014 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Auckland |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 01 July 2014 |
| 12.30pm | New applications (see over for details) |
|  | i 14/NTB/91  ii 14/NTB/93  iii 14/NTB/95  iv 14/NTB/96  v 14/NTB/97  vi 14/NTB/98  vii 14/NTB/99 |
|  | General business:   * Noting section of agenda |
| 3.26pm | 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 Kate O'Connor | Non-lay (other) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Paul Tanser | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Ms Kerin Thompson | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Phyllis Huitema | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |

## Welcome

The Chair opened the meeting at 12.11pm and welcomed Committee members, noting that no apologies had been received.

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 1 July 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTB/91** |
|  | Title: | Developing a new model of funding for ACC Non-Acute Rehabilitation |
|  | Principal Investigator: | Professor Matthew Parsons |
|  | Sponsor: |  |
|  | Clock Start Date: | 02 July 2014 |

Professor Matthew Parsons, Professor Paul Rouse and Ms Christine Smith 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 commended the researchers for the high standard of the application.
* The Committee asked why ethnicity data is not being collected in the dataset as they believe it is an important variable in the delivery of casemix rehabilitation. Professor Parsons explained that ACC do not collect it and it is not one of the fields that the Ministry of Health keeps within its minimum dataset. He advised that he is looking into this and is still hoping that they can get it.
* The Committee noted that UniServices should have been nominated as the sponsor for the study.
* The Committee noted that the study start date listed in the application was February 2014.
* Professor Parsons confirmed that the CDROMs with data will be destroyed when the data has been linked and that there will be no link to individuals once it is matched.

Decision

This application was *approved* by consensus.

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| **2** | **Ethics ref:** | **14/NTB/93** |
|  | Title: | A randomized, double-blind, placebo-controlled trial crossover study to assess the efficacy of LipZip in reducing mouth breathing on CPAP treatment |
|  | Principal Investigator: | Dr A G Veale |
|  | Sponsor: |  |
|  | Clock Start Date: | 24 July 2014 |

Dr Andrew Veale, Mrs Kareen Redulla and Ms Carol Veale 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 commended the standard of the application.
* Dr Veale explained that it would be difficult for this study to be truly double blinded because there are obvious differences in the LipZip and the placebo. This would be partially addressed by an initial parallel group comparison where participants are truly blinded before switching to the intervention, where it will become obvious which treatment they are receiving. Dr Veale also advised that data will be taken directly from the CPAP machine which will give a good objective measure despite the lack of double blinding.
* The Committee asked if the researchers would see the questionnaire immediately after completion. Dr Veale advised that they would not check them during the study unless a patient had made a complaint.
* Dr Veale advised that he had received advice from a statistician for the power calculation.
* Dr Veale explained that that the most common reasons for non-compliance with CPAP treatment are mouth leak, dry mouth and blocked nose. This study is limited to trying to control mouth leak.
* The Committee noted there was no sponsor for the study (A.5.1) and asked who the researcher considered would be responsible for the initiation, management and funding of the study. Dr Veale advised that LipZip had approached the New Zealand Respiratory and Sleep Institute (NZRSI) for advice on study trial and design. He explained that LipZip had wanted to target the study towards snorers as this is a large market. Dr Veale explained that the NZRSI were not interested in snorers but it was possible that it would be effective in managing mouth leak for those with Obstructive Sleep Apnea (OSA). He said that if the study is successful the NZRSI may become the New Zealand distributor of LipZip. The Sleep Institute is self-funding the study and holds insurance for the study. The Sleep Institute are considered sponsor for the study. He agreed to send a copy of the insurance certificate to the Committee.
* The Committee asked whether the coordinating investigator has a commercial interest in the study. Dr Veale explained that he has not yet entered into any arrangement with the LipZip but this is a possibility at a later stage. He said that it will not be a dramatically profitable venture for the NZRSI as they will only be concentrating on people who come through the sleep lab. If they had focused on snorers, there would have been the potential for greater financial benefit. The Committee were satisfied with that the researcher does not have a commercial interest.
* Dr Veale confirmed that LipZip is not currently available in New Zealand.
* Mrs Redulla advised that she had emailed Medsafe who had told her that SCOTT approval was not required and LipZip has been categorised as a medical device.
* The Committee asked how participants would be monitored for a reoccurrence of their OSA symptoms. Dr Veale advised that this will be done by asking participants to rate their sleepiness levels. He noted that in general people can come off CPAP for five days before their previous levels of obstruction of sleep are reached. He said that patients are likely to notice a difference after the end of the first week. Patients will be seen every two weeks but they can ring in if they have any concerns.
* The Committee asked what the criteria for terminating the whole study would be and who would have oversight for these decisions. Dr Veale advised that it would be him as principal investigator. He explained that that product has been used before but the criteria for termination would be any serious adverse events, for example swollen lips or if everybody’s conditions worsened. The Committee recommended getting a colleague who is independent of the study to look at the study trends. Dr Veale agreed to talk to the colleague who had peer reviewed the study but noted that as the study will be short, there will not be time to realise if there is a systemic issue.
* Dr Veale advised that clinical files and study files will be kept in a locked facility with access control to maintain the confidentiality of health information.
* Dr Veale confirmed that the summary of findings (P.2.9) would be provided in lay language.
* The Committee recommended using the New Zealand census question to collect ethnicity data.
* The Committee requested the following changes to the PIS and consent form:
  + Please simplify the title of the PIS.
  + Please simplify some of the language in the PIS, for example references to compliance and adherence.
  + Please amend “non-active treatment” (page 2 of the PIS) to “standard treatment” as the PIS currently reads as if Group B will be not be having any treatment.
  + Please amend from references to treatment gels to gel 1 and gel 2 as one of the gels is not a treatment.
  + Please advise in the PIS that LipZip will only be available for the duration of the study.
  + Please remove references to Good Clinical Practice guidelines and add an Investigator statement in line with HDEC template to consent form (page 7 of the PIS/CF).

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide evidence of insurance *(Ethical Guidelines for Intervention Studies, para 8.3 )*

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

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| **3** | **Ethics ref:** | **14/NTB/95** |
|  | Title: | The JANUS 1 Study |
|  | Principal Investigator: | Dr Dean Harris |
|  | Sponsor: | Quintiles Pty Limited |
|  | Clock Start Date: | 17 July 2014 |

No researchers were present for discussion of this application.

Potential conflicts of interest

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

Ms Kerin Thompson declared a potential conflict of interest, and the Committee decided that she would not take part in the discussions or voting.

Summary of ethical issues

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

* The Committee noted that this is a very important study.
* The Committee asked in what other countries the study drug is available.
* The Committee commended the researcher on the excellent pre-entry evaluation.
* The Committee commended the researcher on the clear explanation of the radiation risk.
* The Committee noted that the researcher had identified the main ethical issue as the use of placebo but believed that this was not a concern as there is no other treatment available for those with this stage of pancreatic cancer.
* The Committee asked whether the DSMB will have any members not associated with the pharmaceutical company and asked for a copy of the DMC charter.
* The Committee asked whether there would be a 24 hour number listed on the patient emergency card.
* The Committee noted that the description “this subject is currently participating in a clinical trial of an investigational drug” on the patient emergency card is misleading and suggested amending it to “this subject may or may not be on the investigational product”.
* Please provide specific information on the emergency unblinding procedures within New Zealand.
* The Committee noted that the researchers had listed the data as being de-identified (B.4.4.1) but advised that for future applications (as per later descriptions in the application) that the data was potentially identifiable.
* The Committee asked how the researchers would deal with any unexpected individual clinical findings for participants (R.4.1).
* The Committee noted that participants had not been identified as vulnerable (P.3.2). While participants will be able to give consent, according to the NEAC guidelines, they meet the definition of vulnerability. The Committee asked for clarification on how this vulnerable population will be protected.
* The Committee noted that this was a well written and thorough PIS but asked, given the length and technical language, what will be done to ensure that participants understand it.
* The Committee requested the following changes to the PIS and consent form:
  + Please simplify study title.
  + Please confirm whether an interpreter will be provided.
  + Please remove the “flipping the coin” reference to randomisation.
  + Please clarify whether the reference to not being able to take part in any other studies refers only to other investigational medicines, for example, can they take part in quality of life studies. Please also clarify whether a participant can take part in other studies once this study reaches its end point.
  + Please clarify in the PIS that participants can take the drug indefinitely as long as they are benefitting from it. At the moment, this is unclear as page 13 of the PIS states that the drug will not be available to participants at the end of the study.
  + Please amend the bullet point “I hereby state that I have the legal capacity to enter into contract and that no Guardian has been appointed for me” in both consent forms. Participants are not being asked to enter into contract but rather to indicate their understanding and willingness to participate.
  + Please correct the spelling of whanau on page 1 of the consent form for pregnant partners.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please advise how the vulnerable population group will be protected *(Ethical Guidelines for Intervention Studies, para 5.28).*
* Please provide a copy of the DMC charter *(Ethical Guidelines for Intervention Studies, para 6.50).*
* Please provide information on the emergency unblinding procedures *(Ethical Guidelines for Intervention Studies, para 6.62).*

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

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| **4** | **Ethics ref:** | **14/NTB/96** |
|  | Title: | Ultrasound debridement in management of lower limb wounds |
|  | Principal Investigator: | Mrs Jo Krysa |
|  | Sponsor: |  |
|  | Clock Start Date: | 17 July 2014 |

Professor Andre van Rij 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 commended the standard of the peer review.
* The Committee noted that the researcher had answered that the data generated would be anonymous (B.4.4.1) and advised that if data can be linked back to the source, it is potentially identifiable or partially de-identified. Professor van Rij confirmed that the data would be partially de-identified as patients would be identifiable when the data was collected and the data would be anonymised when put in the dataset.
* The Committee asked whether the researchers had considered how risks such as poor recruitment would be monitored (R.1.5). They asked what trial governance is in place and who specifically will review any adverse events. The Committee recommended using external colleagues for this. Professor van Rij advised that the clinical team, consisting of one independent member and the study investigators, would monitor the adverse events.
* The Committee noted that the researchers stated that the criteria for terminating the study were not applicable (R.1.6). They advised that there may be other reasons for terminating the study, for example lack of recruitment, poor compliance and withdrawals and that there needs to be a process for monitoring these risks. The Committee recommended a governance committee including an external colleague and a statistician.
* The Committee asked for the rationale for keeping data for five years post study completion as this is normally ten years (R.2.5). Professor van Rij advised that this was an error in the application.
* The Committee asked whether consent will be taking place on the same day as the patient is being told about study (P.1.1). Professor van Rij advised that as the treatment needs to be implemented within 24 hours, the researchers will get an independent person to go through the consent process and the researchers will come back to the patients later in the day.
* The Committee noted that for future reference P.4.1 should contain a more definitive statement than “Maori may suffer leg ulceration at a younger age”.
* The Committee noted that sharp debridement and debridement with an autolytic agent had been identified as the two main variables but asked whether antimicrobial acticoat dressings or the use of antibiotics could be considered as another set of variables. Professor van Rij explained that there were a huge number of variables but that as antibiotics are rarely used for treatment of ulcers, that this would not affect the randomisation.
* The Committee asked where the Māori consultation would be taking place. Professor van Rij confirmed that this would be the University of Otago Māori Review Committee.
* The Committee asked for clarification on the independent assessor. Professor van Rij advised that Dr Greg Jones will be looking at the feasibility and statistical elements of the study and Dr Ian Thompson will assess the clinical element of the study. The research team will assess the study photos and pass these on to Dr Thompson for review.
* The Committee asked how the photos will be matched to an individual if there is no identifying information on the photo. Professor van Rij advised that a study identifier can be added to the photo electronically.
* The Committee requested the following changes to the PIS and consent form:
  + Please review the PIS and rewrite in lay language addressing it directly to participants who will be reading it, particularly the first paragraph on page 3 of the PIS.
  + Please provide information on what will happens at each visit, for example will there be debridement at every visit or will some visits be follow ups, how often will there be low frequency ultrasound debridement, how often will photographs be taken.
  + Please amend “you would be eligible for compensation from ACC” to “you may be eligible for compensation from ACC” (page 4 of the PIS)
  + Please remove the yes / no boxes on the consent form for those statements that are not truly optional.
  + Please remove any statements in consent form not applicable to this study.
  + Please include contact details for the Health and Disability Advocate (page 5 of the PIS).

Decision

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

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

This following information will be reviewed, and a final decision made on the application, by Ms Kerin Thompson and Ms Tangihaere Macfarlane.

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| **5** | **Ethics ref:** | **14/NTB/97** |
|  | Title: | FASTER: Feasibility of Accelerating STrokE Recovery |
|  | Principal Investigator: | A/Prof Cathy Stinear |
|  | Sponsor: |  |
|  | Clock Start Date: | 17 July 2014 |

Dr Suzanne Ackerley 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.

Mrs Phyllis Huitema declared a potential conflict of interest, and the Committee decided that she would not take part in the discussions and voting.

Summary of ethical issues

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

* The Committee congratulated the researcher on the HRC funding.
* The Committee noted that the PIS was well written and commended the researchers for the inclusion of a photo in the PIS.
* The Committee noted that the placebo transcranial direct current stimulation (TDCS) was only mentioned on page 1 of the PIS and the rest of the PIS reads as if the participant will be getting real TDCS. Please include information on the randomisation of the groups in the PIS.
* The Committee commended the use of a DSMB in a trial that they considered to be low risk.
* The Committee asked whether participants would get a headache from the TDCS. Dr Ackerley explained that while this is unlikely, it has been reported but is transient and does not require treatment. She advised that they will ask participants to let the researchers know if they have a headache who can then advise whether they need to take anything for it.
* Dr Ackerley explained that participants will be assessed for six weeks post stroke and that those who are discharged from hospital during this time will be visited at home. Please explain in the PIS what will happen in the hospital and what will happen after being discharged.
* Dr Ackerley advised that participants will not be eligible for the study if they cannot give consent. She advised that the witness in the consent form will not be anyone in the research team or a participant’s treating therapist. Please remove “and have been authorised by the subject to sign this consent form on their behalf” from the declaration by witness on page 7 of the PIS/CF as this currently reads as if the witness is giving proxy consent.
* The Committee commended the researcher on the responses to Māori consultation in the application.
* The Committee requested the following changes to the PIS and consent form:
  + Please amend “you would be eligible for compensation from ACC” to “you may be eligible for compensation from ACC”.

Decision

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

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

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| **6** | **Ethics ref:** | **14/NTB/98** |
|  | Title: | Characteristics of 6-methylmercaptopurine preferential production in paediatric acute lymphoblastic leukaemia |
|  | Principal Investigator: | Dr Siobhan Cross |
|  | Sponsor: | Children's Cancer Research Trust |
|  | Clock Start Date: | 17 July 2014 |

Dr Siobhan Cross was present by teleconference for discussion of this application.

Potential conflicts of interest

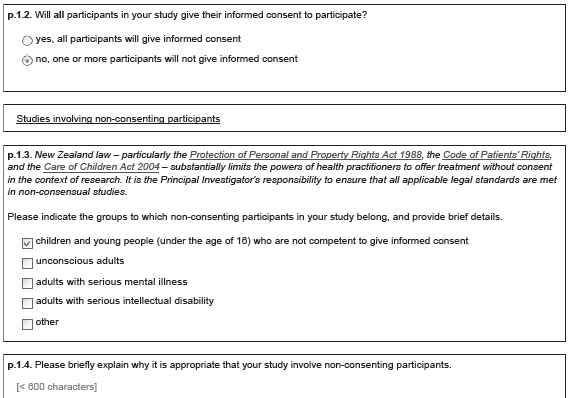
The Chair asked members to declare any potential conflicts of interest related to this application.

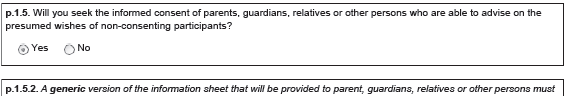
No potential conflicts of interest related to this application were declared by any member.

Summary of ethical issues

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

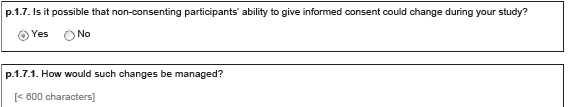
* The Committee acknowledged that this was a low risk, worthwhile study with a PIS for parents that was easy to understand.
* The Committee commended the researcher for the ACC clause in the PIS.
* The Committee asked for information on Te Komiti Whakarite (P.4.3.1). Dr Cross advised that they are a local Māori committee used by the Canterbury DHB, based in the Canterbury region, consisting of primarily Ngai Tahu members.
* The Committee advised that for future reference A.1.5 should give a brief plain English summary.
* The Committee queried the consent process for the tissue bank (R.3.12). Dr Cross explained that Canterbury Health Labs and the Otago Medical School have a tumour bank, funded by the Cancer Society, where tumour samples and blood samples with genomic extracted DNA are stored. Any research on these samples needs to go back through an HDEC before the samples will be released for research. Parents will be asked at the time of giving consent for this study to give consent to store their tissues. The consent form for this is a separate form and has already received HDEC approval. Dr Cross advised that it is the responsibility of the tissue bank to seek consent for participants when they turn 16.
* The Committee asked what was the age range of paediatric acute lymphoblastic leukaemia (ALL) patients. Dr Cross explained that they treat patients from one to sixteen years but there are some aged 18 as treatment can last for up to three years. The Committee advised that a separate PIS and assent form should be provided for those under 16.
* The Committee asked whether Te Komiti Whakarite had any concerns about Māori cultural beliefs on genetic testing. Dr Cross advised that while they had comments on the inclusion of whanau, they had no concerns about the genetic testing.
* The Committee queried how many participants would be recruited as the protocol states 100 and the application states 30. Dr Cross confirmed that this would be approximately 30, consisting of a cross section of patients on maintenance. The Committee asked how this would affect the statistics for the project given that the peer review is based on 100 people being recruited. Dr Cross advised that she considers this a pilot study as there is currently very little information on the metabolism of 6MP in leukaemia patients. If the study is successful they will look at increasing the number of participants in New Zealand and Australia. She explained that 30 participants will give an idea but will not have any statistical significance.
* The Committee noted that the commencement date is listed as 1 June 2014.
* The Committee noted that the answer to P.1.2 should have been no. Please provide answers to the question below.

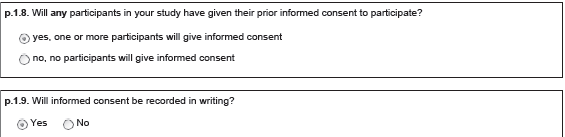












* The Committee requested the following changes to the PIS and consent form:
  + Please include a statement in the PIS that health information will be collected and that what steps will be taken to maintain patient confidentiality.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide an age appropriate PIS and assent form for participants under the age of 16 *(Ethical Guidelines for Intervention Studies, para 6.22).*

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

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| **7** | **Ethics ref:** | **14/NTB/99 (CLOSED)** |
|  | Title: | In vitro TNF alpha modulation by novel compounds |
|  | Principal Investigator: | Mr Kelvin Wang |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 17 July 2014 |

## General business

1. The Committee noted the contents 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:** | 02 September 2014, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Auckland |

No members tendered apologies for this meeting.

The meeting closed at 3.26pm.