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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 02 December 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 04 November 2014 |
| 12.30pm | New applications (see over for details) |
|  | i 14/NTB/185  ii 14/NTB/187  iii 14/NTB/193  iv 14/NTB/194  v 14/NTB/198  vi 14/NTB/199  vii 14/NTB/200  viii 14/NTB/202  ix 14/NTB/196  x 14/NTB/201 |
| 4.40pm | General business:   * Noting section of agenda |
| 4.45pm | 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 | 01/07/2015 | Present |
| Mrs Kate O'Connor | Non-lay (other) | 01/07/2012 | 01/07/2015 | Apologies |
| 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 12.13pm and welcomed Committee members, noting that apologies had been received from Mrs Kate O’Connor.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

The Committee noted the number of studies on the agenda where researchers were not available to discuss the application. They recommended that the HDEC Secretariat puts a note on the HDEC website advising researchers of the benefits of either dialling in or attending the meeting.

## Confirmation of previous minutes

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

## New applications

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| **1** | **Ethics ref:** | **14/NTB/185** |
|  | Title: | 1237.19 DYNAGITO |
|  | Principal Investigator: | Dr Andrew G. Veale |
|  | Sponsor: | Boehringer Ingelheim Pty Limited |
|  | Clock Start Date: | 20 November 2014 |

Dr Andrew Veale, Ms Carol Veale and Ms Mel Gane 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 (resolved)

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

* The Committee asked for an explanation of the publications policy. Dr Veale advised that this was a multi-centre study and he was not aware of any constraints in publication. The Committee asked that the response letter includes the section in the CTRA on publication referred to in the protocol.
* Ms Gane advised that SCOTT approval had been applied for.
* The Committee asked what was the risk of participants taking part in the study at multiple sites. Dr Veale explained that it had happened once but they had added checks and balances to stop this from happening. This includes good communication amongst the research offices in Auckland DHBs and notifying participant’s GPs of intended participation before a study starts.
* The Committee asked for clarification on how the data generated may be used for future research (B.4.4). Dr Veale explained that many pharmaceutical company studies look at differences in gene type and use samples for future research. Please clarify in the PIS if it is data or samples that will be used for future research and if it is samples, a separate PIS for future unspecified research needs to be provided.
* The Committee asked for confirmation on the site processes for confidentiality (R.2.1.1). Dr Veale explained that all of the data is kept in locked spaces, with the laboratories only having swipe card access. Access is limited to staff involved in the study and monitors do not have access to common storage areas and are limited to the study files kept in a separate room.
* The Committee asked how any unexpected clinical findings would be managed. Dr Veale advised that researchers would discuss these with the patient and their GP. This needs to be included in the PIS.
* Dr Veale confirmed that trial results would be available in lay language and that this is often done by telephone.
* Dr Veale confirmed that Māori consultation had been approved by Dr Helen Wihongi at Waitemata DHB and that no changes were required to the PIS or protocol.
* Ms Veale advised that there is a separate consent form for advising a participant’s GP which is completed after the PIS has been signed.
* The Committee advised that participants do not need to advise of their withdrawal in writing.
* Ms Veale advised that a participant’s study number would be used on the questionnaires.
* The Committee noted that the start date listed in the application is January 2015 but the insurance start date is 15 February 2015.
* The Committee recommended including a brief description of the study, if possible, on the patient emergency card.
* The Committee noted for future applications that data is likely to be potentially identifiable as per the NEAC guidelines as it is likely that there will be a spreadsheet archived with the study records linking the patient name with the study.
* The Committee noted that they preferred the tables on page 7 which had the lay term before the scientific term, as opposed to page 6, which had the scientific term before the lay term.
* The Committee asked whether the researchers were planning on using the New Zealand Census question to collect ethnicity data. Dr Veale agreed to consider this.

Summary of ethical issues (outstanding)

* The Committee asked if there were any oversight committees other than the one that looked at mortality (R.1.5). Dr Veale agreed to confirm with the sponsor but he thought that in previous studies most had been safety monitoring committees.

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

* Please remove Australian references and replace with relevant New Zealand references, including HDECs, New Zealand privacy laws, compensation guidelines and Medsafe rather than the TGA.
* Please include a short lay title on the PIS.
* Please include that there may be possible cultural issues for Māori in relation to samples being sent overseas.
* Please remove the sentence “There is a possibility that you may be in the screening time of the study…” (page 2 of the PIS) as recruitment should be managed to prevent this.
* Please include more information on where the overseas laboratory is, whether samples can be returned and how they will be destroyed.
* Please remove the reference to placebo (13d) as this is not relevant for this trial (page 9 of the PIS)
* Please make it clear in the PIS that tiotropium is approved for use in New Zealand but olodaterol is not.
* Please include that this study has been approved by the Northern B HDEC including the study reference number.
* Please include whether an interpreter will be offered if required.
* Please be more specific on what testing for general health will involve.
* Please check versions on the consent form.
* Please remove the words “if applicable” from point 5 of the consent form.
* Please review the HDEC PIS template at <http://ethics.health.govt.nz> and include the declaration by participant and declaration by member of research team as sign off on the consent form.

Decision

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

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

This following information will be reviewed, and a final decision made on the application, by the Secretariat.

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| **2** | **Ethics ref:** | **14/NTB/187** |
|  | Title: | Nitrate supplementation in acute stroke |
|  | Principal Investigator: | Dr Shieak Tzeng |
|  | Sponsor: |  |
|  | Clock Start Date: | 20 November 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 (outstanding)

The Committee believed that this was an important study question but were concerned about the study design. They identified the following issues which needed to be addressed in a future application.

* The Committee noted a lot of inconsistencies between the protocol, application and PIS.
* The Committee were concerned that there was nothing in the protocol on how data will be analysed and no justification for data numbers.
* The Committee noted that the peer review referred to analysis techniques described but these were not mentioned in the protocol reviewed by the Committee.
* The Committee noted that the peer review commented on the exclusion criteria affecting the ability to recruit in a timely fashion but they could not see this listed in the protocol.
* The Committee were unsure of how participants would receive the nitrate supplementation and noted that if it was in the form of beetroot juice, it would be difficult for the study to be double-blinded.
* The Committee noted that there were inconsistencies in the application with the number of participants.
* The Committee asked why the stroke group were 50 to 80 years while the controls would be 20 to 80 years.
* The Committee noted that the wash out period is inconsistent.
* The Committee asked for clarification on how healthy controls will be identified and recruited.
* The Committee asked why healthy controls were being used when there is also a placebo.
* The Committee noted that the health history questionnaire contains a lot of personal information and it is unclear how this is relevant to the study. They advised that data should not collected if it is not planned to be used for the study.
* The Committee asked for clarification on how ill the patient cohort would be and whether they would be capable of completing the consent form and questionnaire.
* Please review the NEAC guidelines and confirm whether data is truly de-identified.
* The Committee advised that if future unspecified research is planned (R.3.8.1), this needs to be optional and a separate PIS needs to be provided.
* Please clarify whether a new tissue bank is being established (R.3.11)
* Please include an acknowledgement that there is a possible conflict of interest for participants being invited to participate in a study by someone treating them and explain how this will be managed (R.5.4.1).
* Please specify how this study will provide a direct health benefit to the participants (R.8.1).
* Please include more detail on the consent process, including how long participants will have between being told about the study and having to give consent.
* Please confirm that results will be given in lay language.

The Committee recommended the following changes to the Participant Information Sheet and Consent Form for a future application:

* Please rewrite section 1 as it is not in lay language.
* Please clarify TIA patients,
* Please reword “Improving our understanding of the impact of the dietary supplementation on the cerebrovascular health of stroke patients should be a priority” as it is too emotive (page 2 of the PIS).
* Please write inclusion criteria in lay language.
* Please explain placebo.
* Please be consistent with the age ranges.
* Please use bullet points for the information on page 4.
* Please confirm what information is being sought from health records. This needs to be confined to information that is relevant to this research.
* Please remove “if you feel you cannot do more, or if you experience considerable discomfort” after “you can voluntarily stop at any time point” as participants can withdraw at any stage and for any reason.
* Please include Māori cultural support contact details.
* Please remove the reference to discharge from hospital (page 2 of the PIS for healthy controls) as they will not be in hospital.
* Please include whether travel costs will be reimbursed.
* Please use the ACC compensation clause from the PIS template available on the HDEC website.

Decision

This application was *declined* by consensus, as the Committee did not consider that the study would meet the following ethical standards.

* The study design should be the one best suited to answer the study question, while minimising harm, maximising benefit and meeting other ethical standards *(Ethical Guidelines for Intervention Studies, para 5.4).*
* The study protocol should contain an overview of the planned statistical analyses, and these planned analyses should be adhered to in conducting the study *(Ethical Guidelines for Intervention Studies, para 5.7).*

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| **3** | **Ethics ref:** | **14/NTB/193** |
|  | Title: | CINC280X2202 |
|  | Principal Investigator: | Professor Mark McKeage |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 20 November 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 and voting.

Summary of ethical issues (resolved)

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

* The Committee noted for future reference that A.1.5 and B.1.1 are asking for plain English answers.
* The Committee commended the researchers on the acknowledgement of vulnerability in participants.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher were as follows.

* The Committee asked for clarification on what standard treatment is for this patient population and whether they will be giving up conventional treatment by taking part in this study.
* The Committee noted that there would be 200 patients recruited worldwide but only six would come from New Zealand. They also noted that there are 1.4 million people worldwide suffering from lung cancer and asked if the small sample size was because most participants would not fit the inclusion criteria.
* The Committee advised that because New Zealand participants are only taking part in the Phase II dosing stage, the dose escalation information is not required in the PIS.
* The Committee asked how many participants were expected in New Zealand as the application states five to six, while the insurance certificate provides coverage for approximately three participants.
* Please confirm the number of fresh biopsies participants will have (molecular screening, screening, day 1 and day 15) and are they mandatory for phase 2 at all these time points. Please include details of the biopsies in the PIS.
* The Committee asked for clarification on the DMC (R.1.5) including who would be looking at the individual and aggregate data. The Committee recommended including one New Zealand member.
* The Committee advised that as per para 6.65 of the *NEAC Guidelines for Intervention Studies*, studies cannot be terminated for commercial reasons.
* Please clarify the answer to R.1.7 that participants will not be given treatment by or at the direction of a registered health professional.
* Please confirm whether all scans and x-rays are as per standard care and are not in addition to a participant’s normal clinical management (R.1.13).
* Please confirm whether samples will be returned or destroyed, as the answers to R.3.7 and R.3.12 are contradictory.
* Please confirm how any unexpected clinically significant findings will be managed (R.4.1).
* Please confirm how any prohibited medication will be managed and participants and their GPs made aware given that it is impractical to include a huge list of these in the PIS.
* Please be careful on making unsubstantiated claims (P.4.1), for example “Published data show people who participate in clinical trials have better health outcomes. Therefore any eligible Māori participants will be offered this study.” and “New Zealand Ethics Committee support tissue banking” (P.4.2). The answer to P.4.1 should include information on the incidence of lung cancer in Māori.
* The Committee advised that results should be made available to participants in lay language (P.2.9).
* The Committee noted that ethnicity data should be collected as per the New Zealand census question (P.4.6).
* Please advise the outcome of Māori consultation (P.4.3.1).
* Please explain how the female partner of male PIS will be used, for example will it be given to males to give to their partner.
* Please clarify the statement “this authorisation will expire in 50 years” on page 2 of the pregnancy follow-up informed consent document.

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

* Please include a lay study title on all PIS and consent forms.

Molecular Screening PIS

* Please include a brief summary of the main study.
* Please simplify the opening invitation.
* Please be clear in the invitation that this is for screening only and not participation in the study.
* Please describe the incidence of c-MET amplified disease.
* Please include whether the results from the optional tumour markers will be made available to clinicians and if there will be any impact on the patient’s clinical management.
* Please review the bullet points on the consent form for relevance to this screening component.

Main PIS

* Please review and simplify technical terms.
* Please soften the wording around checking your survival status (page 2), for example “check on how you are doing”.
* Please state how many participants have been exposed to the experimental drug (page 7).
* Please remove the reference to blood tests being the most unpleasant tests (page 8).
* Please check if the reference to bone scans (page 9) is an error as this is not mentioned in the protocol.
* Please include male responsibilities around pregnancy and contraception (page 10).
* Please include that blood samples will be sent overseas.
* Please review the statements on the consent form and remove the yes / no boxes for those statements that are not truly optional.
* Please include a statement in the consent form about pregnancy and contraception responsibilities.
* Please explain how the female partner participation sheet will be used – will It be given to the male to give to partner
* Please note that withdrawal of participation does not have to be in writing.
* Please include in PIS how confidentiality will be maintained when images and cytology specimens are sent to Novartis for review.

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions 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 Phyllis Huitema and Mrs Stephanie Pollard.

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| **4** | **Ethics ref:** | **14/NTB/194** |
|  | Title: | Effects of ISMO on bone density in premenopausal women |
|  | Principal Investigator: | Dr Susannah O'Sullivan |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 20 November 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 Study

* The Committee commended the researcher for a clear PIS.

Summary of ethical issues (resolved)

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

* The Committee noted this was a low risk trial but recommended that the study uses a small independent data safety monitoring board, which may include an endocrinologist from a different DHB.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher were as follows.

* Please confirm whether this is considered a pilot study
* Please confirm what will happen to the samples if the patient withdraws consent for their use (R.3.11). Please include this information in the PIS.
* Please confirm whether consultation with Māori has taken place.
* The Committee noted that the coordinating investigator will not be involved in the consent process and this will conducted by non-clinical study personnel (R.5.4.) . The Committee asked for clarification on how the CI will balance their clinical role and GCP expectations. They asked what is the CI’s role in the consent process and what parts of the consent process have been delegated to non-clinical study personnel.
* Please clarify why past zoledronic acid use is listed separately in the exclusion criteria from bisphosphonate therapy (F.2.1).
* Please make results of the study available to participants in lay language.

Please use the New Zealand Census question to collect ethnicity data.

* Please consider using the wording on ACC compensation used on the PIS template on the HDEC website http://ethics.health.govt.nz.
* The Committee noted that as per the NEAC guidelines, information is more likely to be potentially identifiable, rather than anonymous (R.2.4.1).
* Please clarify why this study will not contribute to reducing inequalities in health outcomes between different populations (F.1.1).

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

* Please include a separate heading for exclusion criteria (page 3 of the PIS) and simplify eligibility criteria.
* Please amend “friend, family or whanau support to help you to understand the risks and/or benefits” to “have had the opportunity to discuss with family and whanau” (page 3 of the PIS)
* Please review the PIS and ensure that all references are to the first person.
* Please include HDEC contact details.
* Please describe double blinding and randomisation.
* Please include whether participants will have access to the study drug after completing the study.
* Please include Māori cultural support contact details.
* Please include where blood samples will be stored and whether they will be destroyed.
* Please include that any significant condition identified will be discussed with participants, their GP and specialist.
* Please indicate at what time points the four visits are.
* Please refer to the option of future research in the PIS and that there is a separate consent which will not impact on them taking part in the main study.
* Please remove second bullet point of the consent form “I have had the opportunity to use whanau support or a friend to help me ask questions and understand the study”.

Decision

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

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

This following information will be reviewed, and a final decision made on the application, by the Secretariat.

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| **5** | **Ethics ref:** | **14/NTB/196** |
|  | Title: | Anaesthetists, micro-organisms and surgical site infection: the ‘Z-bugs' RCT |
|  | Principal Investigator: | Professor Alan Merry |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 20 November 2014 |

Professor Alan Merry and Mrs Derryn Gargiulo 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 (resolved)

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

* The Committee noted that this new study was observational.
* The Committee asked why the researchers believed an opt out consent was adequate. Professor Merry explained that this study is technically quality improvement which would not require consent but he felt it was a courtesy to inform participants.
* Mrs Gargiulo confirmed that participants would be given the PIS and consent form the night before surgery or for day cases on the day of surgery. It would be researchers rather than the anaesthetists giving the PIS to participants.
* The Committee asked what data would be collected over and above the surveillance programme. Mrs Gargiulo advised that this would be length of anaesthetic, ethnicity, diabetes, renal disease and steroid use.
* The Committee agreed that the PIS could be shortened as long as it is made clear that the consent is to use participant’s data. The PIS should include an explanation that the study is being done as part of quality improvement, that some health information will be collected, the nature of the data being collected and that participants can choose not to consent to the use of this data. Participant should be informed that there will be follow-up up to 90 days post-surgery. The ACC compensation clause can also be removed.

Decision

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

* Please amend the participant information 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 Mrs Stephanie Pollard and Ms Tangihaere Macfarlane

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| **6** | **Ethics ref:** | **14/NTB/198** |
|  | Title: | The DREAM study |
|  | Principal Investigator: | Dr Scott Harding |
|  | Sponsor: |  |
|  | Clock Start Date: | 20 November 2014 |

No researchers were present 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 (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher were as follows.

* Please review the NEAC guidelines to confirm whether the data generated is potentially identifiable (R.2.4).
* Please confirm what will happen to a participant’s samples or data after 72 hours if they have died or have ongoing complications that would prevent them giving informed consent.
* Please confirm who is responsible for the initiation, management and financing arrangements of the study (A.5.1).
* Please submit the questionnaire referred to in R.1.1.
* Please confirm if Māori consultation has been received and if this results in any changes to the PIS.
* Please ensure that the New Zealand Census question is used when collected ethnicity data.

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

* Please number the pages of the PIS and consent form.
* Please include a statement in the opening paragraph that patients have previously signed an abbreviated PIS because of time constraints and this process is now providing them with more time to consider the study.
* Please include what will happen if participants have signed the abbreviated PIS but have then changed their mind about taking part in the study.
* Please amend “”we suggest your family/whanau is involved” to “we invite you to involve your family/whanau” (page 1 of the PIS).
* Please include contact details for Whanau Care Services (page 2 of the PIS).
* Please change Central HDEC to Northern B HDEC (page 3 of the PIS).
* Please change “you will be covered by the accident compensation legislation” to “you may be covered by the accident compensation legislation” (page 3 of the PIS).

Decision

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

* Please amend the participant information 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 the Secretariat.

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| **7** | **Ethics ref:** | **14/NTB/199** |
|  | Title: | Evaluation of Sofosbuvir/GS-5816 Fixed Dose Combination With Ribavirin For 24 Weeks In Chronic HCV Infected Subjects. |
|  | Principal Investigator: | Dr Catherine Stedman |
|  | Sponsor: | PPD Global Limited (New Zealand Branch) |
|  | Clock Start Date: | 20 November 2014 |

Dr Catherine Stedman was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

* The Committee commended the researcher for a PIS and consent form that were very clear.

Summary of ethical issues (resolved)

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

* The Committee asked why participants for this study needed to have taken part in a previous Gilead study. Dr Stedman explained that the sponsor was providing this as a rescue study to participants who had been on a previous shorter study and had relapsed.
* The Committee asked for clarification on the archived blood sample for future research (page 7 of the PIS). Dr Stedman explained that sometimes in trials researchers like to go back and look at samples depending on whether they have had successful or unsuccessful results and look for predictors. She confirmed that samples would be sent to an overseas lab and would eventually be destroyed but she was unsure of the timeframe. This information needs to be included in the PIS.
* Please review the NEAC guidelines and consider whether data is truly de-identified (R.2.4).
* Please ensure that a summary of the study results is made available in lay language.
* Please ensure that the New Zealand Census question is used to collect ethnicity data (P.4.6).

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher as follows.

* The Committee asked for clarification on the composition of the DSMB and recommended having a New Zealand investigator on it. Dr Stedman agreed to confirm this.
* Please confirm whether the UTN has been received (B.4.7).

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

* Please include a lay study title on the PIS and consent form.
* Please add the words “as appropriate” after kaumatua (page 8 of the PIS).
* Please amend “report all side effects to your study doctor as it is possible that these side effects could be potentially serious or fatal” (page 10 of the PIS).
* Please clarify why participants may be limited from participating in future studies related to the study drug (page 14 of the PIS).
* Please amend typo on the sentence “you do not give you any legal rights by signing this form” (page 16, 2nd para of the PIS).
* Please use the compensation wording from the PIS template on the HDEC website.
* Please amend “you can also contact Northern B HDEC that approved this study responsible ….(page 17 of the PIS).
* Please review and remove references to US law.
* Please remove reference to the main study under Source for Additional Information (page 16 of the PIS) as this is the PIS for the main study.
* Please include Māori cultural support contact details (page 16 of the PIS).
* Please include that the additional unanticipated medical and and/or scientific research projects are optional and that participants will be asked for additional consent (page 17 of the PIS).
* Please remove the reference to withdrawal having to be in writing as this can also be done verbally (page 18 of the PIS).
* Please include an option box of “not participating” in the flowchart on page 20 of the PIS).
* Please include in the PIS whether participants’ GPs will be informed of the drug test results.

Decision

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

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

This following information will be reviewed, and a final decision made on the application, by the Secretariat.

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| **8** | **Ethics ref:** | **14/NTB/200** |
|  | Title: | Oxygen versus air driven nebulisers in COPD exacerbation |
|  | Principal Investigator: | Dr Janine Pilcher |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 20 November 2014 |

Dr Michael Richards was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

* The Committee acknowledged the researcher for a clear application.
* The Committee commended the researchers for the inclusion of independent data monitoring arrangements.
* The Committee congratulated the researcher on receiving HRC funding.

Summary of ethical issues (resolved)

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

* The Committee asked what nebulisers are used as standard of care in New Zealand. Dr Richards explained that standard care is oxygen but there are a few areas in New Zealand where they also have air. He noted that standard care in Wellington and Hutt Valley is oxygen. The Committee asked if availability of air would be an issue for the study. Dr Richards advised that for this study they would be using portable oxygen and air canisters.
* The Committee asked if all participants would be able to give consent. Dr Richards advised that participants will not be able to take part if they do not have the capacity to make their own decisions.
* The Committee asked for an explanation of the consent process. Dr Richards explained that researchers will go round the wards at 9am to see people who have admitted. They will give them the PIS and a brief explanation of the study. Researchers will come back after lunch (around 1pm) and if participants are interested they will proceed with consent. The time between giving the PIS and consent will allow participants to discuss the study with their medical team or family. Dr Richards explained that they would like to allow more time for the consent process but this is not possible as participants may move out of the ward.
* The Committee noted that some participants may have to switch nebulisers due to randomisation and asked if there were any risks to switching and any differences in the apparatus. Dr Richards confirmed that for patients not specifically prescribed an air driven nebuliser, there are no risks to switching and both are face mask nebulisers.
* The Committee noted that the peer review commented on putting an inpatient admission time to study intervention time limit to exclude participants who have improving COPD symptoms. Dr Richards advised that in similar studies of acute exacerbations it is difficult to get the numbers so it is better to have a range of admission times.
* Mr Richards confirmed that the New Zealand Census question will be used to collect ethnicity data.

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

* Please change “you would be eligible for compensation from ACC” to “you may be eligible for compensation from ACC”
* Please review the consent form and remove the yes / no boxes for statements that are not truly optional.
* Please add a Māori cultural support contact.

Decision

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

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

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| **9** | **Ethics ref:** | **14/NTB/201** |
|  | Title: | Study Evaluating Tenofovir Alafenamide Pharmacokinetics in Subjects with Normal and Severe Impairment of Hepatic Function |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 20 November 2014 |

Professor Edward Gane was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

* The Committee commended the researcher for a clear PIS.
* The Committee commended the plain English summaries for A.1.6 and B.1.1.

Summary of ethical issues (resolved)

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

* The Committee asked what was the rationale of including healthy participants in this study. Professor Gane explained that it was necessary for a comparison of how much of the drug is absorbed and metabolised. He advised that they were a control group and the study needed to be done at the same time in case of a change of the batch of medication. Professor Gane noted that most PK studies have one to one matching in healthy volunteers.
* Professor Gane explained that people with mental illness would be excluded as they would need to stay at the clinic for seven days with other people which may create stress for them.
* Professor Gane confirmed that the New Zealand Census question will be used to collect ethnicity data
* Professor Gane advised that the $3,000 payment is usually paid in instalments to ensure that people will not lose access to their benefits. He was not sure of the threshold but agreed to check.
* The Committee asked if there was an advertisement for healthy participants (P.3.1). Professor Gane explained that ACS has a database of several thousand healthy volunteers which they recruit from.
* The Committee asked if the DSMB was independent (R.1.5). Professor Gane agreed to confirm but thought that it may be independent as this is a Phase 3 study. The Committee recommended having a New Zealand member on the DSMB.
* The Committee asked if participants will be given emergency contact cards. Professor Gane confirmed that they would and that ACS have an arrangement with ED so there is an alert on the patient’s electronic medical records.
* Professor Gane explained that while Māori will not benefit directly from this study, they will benefit from having a better drug available, particularly given the higher rates of Hepatitis B in Māori (P.4.1).
* The Committee asked why the risks of this study are considered proportional to the expected benefits (R.8.1). Professor Gane explained that the risk to participants in this study are small but include the risk of blood tests, while the only tangible benefits are financial.

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

* Please include a lay study title on the PIS and consent form.
* Please remove references to state law (page 3 of the PIS).
* Please note that revoking authorisation for collection and use of information does not need to be done in writing.
* Please include an option of not participating in the flowchart (page 14 of the PIS).
* Please include a contact name for any information on the study (page 5 of the sub-study).
* Please include in the PIS that participant’s GPs will not be told the results of drug and alcohol testing.
* Please make it clear that the participant needs to stay in the unit for eight days, whether they can go out and whether they can have visitors.

Decision

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

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

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| **10** | **Ethics ref:** | **14/NTB/202** |
|  | Title: | BIOFLOW-IV |
|  | Principal Investigator: | Dr Dougal McClean |
|  | Sponsor: | BIOTRONIK |
|  | Clock Start Date: | 20 November 2014 |

Dr Dougal McLean was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

* The Committee noted this was a well put together application.
* Dr McLean explained that this study was a post marketing non-inferiority trial of an approved stent.

Summary of ethical issues (resolved)

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

* The Committee asked if patients are told as part of routine care about the implications of stent failure. Dr McLean explained that there is a small risk of stent failure and patients are given blood thinners to stop future heart attacks and thrombosis of the stent.
* The Committee asked for clarification on timing of the consent process. Dr McLean explained that participants at Christchurch Hospital are given the PIS before the angiogram, preferably the night before the procedure. Participants have time to ask any questions before the procedure. Dr McLean noted that a lot of patients give informed consent but are then not suitable to take part in the study depending on the results of their angiogram.
* Please review the NEAC guidelines and consider whether data stored is truly anonymous as it is more likely to be potentially identifiable. Researchers need to ensure that they have good storage facilities with access limited to study personnel to maintain confidentiality.
* The Committee asked how any unexpected clinically significant findings would be managed, for example pregnancy (R.4.1). Dr McLean advised that any findings would be reported to the participants and they would be referred to their GP.
* The Committee asked if the results of the study could be given to participants in lay language (P.2.9). Dr McLean advised that they had a lot of experience in stent based trials and were used to giving participants information in lay language.
* Dr McLean advised that he thought Māori consultation had been received. The Committee advised that they would need to see any changes to the PIS that may result from Māori consultation
* Dr McLean advised that he thought that ethnicity data would be collected using the New Zealand Census question (P.4.6).

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

* Please include a lay study title on the PIS and consent form.
* Please clarify CE Mark.
* Please review for grammatical errors.
* Please include the number of patients in New Zealand as it currently only refers to 555 eligible patients in Europe and Japan (page 2 of the PIS).
* Please review paragraph “Who pays for the study” (page 5 of the PIS) and amend for a New Zealand setting as New Zealanders do not pay for medical care.
* Please remind sponsor that they cannot stop the study purely for commercial reasons as per para 6.65 of the *NEAC Guidelines for Intervention Studies.*
* Please remove references to state authorities as this is not applicable to New Zealand (page 6 of the PIS).
* Please include in the PIS that if the patient decides that they want to withdraw from the study, that the stent cannot be removed.
* Please remove sentence in italics in the interpreter box as these are instructions for the researchers (page 8 of consent form).
* Please review statements on the consent form and remove the yes / no boxes if the statement is not truly optional.

Decision

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

* Please amend the participant information 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:** | 03 February 2015, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

No members tendered apologies for this meeting.

The meeting closed at 4.55pm.