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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 04 March 2014 |
| **Meeting venue:** | CEO Meeting Room, Level 3, Hocking Building, Waikato Hospital Campus |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.10pm | Confirmation of minutes of meeting of 04 February 2014 |
| 12.30pm | New applications (see over for details) |
|  | i 14/NTB/19  ii 14/NTB/20  iii 14/NTB/21  iv 14/NTB/22  v 14/NTB/23  vi 14/NTB/24 |
| 3.30pm | General business:   * Noting section of agenda |
| 3.50pm | 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 | 01/07/2014 | Apologies |
| 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 | 01/07/2014 | Apologies |
| Ms Kerin Thompson | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Dr Paul Tanser and Mrs Maliaga Erick.

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. Mrs Helen Walker confirmed her eligibility, and was co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair welcomed Helen Walker, Helen Colebrook and Kelly Traynor to the meeting.

Mrs Stephanie Pollard noted that Australian researchers had praised the New Zealand streamlined ethics process.

The Committee congratulated Helen Colebrook on her appointment as Manager, Ethics Committees.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 4 February 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTB/19** |
|  | Title: | Metacognitive Therapy for Anorexia Nervosa |
|  | Principal Investigator: | Associate Professor Janet Carter |
|  | Sponsor: |  |
|  | Clock Start Date: | 20 February 2014 |

Associate Professor Janet Carter 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 thanked Associate Professor Janet Carter for making the time to speak to the Committee.
* The Committee noted the adjustments to the protocol in response to the declined application which has made it a safer study for participants.
* The Committee noted that the application and participant information were clear and easy to understand and thanked Associate Professor Janet Carter for addressing the questions raised in the decline letter.
* The Committee asked for the timing of recruitment. Associate Professor Janet Carter explained that when a referral comes to the South Island Eating Disorder Service (SIEDS) patients fill in questionnaires and are allocated a clinician. These assessments are taken to a clinical team meeting where a plan is agreed on for a patient, for example, patients may be allocated a therapist, physiotherapist, psychiatrist or dietician. Patients will then agree to this plan.
* Associate Professor Carter noted that metacognitive therapy has been done in SIEDS for some time with individuals and groups and that she wants to collect data on its effectiveness.
* The Committee noted that the researcher wants patients to be on stable medications and noted that dosages might be changed by psychiatrists. Associate Professor Carter explained that while they would prefer patients to be on stable medication, this won’t necessarily happen as some patients will have their medication changed. Any changes to medications will be noted.
* Associate Professor Carter confirmed that the planned commencement date of February 2015 was a typo.
* The Committee asked for clarification on the number of weekly sessions. Associate Professor Carter confirmed that the aim will be weekly for at least the first four weeks, with a total of 10 to 20 sessions.
* The Committee asked for the source of the funding of the study as this was not clear in the application (R.5.1). Associate Professor Carter confirmed that there was no external funding and that the study would be funded within the SIEDS’s existing budget. She explained that she has an RA who helped with putting an application together and will assist with some of the data input and administration.
* The Committee queried the response to F.1.1 and F.1.2 on how the study would contribute to reducing inequalities between different populations. Associate Professor Carter was unsure if there would be any Māori patients and if the metacognitive therapy would be particularly beneficial to Māori or Pacific people but that it was hoped that it would be.
* Associate Professor Carter confirmed that the New Zealand census question would be used for collecting ethnicity data.
* The Committee requested the following changes to the participant information sheet and consent form:
  + Please tell participants to take medication that is prescribed to them.
  + Please tell participants that they will continue to receive metacognitive therapy if they choose to withdraw from the study.
  + In the consent form, please tell participants that the study team will be telling their GPs that they are taking part in this study.

Decision

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

* 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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| **2** | **Ethics ref:** | **14/NTB/20** |
|  | Title: | Aspirin 25 mg/dipyridamole 200 mg bioequivalence study conducted under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 20 February 2014 |

Dr Noelyn Hung, Dr Tak Hung and Ms Linda Folland were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The Committee thanked the researcher for a clear and easy to understand application.
* The Committee commended the independent peer review.
* The Committee asked whether data would be archived on site or with an offsite archive company. Ms Folland confirmed that this is stored onsite in a fire proof archive. The Committee recommended that the researchers read the *NEAC Guidelines* *Intervention Studies* and confirm whether the data is potentially identifiable or partially de-identified, rather than de-identified. The Committee explained that if the linking spreadsheet is stored in the archive, there is the potential for data to be re-identified. Dr Tak Hung explained that FDA and EU regulatory auditors require the information to be kept identified as in overseas studies a number of participants have been found to be fictitious. Auditors will only have access to the information on site and will not be allowed to make photocopies.
* The Committee asked how unexpected findings of clinical significance would be dealt with (R.4.1.). Dr Noelyn Hung explained that counsellors would be provided if HIV was diagnosed and that any other significant results would be sent to the participant’s GP. The Committee noted that for future reference the answer to R.4.1 should be yes.
* The Committee queried the information reading process. Ms Folland advised that potential participants come to a group session where a recruitment administrator reads the PIS to the group. Individuals are then able to ask a trial participant any questions, with the option of doing this in a private room if preferred.
* The Committee asked how much time would be allowed between reading the PIS and consenting. Ms Folland advised that this was generally after the information reading process but participants were able to go away and consider the information.
* The Committee asked if participants were reminded that they can withdraw at any time. Ms Folland advised that participants often changed their mind and they would be taken off the study if this happened.
* The Committee asked whether the aspirin/dipyridamole combination is currently available in New Zealand. Dr Tak Hung explained that combination drugs are difficult to get approved in New Zealand. If the drug is not available in the New Zealand market, please include on page 1 of the PIS that the drug is available on the global market.
* Ms Folland confirmed that Medsafe approval has been received for all three studies.
* The Committee noted that the consent form had an option for having unused blood cells returned and asked whether this was possible. Ms Folland confirmed that blood was put in separate, labelled containers and that it was possible to return blood cells.
* The Committee queried whether international student’s GPs would be contacted. Dr Noelyn Hung explained that they would be contacted if any issues were identified in the screening process but that Student Health is usually given as their local doctor. Participants will have consented to have their doctors contacted.
* Dr Noelyn Hung confirmed that international students’ English was improving and that participants would not take part if it was felt that they did not understand the PIS.
* The Committee queried whether recruitment was done at the University. Ms Folland advised that advertisements were put on Zenith’s windows and interested participants could register on the Zenith website. An advertisement is also placed in the student magazine but this is general advertising rather than for a specific study.
* The Committee were concerned that the space for participant’s initials on each page of the PIS makes it look like a contract. Dr Tak Hung advised that it is part of the protocol that participants have had the PIS read to them and initialling each page allows participants to show that they have. The Committee confirmed that this could be removed or left in at the researcher’s discretion.
* The Committee commended the researchers on the collecting of ethnicity for Maori.
* Dr Noelyn Hung confirmed that the 0800 and Principal Investigator numbers are monitored 24/7.
* The Committee noted the response to P.4.1 which stated that Zenith would strive to recruit 7-9% Māori in the study and asked whether this could be achieved. Ms Folland explained that there were a lot of Māori on the Zenith database and that while they could not control the recruitment, they would aim to get Māori in the study.
* Ms Folland advised that the indemnity policy expired on 3 March but that an extension is in place and the policy will be renewed in a week. She will send this to the HDEC Secretariat.
* The Committee requested the following changes to the participant information sheet and consent form:
  + Please remove the reference to US Law in the last paragraph of page 9 of the PIS. As New Zealand participants are being recruited, the PIS needs to be as relevant for them as possible.
  + Please explain double blinding in the PIS.
  + Please include in the PIS that payments to volunteers may affect any benefits they are receiving (P.3.1).
  + Please make it clear on page 1 of the PIS that participation is voluntary and that participants can withdraw at any stage.

Decision

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

* 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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| **3** | **Ethics ref:** | **14/NTB/21** |
|  | Title: | Aspirin 25 mg/dipyridamole 200 mg bioequivalence study conducted under fed conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 20 February 2014 |

Dr Noelyn Hung, Dr Tak Hung and Ms Linda Folland were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The Committee noted that the application was similar to the 14/NTB/20 study and that their queries had been raised in the discussion of that application. Please see 14/NTB/20 for further information.
* The Committee asked whether it was possible for participants to do the non-fasting study and then move straight on to this one. Ms Folland confirmed that a 60 day stand down period was required.

Decision

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

* 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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| **4** | **Ethics ref:** | **14/NTB/22** |
|  | Title: | Doxycycline three-way crossover pilot study under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Mayne Pharma International Pty Ltd |
|  | Clock Start Date: | 20 February 2014 |

Dr Noelyn Hung, Dr Tak Hung and Ms Linda Folland were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The Committee noted that the application was similar to the 14/NTB/20 and 14/NTB/21 study and that their queries had been raised on the discussion of those applications. Please see 14/NTB/20 for further information.

Decision

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

* 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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| **5** | **Ethics ref:** | **14/NTB/23** |
|  | Title: | Usability Study of Adult Optiflow Cannula 3 |
|  | Principal Investigator: | Dr Anthony Williams |
|  | Sponsor: | Fisher & Paykel Healthcare |
|  | Clock Start Date: | 20 February 2014 |

Dr Tony Williams and Dr Geoff Bold 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.

Summary of ethical issues

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

* The Committee thanked the researchers for being available to the Committee and asked whether the researchers had any further information to add to their application. Dr Williams noted that he thought the study was relatively low risk.
* The Committee asked for justification on why the researchers were not planning on having patients give informed consent. Dr Williams explained that in previous development trials nurses had reported that most patients were confused about completing a consent form as they had already consented verbally. Dr Williams noted that requiring consent adds a small additional risk, as patients are started on the original cannula, then change to the new cannula when consent is given.
* The Committee asked how different the new cannula was to the existing one. Dr Williams advised that it was similar with changes to usability and comfort improvements, for example, amendments to the clip at the back and the way it sits on the patient’s face.
* Dr Williams confirmed that Māori consultation had been submitted to the next review meeting which is usually held within the first week of each month. He advised that having had unofficial chats with members of the Committee, he was not anticipating any major issues to arise.
* The Committee asked that an updated certificate of insurance be sent to the HDEC Secretariat as this had nearly expired.
* The Committee noted that the protocol mentions general information leaflets and asked if these had been uploaded to the Portal. Dr Williams confirmed that this had not yet been written and that he would send it to the HDEC Secretariat when this was complete.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **14/NTB/24** |
|  | Title: | ACH102-017: An open label study to investigate the safety and efficacy of treatment with ACH-0143102 and Sofosbuvir in Hepatitis C patients |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Clinical Network Services |
|  | Clock Start Date: | 20 February 2014 |

Professor Ed Gane, Ms Vithika Suri and Dr Lynda Bluck 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.

* Professor Gane explained that sofosbuvir has been approved as standard care in the USA and Europe. It is currently under review by Medsafe but has not yet been approved.
* Professor Gane explained that studies of sofosbuvir and ACH-0143102 have shown an SVR rate of 95-100%. The purpose of this study is not to demonstrate a high SVR but to show that ACH-0143102 and sofosbuvir are effective in combination.
* The Committee noted the high quality of the protocol and application and were pleased that issues in previous applications had been addressed in this application.
* Dr Gane advised that he and the other investigators will be involved in all data safety reviews and he believes that this is the most effective way of dealing with safety issues in real time.
* The Committee noted that the trial is not currently registered (B.4.6) but the PIS refers to the trial being registered. Ms Suri advised that the study currently has a universal trial number and that the sponsors are currently working on a clinical trial register number. .
* The Committee asked how long the participants in the observation group would have to wait for treatment after group 1A had finished their treatment. Professor Gane advised that there would be a relatively short observation period for those in group 1A and that participants in the observation group would begin their treatment approximately 14 weeks from the start of recruitment.
* The Committee noted that the study design was very good but may be difficult for participants to understand. They recommended a pictorial diagram which would explain how participants move from group 1B to other groups. Dr Gane confirmed a flow chart would be included.
* Dr Gane advised that SCOTT approval had been submitted but he had not yet received a final letter of approval.
* The Committee asked whether those on the observation arm of the study also needed to avoid alcohol. Professor Gane confirmed that they would. This needs to be included in the PIS as the observation arm may not see themselves as receiving treatment.
* The Committee asked whether the fasting requirements included not drinking water. Ms Suri advised that water is usually permitted but she would confirm this with the sponsor.
* The Committee queried what it meant in page 8 of the PIS that government health authorities would be notified if an HIV test was positive. Professor Gane explained that as HIV was a notifiable disease, the study team would notify the Community HIV support team at the hospital, who would notify participants and the Ministry of Health and provide counselling.
* The Committee queried whether the statistical element of the study had been peer reviewed. Professor Gane advised that this had not been reviewed as there was no control arm and it was a cohort study to show that high SVR rates could be achieved.
* The Committee queried whether tax was payable on the payments of $100 to participants. Ms Suri advised that it was and that participants are given a tax form at the beginning of their study.
* The Committee requested the following changes to the participant information sheet and consent form:
  + Please include in the PIS that all study participants, including the observation arm should refrain from drinking alcohol during the study.
  + Please describe the process for participants if an HIV testing result is positive.
  + Please include in the PIS that a participant’s GP or specialist will be informed that they are participating in the trial.
  + Please include in the PIS that the drug will not be available for participants after the study is complete.
  + Please include a diagram explaining how participants will move from group 1B to other treatment groups.
  + Please include lay language for the term pancytopenia on page 9 of the PIS.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made 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:** | 01 April 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 2.37pm.