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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 03 June 2014 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Auckland |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.10pm | Confirmation of minutes of meeting of 06 May 2014 |
| 12.30pm | New applications (see over for details) |
|  | i 14/NTB/61  ii 14/NTB/64  iii 14/NTB/65  iv 14/NTB/68  v 14/NTB/69  vi 14/NTB/70  vii 14/NTB/71 |
| 3.25pm | General business:   * Noting section of agenda |
| 3.45pm | 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 | 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 | 01/07/2014 | 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 12.00pm and welcomed Committee members, noting that no apologies had been received.

The Chair welcomed the new members Mrs Phyllis Huitema and Miss Tangihaere Macfarlane to the Committee.

The Committee discussed the issue of participants being unable to give consent and noted that there was some confusion with the use of the term proxy consent, which cannot be legally given in New Zealand.

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 6 May 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTB/61** |
|  | Title: | Cough testing in COPD |
|  | Principal Investigator: | Ms Rebecca Owen |
|  | Sponsor: | Waitemata District Health Board |
|  | Clock Start Date: | 22 May 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.

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 this was a very easy to follow PIS.
* The Committee noted that the range of people with swallowing difficulties was very wide (17-85%) and asked for clarification on why this was so large.
* The Committee asked why the study commencement date was given as February 2014 (A.1.4).
* The Committee asked for clarification on why the researchers were repeating the test at admission and discharge.
* The Committee noted the view of the peer reviewer that the exclusion criteria may hinder recruitment and asked what adjustments have been made to the protocol in relation to inclusion of participants.
* The Committee noted that R.2.3 refers to a biostatistician and noted that the protocol does not refer to how the data would be analysed. Please provide information on how this will be analysed.
* The Committee commended the plain English version of the procedures set out in R.1.1.
* Please review theNEAC *Ethical Guidelines for Intervention Studies* for the definitions of the data and confirm whether it will truly be de-identified, that is there is no data that could be linked back to the individual patient (R.2.4)
* Please confirm whether the New Zealand census question will be used to collect the ethnicity data (P.4.6)
* The Committee requested the following changes to the PIS and consent form:
  + Please include a version number and page numbers.
  + Please include the ACC compensation clause in the PIS. This wording can be found on the PIS template at http://ethics.health.govt.nz/.
  + Please refer to Northern B HDEC and New Zealand privacy laws.
  + Please include in the PIS that if patients continue to cough during the placebo dose, they will be excluded from the study.
  + Please include a New Zealand contact for complaints.
  + Please remove reference to UK data protection (point 5 of the consent form).
  + Please include in the PIS that the food and drink will be coloured for the swallow test.

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 further information will be reviewed, and a final decision made on the application, by Ms Kate O’Connor and Mrs Mali Erick.

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| **2** | **Ethics ref:** | **14/NTB/64** |
|  | Title: | The STARtrino Trial |
|  | Principal Investigator: | Dr Geoffrey Shaw |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 May 2014 |

Dr Geoffrey Shaw and Dr Matt Signal 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.

* Dr Shaw explained that a similar study was being run using continuous glucose monitors (CGM) on unconscious patients in ICUs but that the other study was observational.
* The Committee asked if the CGM device was approved for use in New Zealand. Dr Shaw explained that it had CE marking, which would meet the regulatory requirements for any European country but that it was not registered or licensed for use in New Zealand.
* The Committee asked if similar devices are used in hospitals in New Zealand. Dr Shaw explained that the devices are used in mobile populations but are not used on hospital inpatients to the best of his knowledge.
* The Committee noted the answer to A.1.6 that researchers would be seeking proxy consent from patients’ relatives. They explained that legally no adult can give consent for another adult to take part in research but that researchers can ask relatives what they believe the unconscious patients views on research would be.
* The Committee were concerned with some of the wording on the PIS for relatives as it implies that the relative is giving consent on the patients’ behalf.
* The Committee asked if the researchers had taken any steps to ascertain whether this study was lawful. Dr Shaw confirmed that no legal opinion had been obtained.
* The Committee noted that Canterbury DHB should be considered the sponsor of this study (A.5.1). Dr Shaw asked for clarification on what constitutes a sponsor. The Committee noted that the sponsor has overall responsibility for the initiation, management and financing arrangements of a study. While the sponsor does not have to provide funding, they have responsibility for the governance of the study.
* The Committee asked for clarification on the criteria for terminating the study (R.1.6). Dr Shaw explained that the only possible reason the whole study would be terminated for everybody would be if the manufacturer identified a problem with the sensor.
* The Committee asked why the study would be in the patients’ best interests given that they are not able to give informed consent. Dr Shaw believes that the CGM would be a useful tool in ICU patients but it needs to be validated in this patient group before it can be used as standard care.
* The Committee noted that participants would be offered the opportunity to receive scientific papers (P.2.9) and recommended making this a lay summary written for a general audience. Dr Shaw advised that the researcher offers to give participants their own results and most participants are happy with that.
* Dr Shaw confirmed that he was still awaiting the outcome of Māori consultation.
* Please confirm that the ethnicity data will be collected as per the questions of the New Zealand census.
* The Committee advised that just as relatives are unable to provide consent on a patient’s behalf, they also cannot withdraw on their behalf. Please reword the references to withdrawing a relative from the study (page 3 of the PIS for relatives) to advise relatives that they can ask the researchers to stop the study at any stage.
* The Committee asked how robust the process is for considering which family member or friend will sign the statement on behalf of the patient. Dr Shaw advised that researchers will discuss with nursing staff and colleagues and refer to patient case notes to find the most appropriate person.
* The Committee asked how this study would reduce inequalities (P.4.1 and P.4.2). Dr Shaw noted that this study does not specifically seek to address inequalities but it would allow for better use of the health budget which could help reduce inequalities.
* The Committee requested the following changes to the STARtrino Project Notice:
  + Please include a picture of the device on the poster.
  + Please include on the poster that the new device is subcutaneous or under the skin.
  + Please reconsider the wording “you may be invited to allow your relative/friend to participate in this study” as this sounds too legal.
* The Committee requested the following changes to the PIS and consent form:
  + Please simplify the language in both PIS as it is currently too technical.
  + Please look at the language around proxy consent and consider changing references from “consent” to “opinions”
  + Please include in the participation paragraph of the PIS that relatives are being asked to sign the statement because their relative is unconscious and cannot give consent but once their relative is conscious, they will be asked to give retrospective consent.
  + Please amend the compensation provisions on both PIS from “you will be covered by the accident compensation legislation” to “you will be able to apply for accident compensation”.
  + Please change “ethical approval from the Southern Health and Disability Ethics Committee” to “Northern B Health and Disability Ethics Committee”.
  + Please include on both PIS that the CGM device has not been registered for use in New Zealand.
  + Please include ICU contact details on the PIS.
  + In the last sentence of the Confidentiality paragraph of the statement for relatives, please amend “By signing the consent form, you consider your friend or relative would agree to the record review, information storage and data transfer” to “By signing the statement, you consider your friend or relative would agree to the research, record review, information storage and data transfer
  + Blood Access Storage and Handling (page 2 of the PIS) – Please use lay language for the Standard.
  + Please review the grammar for both PIS.
  + Please include contact details for Māori cultural support.
  + Please ensure that the dates and version numbers on the PIS match.
  + Please move the three yes / no options on page 2 of the statement by relative to the bottom of page 3 (under statement by participant).
  + Please change “I agree to my GP being informed” to “I agree to my relative/friend’s GP being informed” (third yes/no box, page 2 of the statement for relatives).

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 Mrs Raewyn Sporle and Mrs Kate O’Connor.

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| **3** | **Ethics ref:** | **14/NTB/65** |
|  | Title: | Tiger 2 self-advancing nasojejunal tube in adhesive small bowel obstruction – A pilot study to assess feasibility |
|  | Principal Investigator: | Associate Professor Ian Bissett |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 22 May 2014 |

Dr Jason Robertson was present in person for discussion of this application.

Potential conflicts of interest

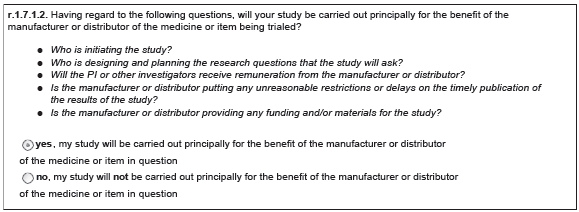
The Chair asked members to declare any potential conflicts of interest related to this application.

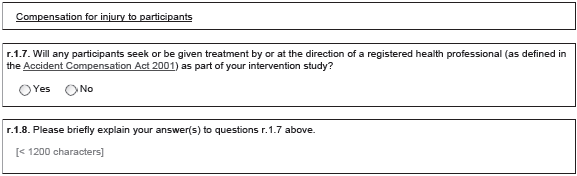
No potential conflicts of interest related to this application were declared by any member.

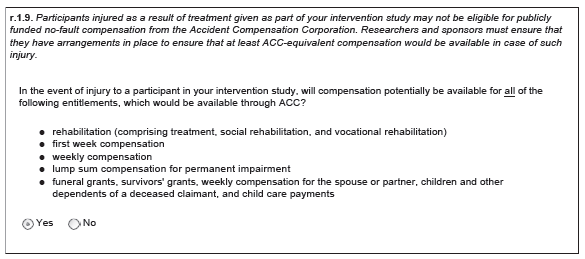
Summary of ethical issues

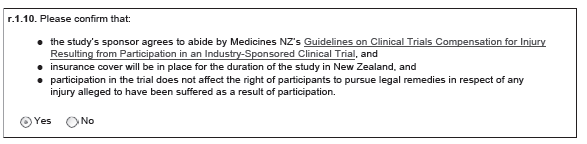
The main ethical issues considered by the Committee were as follows.

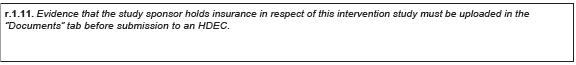
* Dr Robertson explained that this is a pilot study, using a small number of participants, to investigate whether the Tiger 2 nasojejunal (NJ) tube will leave the stomach and advance into the small bowel in a timely manner. This may help reduce the need for surgery for small bowel obstructions (SBO). While NJ tubes have been used before, they require endoscopy or fluoroscopy guidance, access to which is not available if a patient presents with an SBO in the middle of the night.
* Dr Robertson explained that the standard treatment for an SBO is a nasogastric tube. If the SBO is not cleared within 48 hours, then the obstruction is removed by surgery.
* The Committee asked why this was a pilot trial instead of an investigation. Dr Robertson explained that in order to prove a therapeutic benefit they need a large number of participants. This pilot study is to investigate whether the tube can advance to the correct place within a reasonable timeframe.
* The Committee asked for clarification on the duration of the study. Dr Robertson confirmed that this would only be about six or seven weeks.
* The Committee asked why the researcher considered this an observational study and not an intervention. Dr Robertson explained that aside from the tube, the study was following the same protocol as standard treatment. The Committee recommended looking at the NEAC *Ethical Guidelines for Intervention Studies* and *Ethical Guidelines for Observational Studies* which provide clear definitions on the differences between observational and intervention studies.
* The Committee noted that because the researcher had answered the application as though this was an observational study, some of the questions not been asked. Please provide answers to the following questions:

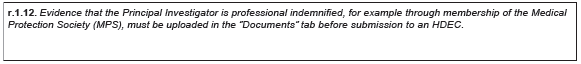


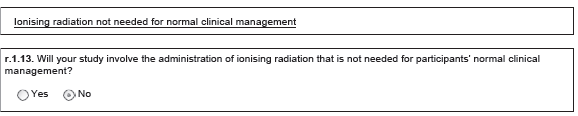


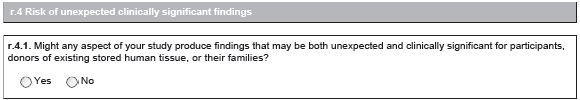












* The Committee noted the high quality of peer review and commended the researcher for the changes made to the study based on the peer review.
* The Committee asked how long a participant would have to decide whether to take part in the study. Dr Robertson advised that they will need to decide on the same day in order to get treatment. The Committee asked how the researchers would balance the time needed to consider whether to participate vs ensuring that a patient gets timely treatment. Dr Robertson explained that they will only recruit during office hours so a participant will have a better chance of being able to consult with family members. If a patient is unable to decide whether to take part, the standard treatment will be used.
* The Committee asked for clarification on participants consenting to store data for future research. Dr Robertson explained that the outcomes of this study would be stored on a password protected computer and may be used to help develop larger studies in the future.
* Dr Robertson confirmed that he was still awaiting the outcome of Māori consultation.
* The Committee requested the following changes to the PIS and consent form:
  + Please explain in lay language to participants what an observational study is.
  + Please amend the ACC Compensation statement from “you would be eligible for compensation” to “you may be eligible for compensation”.
  + Please move the information on radiation exposure from the “Risk and Benefits” section to the “What happens during the study” section.
  + Please include information in the “Risks and Benefits” section that if the procedure does not alleviate symptoms, participants may still have to undergo surgery.
  + Please include a landline number for any questions, concerns or complaints on the PIS.
  + Please remove the yes / no boxes on the consent form for those statements that are not truly optional, for example “I consent to members of the research team having access to my data and/or clinical records during, or after, the study.”
  + Please change “approved by the Northern A Health and Disability Ethics Committee” to “approved by the Northern B Health and Disability Ethics Committee” (page 2 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 Dr Paul Tanser and Mrs Mali Erick.

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| **4** | **Ethics ref:** | **14/NTB/68** |
|  | Title: | Tretinoin bioequivalence study conducted under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Douglas America Ltd |
|  | Clock Start Date: | 22 May 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 agreed that as the two tretinoin studies were very similar, they would discussed together (14/NTB/68 and 14/NTB/69).
* The Committee noted a high quality application that was very easy to read.
* The Committee noted that transport would be provided between the clinical site and Zenith offices and asked whether there was a provision for participants to get transport home if required (R.1.5). Ms Folland explained that this was usually for transport from the clinical site to the Zenith offices and return but if any of the clinical staff believed that staff should be transported home, this would be provided.
* The Committee noted that Zenith aims for Māori participation rates that are equivalent to the number of Māori in the Otago area (7-9%) and asked whether their aims are being met. Ms Folland confirmed that some studies have had Māori participation rates as high as 20% but some are much lower. She noted that this is very difficult to control. The Committee suggested that it may be useful for Zenith to prepare a report comparing Māori participation rates for each study. This would be useful to give information for future applications and may be of interest to other researchers.
* The Committee asked for clarification on why participants initial each page. Dr Noelyn Hung explained that this draws participant’s attention to each page and prevents people from skipping sections of the PIS.
* The Committee asked for clarification on the consent process. Dr Noelyn Hung explained that a doctor attends an information session with a group of students. The PIS is read aloud to them by a staff member. There is then a session where a doctor will ask if participants have any questions, which can be answered either in public or in private.
* The Committee asked what would happen in the event of a positive HIV or Hepatitis test. Dr Noelyn Hung explained that participants would be referred to a counselling service. She would phone the participant’s GP to let them know that they had been referred to a counselling service.
* The Committee asked if there was an alternative breakfast available for the fed study. Dr Tak Hung confirmed that this breakfast was approved by the FDA and had an approved amount of protein, starch and fat. He said that this was non-negotiable as some drugs are affected by food but if people were unable to eat the breakfast due to cultural reasons, they could do the fasting study.
* The Committee asked for justification on why there was no independent data monitoring committee. Dr Tak Hung explained that for new drugs it was usual practice to have an independent DSMB, who would agree on any increase or changes to doses. However, he believes that this is not required for this study as it is a generic drug being tested on healthy volunteers who will be closely monitored by a trial doctor throughout the study. Dr Tak Hung noted that the protocol is recommended by the US FDA and there is very little room to deviate from the protocol.
* The Committee asked which doctor would sign the consent form (P.2.1). Ms Folland confirmed that this would be either the clinical investigator or another doctor at the information reading stage.
* The Committee requested the following changes to the PIS and consent form:
  + Please include vegetarianism as an exclusion criteria for the fed study.
  + Page 6 of the PIS – Please change references from “physician” to “study doctor” as physician is a very American term.

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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| **5** | **Ethics ref:** | **14/NTB/69** |
|  | Title: | Tretinoin bioequivalence study conducted under fed conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Douglas America Ltd |
|  | Clock Start Date: | 22 May 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.

* Please see comments above for 14/NTB/68.
* The Committee requested the following changes to the PIS and consent form:
  + Please include vegetarianism as an exclusion criteria for the fed study.
  + Page 6 of the PIS – Please change references from “physician” to “study doctor” as physician is a very American term.

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/70** |
|  | Title: | Fingolimod bioequivalence study conducted under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Alembic Pharmaceuticals Ltd |
|  | Clock Start Date: | 22 May 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 agreed that as the two fingolimod studies were very similar, they would be discussed together (14/NTB/70 and 14/NTB/71).
* The Committee asked for the rationale of 1.5mg doses when the recommended dose is 0.5mg. Dr Tak Hung explained that the FDA believes that this dose is too low. He advised that the purpose of this study is to match the blood concentration profile of participants and the 0.5mg dose is not determinable in the blood. He said the US FDA allows three doses of 0.5mg as they believe this is safe dose and is able to be detected in blood tests.
* The Committee noted that the adverse reactions were for the lower doses and not the 1.5mg dose. They asked if the higher dose has a higher rate or intensity of adverse events. Ms Folland explained that the pilot study had a dose of 1.5mg. Dr Noelyn Hung also confirmed that published studies had involved doses of 5mg.
* The Committee noted that the peer reviewer, Professor Paul Glue, was involved in the clinical development of fingolimod and has two patents on its use. The Committee asked whether he had a vested interested in giving a peer review. Dr Tak Hung explained that Professor Glue does not have any financial interest in the patent or this study. Dr Noelyn Hung advised that Professor Glue was merely advising on the safety of the study. The Committee noted that SCOTT approval had been applied for and asked to see this as evidence of scientific review.
* The Committee asked for clarification on the number of participants. Dr Tak Hung confirmed that this was 26.
* The Committee requested the following changes to the PIS and consent form:
  + Please amend the typo on page 4 of the PIS “721 hours after taking each dose”.

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).*
* Please provide evidence of SCOTT review *(Ethical Guidelines for Intervention Studies, para 5.11).*

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| **7** | **Ethics ref:** | **14/NTB/71** |
|  | Title: | Fingolimod bioequivalence study conducted under fed conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Alembic Pharmaceuticals Ltd |
|  | Clock Start Date: | 22 May 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.

* Please see comments above for 14/NTB/70.
* The Committee requested the following changes to the PIS and consent form:
  + Please amend the typo on page 4 of the PIS “721 hours after taking each dose”.

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).*
* Please provide evidence of SCOTT review *(Ethical Guidelines for Intervention Studies, para 5.11).*

## 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 July 2014, 12:00 PM |
| **Meeting venue:** | Rydges Auckland, 59 Federal St, Auckland |

No members tendered apologies for this meeting.

1. The Committee agreed to discuss the changes to the Members’ Portal at the next meeting.

The meeting closed at 3.05pm.