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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 30 September 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 02 September 2014 |
| 12.30pm | New applications (see over for details) |
|  | i 14/NTB/147  ii 14/NTB/150  iii 14/NTB/151  iv 14/NTB/152  v 14/NTB/154  vi 14/NTB/155  vii 14/NTB/139  viii 14/NTB/140  ix 14/NTB/156  x 14/NTB/157 |
| 4.40pm | General business:  Noting section of agenda |
| 5.00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Raewyn Sporle | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Kate O'Connor | Non-lay (other) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Paul Tanser | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Ms Kerin Thompson | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Phyllis Huitema | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |

## Welcome

The Chair opened the meeting at 12.18pm and welcomed Committee members, noting that no apologies had been received.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 2 September 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTB/139** |
|  | Title: | Hibiscus II |
|  | Principal Investigator: | Dr Stephen Inns |
|  | Sponsor: | Quintiles Pty Limited |
|  | Clock Start Date: | 18 September 2014 |

Mrs Amy Champion and Mr Diego Morais 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.

Dr Paul Tanser declared a conflict of interest and it was agreed that he would not take part in the discussions or voting.

Summary of ethical issues

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

* The Committee noted that only people who have been through Hibiscus II study will be asked to go through to the open label Cottonwood study. They asked why there would be approximately 350 participants in the Hibiscus II study and approximately 2600 participants in the Cottonwood study. Mr Morais explained that this is worldwide and includes two other studies. The Committee asked for clarification on why there would be 15 New Zealand participants in the Hibiscus II trial and 22 in the Cottonwood trial.
* The Committee noted that the rate of Ulcerative Colitis (UC) is lower in Māori and asked what the reasons for this were (P.4.3.1). Mrs Champion explained that UC tends to be more common in those of European descent but they were not sure if this was due to genetics or diet. She explained that they were not realistically expecting any Māori participants in the study.
* The Committee asked for confirmation that ethnicity data will be collected as per the New Zealand Census question.
* The Committee noted that a history of drug or alcohol abuse within six months was an exclusion criteria and asked how this would be ascertained. Mrs Champion advised that it would probably be through a discussion of the participant’s medical history. The Committee recommended including this as an exclusion criteria in the PIS.
* The Committee advised that the study cannot be terminated by the sponsor purely for commercial reasons *(Ethical Guidelines for Intervention Studies, para 6.65).*
* Mr Morais advised that they were awaiting SCOTT approval.
* The Committee advised for future reference that researchers should be more specific on who the local Māori advisor will be (P.4.3.1). Mrs Champion advised that they do not currently know of anyone of Māori descent with UC but that if they were to find anyone they would consult with a Māori advisor.
* The Committee advised for future reference that, given the side effects, the statement “Risks are exceptionally minimal with a potential enormous benefit to UC patients” (R.8.1) was overstated.
* The Committee asked if there would be any safety concerns for participants only receiving standard treatment and placebo. Mrs Champion advised that they would be closely monitored and given other treatment if their symptoms are worsening.
* The Committee noted that the placebo justification was a useful document.
* The Committee asked whether there were any New Zealand representatives on the DSMB. Mr Morais agreed to check the DSMB charter.
* The Committee requested the following changes to the PIS and consent form:
  + Please simplify and remove repetition where possible. The Committee recommended giving the PIS to a lay person for review.
  + Please review for American spelling.
  + Please simplify the table as the footnotes are complicated.
  + Please remove sentence “You or your health plan will need to pay for medicines…” (page 21 of the PIS).
  + Please remove reference to “if required by law” if it is not New Zealand law (page 21 of the PIS).
  + Please make it clear in the PIS that if a participant has responded to the study drug, they may be eligible for seven years treatment in the open label extension.
  + Please include in the PIS that adalimumab is not approved or funded for treatment in New Zealand and is being considered a comparator in this study.
  + Please include an option in the consent form for future unspecified research, for blood samples to be stored for DNA testing (as referred to on page 2 of the PIS).
  + Please remove the words “which is unlikely” from the section on what happens if I am injured (page 21 of the PIS).
  + Please remove the yes / no boxes in the consent if the statement is not truly optional.
  + Please include Māori support contact details for both PIS.

Decision

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

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

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

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| **2** | **Ethics ref:** | **14/NTB/140** |
|  | Title: | Cottonwood |
|  | Principal Investigator: | Dr Stephen Inns |
|  | Sponsor: | Quintiles Pty Limited |
|  | Clock Start Date: | 18 September 2014 |

Mrs Amy Champion and Mr Diego Morais 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.

Dr Paul Tanser declared a conflict of interest and it was agreed that he would not take part in the discussions or voting.

Summary of ethical issues

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

* The Committee noted that this was a follow-on study from the previously discussed Hibiscus II study and that a number of the points discussed in that study also applied to this one.
* The Committee asked at what stage of this study people will know what drug they were taking in the Hibiscus II study. Mrs Champion advised that people will not know what drug they were on. The Committee were concerned that participants may have responded well to adalimumab in the Hibiscus II trial and their symptoms may worsen as it is not available treatment for ulcerative colitis in New Zealand.
* The Committee asked how the e-diary would work if participants did not have internet access. Mr Morais advised that participants will be given a sim card so they can use the diary anywhere they have cell access. Please include this in the PIS.
* The Committee requested the following changes to the PIS and consent form:
  + Please simplify and remove repetition where possible. The Committee recommended giving the PIS to a lay person for review.
  + Please review for American spelling.
  + Please simplify the table as the footnotes are complicated.
  + Please remove reference to “if required by law” if it is not New Zealand law (page 13 of the PIS).
  + Please remove the words “which is unlikely” from the section on what happens if I am injured (page 13 of the PIS).
  + Please combine the safety monitoring section for PML for Parts 1 and 2 of the PIS as there is currently a lot of repetition.
  + Please include Maori support contact details for the PIS for Part 1 and Part 2.

Decision

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

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

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

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| **3** | **Ethics ref:** | **14/NTB/147** |
|  | Title: | POLARIS: Personalised neuromodulation and recovery in stroke |
|  | Principal Investigator: | A/Prof Cathy Stinear |
|  | Sponsor: |  |
|  | Clock Start Date: | 18 September 2014 |

Associate Professor Cathy Stinear was present in person for discussion of this application.

Potential conflicts of interest

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

Mrs Phyllis Huitema declared a conflict of interest and it was agreed that she would not take part in the discussions and voting.

Summary of ethical issues

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

* The Committee acknowledged the well-presented application and congratulated the researcher on receiving HRC funding.
* A/Professor Stinear advised that they now have an ANZCTR registration number which was not included in the application form.
* The Committee commended the researcher for the layout and content of the PIS.
* The Committee commended the researcher’s answers to the ethical issues on (A.1.6).
* The Committee noted that the application stated that there is no sponsor for the study (A.5.1) but advised that the University of Auckland Research Office should have been selected.
* The Committee noted for future reference that acronyms should be spelt out.
* The Committee noted that the HRC peer review had questioned the usefulness of genotype analysis. A/Professor Stinear explained that genotyping is typically done to find predictors of disease and that there were questions on what would be learnt from only 120 participants. She said that there is a growing interest in how specific variations of normal genes, such as eye colour, vary on plasticity in the brain and how people learn. If these can be identified, they will be useful for recovery after a stroke.
* The Committee asked if the unfavourable genotype varied among ethnicities. A/Professor Stinear advised it is around 1/3 in Caucasians, about 2/3 in Asians and not known in Pacific Islanders or Polynesians. She noted that this is not stigmatising as it only matters in extreme conditions, such as recovering from a stroke.
* The Committee asked for clarification on the monitoring arrangements for the study. A/Professor Stinear advised that they are still deciding on this and because it is considered a low risk study, it might be a bit less formal than a classic DSMB. The Committee recommended choosing someone from a different medical school or country to be an independent member of a DSMB.
* The Committee asked how the risks for researchers of going into people’s houses would be managed (R.7.1). A/Professor Stinear advised that the assessors will email the coordinator or research assistant before going into participant’s homes and will then call or email when the assessment is completed.
* A/Professor Stinear confirmed that they would be using the New Zealand Census question to collect ethnicity data (P.4.6).
* The Committee asked if the medication referred to in page 1 of the PIS included herbal medication. A/Professor Stinear advised that it did not as they have not yet discovered any herbal medication that reacts with the drugs. She noted that researchers do discuss with participants whether they are taking prescribed and non-prescribed medications. She agreed to include this in the PIS.
* The Committee noted that people may have died after three years and how asked how the researchers would track participants. A/Professor Stinear explained that there are some DHB staff involved in the project and they will be able to access participant records to confirm if they have passed away.
* A/Professor Stinear agreed to check with the DHB Research Office to see if Mata Forbes is still the Māori health support contact.
* Associate Professor Stinear advised that the researchers had answered no in error to B.4.5.3 and that this should have been yes.
* The Committee asked if TMS was standard care. A/Professor Stinear advised that it was not and that participants would not receive it if they were not taking part in this study. This needs to be included in the PIS.
* The Committee commended the answers in the application on reducing inequality and cultural sensitivity.
* The Committee requested the following changes to the PIS and consent form:
  + Please correct typo “have experienced a first stroke within the few days” (page 1 of the PIS).
  + Please elaborate whether the MRI is part of routine care (page 3 of the PIS).
  + Please review the yes / no tick boxes on the consent form and only include yes / no options if the aspects are truly optional.
  + Please consider reordering the statements on the consent form to make it clear that genetic testing is truly an option.
  + Please include in the PIS that visits will be variable in time, participants will be reminded of where they are going and what will happen before each visit and that each visit will be tailored to individuals.

Decision

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

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

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| **4** | **Ethics ref:** | **14/NTB/150** |
|  | Title: | EpiNet Status Epilepticus Study |
|  | Principal Investigator: | Dr Peter Bergin |
|  | Sponsor: | Ministry of Health NZ |
|  | Clock Start Date: | 18 September 2014 |

Dr Peter Bergin 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.

* The Committee noted that this is a worthwhile study.
* Dr Bergin advised that this study is part of a bigger project which has been going on for seven years, to investigate and lead research into epilepsy.
* Dr Bergin explained that there are four components to this study (1) collecting information on episodes of Status Epilepticus (SE) (2) collection of blood, (3) collection of cerebrospinal fluid (CSF) where clinically indicated and (4) follow up. Participants can agree to have their data stored on the EpiNet database and not agree to any other parts of the study.
* Dr Bergin advised that participants who have episodes of SE routinely have their blood taken in the Emergency Department. It is usually not possible to get their consent as the patient is unconscious. When the patient has sufficiently recovered, the researchers will explain the study and gain consent. This will ask people to give their approval to have their data stored on the EpiNet database, agree to have their blood sent to Barcelona to look for antibodies, blood sent to Wellington and Melbourne to look for genetic abnormalities and to store blood and CSF for future research purposes. If patients have been discharged, the researchers will call them and arrange to meet to get the consent forms signed. This will be the same process for children but parents will consent on their behalf.
* Dr Bergin explained that there may be a small number (fewer than 10) of adults who may have intellectual impairment from the seizure and who may not sufficiently recover to give consent. He said that in this case, their next of kin will be asked to give consent. The Committee advised that adults can only legally give consent for other adults when there is an Enduring Power of Attorney or they are a welfare guardian, however they can ascertain the views of next of kin.
* The Committee acknowledged that in order to maintain the integrity of the study, it was important for as many people with SE as possible to be included in this study . The Committee referred to para 6.19 of the *NEAC Ethical Guidelines for Observational Studies* which states:

“Ethical consideration of studies involving individuals or groups who have diminished competence to give free and informed consent on their own behalf (for example, children) must seek to balance:

1. the vulnerability that arises from the participants’ diminished competence; with
2. the injustice that would arise from their exclusion from the benefits of observational studies in these groups.

* The Committee agreed that if participants were excluded from this study, then the result would be unjust. If participants have an Enduring Power of Attorney, then consent still needs to be obtained from them but if there is no legal representative, the views of a family member should be obtained. It is important that this document is not referred to as proxy consent.
* The Committee asked what would happen if any genetic abnormalities were found. Dr Bergin advised that they will inform patients and offer genetic counselling. Please include this in the PIS.
* The Committee noted that consent for those turning 16 in the two year follow up period should be obtained.
* The Committee noted that participants in this study may be as young as four weeks and that this would be a traumatic time for parents with a newborn. Dr Bergin explained that parents would not be approached until after their child had had their first prolonged seizure. He said that one of the study nurses will discuss their child’s seizure and the implications with the parents before asking for consent for their child to be included in the study.
* The Committee asked how consultation with Māori is going. Dr Bergin explained that Dr Helen Wihongi is agreeable to the study in principle.
* The Committee acknowledged the researchers answers to P.4.1 and P.4.2 in relation to cultural sensitivity.
* The Committee noted that the paediatric questionnaire should be reviewed and any questions that are not relevant to this study be removed, for example “I worry that my cancer will come back” and “I don’t like other people to see my scars”.
* The Committee requested the following changes to the PIS and consent form:
  + Please remove “science” from “The science and ethics of this study were reviewed” (page 5 of the PIS).
  + Please review the yes / no options in the consent form and remove the tick boxes for any statements that ticking no would mean a person could not take part in the study.
  + Please rename the proxy PIS and consent form.

Decision

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

* Please amend the participant information sheet and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Observational Studies, para 6.10).*

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

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| **5** | **Ethics ref:** | **14/NTB/151** |
|  | Title: | BGB-283 given in increasing dose levels to participants with solid tumors |
|  | Principal Investigator: | Dr Catherine Barrow |
|  | Sponsor: | Quintiles Pty Limited |
|  | Clock Start Date: | 18 September 2014 |

Dr Anne O’Donnell 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.

Mrs Raewyn Sporle and Mrs Stephanie Pollard declared potential conflicts of interest and it was decided that they could both take part in the discussions and voting.

Summary of ethical issues

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

* The Committee noted that this was a Phase I study of a new drug, with increasing dose levels.
* Dr O’Donnell advised that there has been no outcome from SCOTT yet.
* The Committee noted that there were no plans to report or disseminate results and asked if this was usual practice (B.4.1). Dr O’Donnell advised that results would be internally reported to the investigators and sponsors but at this stage, a publication plan has not been completed. The sponsor does intend to publish results in a peer reviewed publication.
* Dr O’Donnell advised that the universal trial number is pending.
* The Committee asked for clarification on an independent DSMB and asked if there is a charter to describe how it is comprised and how it will function. Dr O’Donnell explained that the DSMB will include representatives from all sites contributing to the trial and will have an independent clinician, experienced in Phase I trials, a biostatistician and a pharmacist. They will meet weekly by teleconference to discuss dosing levels.
* The Committee noted that that researchers had answered no to unexpected and clinically significant findings (R.4.1) and queried whether pregnancy would be considered one. Dr O’Donnell agreed that it could but that the PIS was clear about contraception and ongoing follow up.
* The Committee noted that under the NEAC Guidelines, these patients could be considered vulnerable as there is no standard care available and they are terminally ill. They asked how this vulnerability would be managed, particularly given that the researchers will be participant’s treating oncologist. Dr O’Donnell explained that the principal investigators are experienced in Phase I trials like this and recognise the desperation of the patients. The treating oncologists will identify potential participants and refer them to one clinician who will manage the patients for the trial. This clinician will obtain informed consent and will also have access to palliative care.
* The Committee noted that cultural issues for Māori (P.4.2) may include samples being sent overseas and that the decision to participate may be considered a whanau decision.
* Dr O’Donnell advised that Māori consultation has been applied for but no outcome has yet been received.
* The Committee advised that ethnicity data should be considered that is relevant to the New Zealand population and recommended using the New Zealand Census question (P.4.6)
* The Committee noted that the researchers had answered yes to this study addressing inequalities (F.1.1) but were unsure that this study had been set up to address inequalities in different ethnic groups. Dr O’Donnell explained that this study will allow access to a different drug in a disease that affects Māori and Pacific Island patients.
* Dr O’Donnell confirmed that the contact number on the patient study identification card is available at all times.
* The Committee noted that patients will be asked about their medical history at several visits (pages 4, 5 and 6 of the PIS) and asked if they would have to repeat themselves every time. Dr O’Donnell confirmed that this would just be their medical history since their last visit.
* The Committee noted that for future applications, it is not relevant to refer to Article One of the Treaty (F.1.2).
* Dr O’Donnell explained that study will be supported by a research study nurse who will explain verbal written instructions about the drug.
* The Committee commended the researchers for acknowledging that participants can withdraw verbally.
* The Committee requested the following changes to the PIS and consent form:
  + Please review tenses (page 2, para 5 of the PIS).
  + Please include information on the slight risk of radiation from CT and PET scans in the PIS.
  + Please explain in the PIS that most fridges are around 4°C.
  + Please remove reference to participants needing to pay for medications to address side effects (page 12 of the PIS).
  + Please move the sentence “Please see the Pregnancy and Breastfeeding section below for more information” to the bullet point above as this sentence is not relevant to fertile males (page 8 of the PIS).
  + Please remove the reference to studies being stopped due to commercial interests (page 13 of the PIS) as according to the NEAC guidelines studies should not be stopped simply for commercial interests.
  + Please include in the PIS that blood samples cannot be returned if requested by participant.
  + Please review the yes / no boxes on the consent form and remove the tick boxes for those statements that are not truly optional.
  + Please remove the reference to the National Statement as this is not relevant to New Zealand (page 15 of the PIS).

Decision

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

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

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

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| **6** | **Ethics ref:** | **14/NTB/152** |
|  | Title: | Growing up Milk Lite - GUMLi Trial |
|  | Principal Investigator: | Dr Clare Wall |
|  | Sponsor: |  |
|  | Clock Start Date: | 18 September 2014 |

Dr Clare Wall, Ms Amy Lovell and Ms Tania Milne 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.

Ms Kerin Thompson and Mrs Stephanie Pollard declared potential conflicts of interest and it was agreed that they would both take part in the discussions and voting.

Summary of ethical issues

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

* The Committee commended the quality of the application.
* The Committee noted that there had been no independent peer review for the study and Dr Wall agreed that one could be provided. The Committee recommended using the template available on the HDEC website.
* The Committee asked whether it was truly optional on whether a child’s GP would be informed of incidental findings and asked whether there would be any risk of not informing GPs. The researchers agreed to remove this as an option in the consent form.
* The Committee asked how researchers will ensure that there is ethnic diversity. The researchers explained that while there will not be specific sampling, they will be using a number of different advertisements, as well as going to maraes and kohangas. Ms Milne advised that she has good networks with the Pacific Health team at the University of Auckland and they will pass on the message to these communities.
* The researchers confirmed that the New Zealand Census question will be used to collect ethnicity data.
* The Committee advised that this study does not involve the use of a placebo (F.2.3) as cow’s milk has health benefits.
* The Committee asked if the children are allowed to drink any milk in addition to the study treatment. Dr Wall confirmed that they are but this needs to be either breast milk or regular cow’s milk. Please include this in the PIS.
* Dr Wall confirmed that the cow’s milk can be any type.
* The Committee asked how researchers would deal with the possibility of other children in the house drinking the GUMLi. The researchers advised that each tin contains 26 servings but they have allowed for 15 servings per tin as other people in the house may drink it or participants may lose it. Participants are given a three month supply and researchers will make follow up calls to ensure that participants have enough.
* The Committee requested the following changes to the PIS and consent form:
  + Please simplify the opening paragraph of the PIS and ensure that it is in lay language.
  + Please include in the PIS that GUMLi is fortified cow’s milk.
  + Please tailor the PIS to a New Zealand audience and remove any references to the University of Queensland that are not relevant.
  + Please amend the Health and Disability Ethics Committee New Zealand to Northern B Ethics Committee (page 5 of the PIS).
  + Please include that transport or vouchers will be provided to help participants get to the Grafton Campus (page 5 of the PIS).
  + Please remove University of Queensland Medical Research Ethics Committee contact details.
  + Please include a Māori support contact and include an email contact for the Health and Disability advocate as the one given is for the HDEC Secretariat.
  + Please remove the paragraph on the ethical conduct on research as it is not relevant to the consent form (page 1 of the consent form).
  + Please ensure PIS and consent form and PIS are consistent with dosage amounts.
  + Please clarify in the PIS what 300ml looks like.
  + Please include in the PIS that milk will be supplied in powdered form.
  + Please include the ACC statement in PIS. Suggested wording can be found on the PIS template at http://ethics.health.govt.nz/
  + Please include a section in the consent form for the person who takes consent to sign and date the consent form.
  + Please include a version date and number on footer of the PIS and consent form.

Decision

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

* Please amend the participant information sheet and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide independent peer review *(Ethical Guidelines for Intervention Studies, para 5.11).*

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

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| **7** | **Ethics ref:** | **14/NTB/154** |
|  | Title: | Fight HD |
|  | Principal Investigator: | Dr Melanie Cheung |
|  | Sponsor: |  |
|  | Clock Start Date: | 18 September 2014 |

Dr Melanie Cheung was present by teleconference and Dr Greg Finucane was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The Committee congratulated the researchers on an ethics application that one committee member considered the best they had ever read.
* The Committee noted that no sponsor had been selected for this study (A.5.1) but advised that as this is an HRC contract, the university research office would be regarded as the sponsor.
* The Committee asked where the brain training will take place. Dr Cheung advised that this would be in participant’s homes but there was also the possibility of it taking place at the marae.
* The Committee noted that the training was internet based and asked if participants would be excluded if they did not have home computers and an internet connection. Dr Cheung advised that if participants do not have an internet connection at home, they will be encouraged to train at relatives’ homes.
* Dr Cheung explained that the strength of this training is that it fits a Māori world view.
* The Committee asked what the dummy blind training would look like. Dr Cheung explained that it would consist of 10 different games, for example Battleship and Tetris.
* The Committee asked if the researcher will know whether participants are on active training or placebo. Dr Cheung confirmed that they would not know what treatments the participants are getting.
* The Committee asked whether results would be shared with participant’s GPs if they choose to find out their genetic profile. Dr Finucane advised that they will talk with participants but it will not be mandatory to pass the results on to the GP. Please include in the PIS that researchers will discuss the findings of the genetic profile with participants.
* The Committee asked about the reference to decontaminating blood before it is returned (R.3.12). Dr Cheung advised that biological specimens have to be decontaminated to ensure they do not get any blood-borne viruses.
* The Committee noted that if participants want to continue with brain training after the study is complete that they will have to pay $100 per year and did not feel that this was fair given their contribution to the study. Dr Cheung advised that this is a licensing fee but she will discuss with the vendors as to whether this can be made available to participants for free.
* The Committee asked for clarification on who would be responsible for scientific oversight and monitoring of the study (R.1.5).
* The Committee recommended reviewing the NEAC Guidelines and considering whether the data is anonymous or if it is de-identified (R.2.4).
* The Committee asked if researchers will be visiting participants in their homes and if so, how will this risk be managed (R.7.1).
* The Committee noted that the statement on page 4 of the PIS that study data would be stored for 10 years and then retained for future use was contradictory. Dr Cheung advised that the researchers would want to work with the community in five years to see how long the training lasted for. Please include this in the PIS.
* The Committee requested the following changes to the PIS and consent form:
  + Please simplify the last paragraph on page 1 of the invitation. This could include a plain English version along with the scientific explanation.
  + Please review the PIS for correct spelling and grammar.
  + Please provide more information on what is going to happen in the study, for example, a quick explanation of placebo brain training, information that the training will take place at home, the possibility of going to Auckland for tests (page 3 of the PIS)
  + Please include a statement in the PIS that only people who are comfortable with having an MRI will have one (Page 3 of PIS).
  + Please include in the PIS that samples will be sent and stored overseas.
  + Please amend “you would be eligible for compensation from ACC” to “you may be eligible for compensation from ACC” (page 4 of the PIS).
  + Please remove the word “practicable” (page 4 of the PIS).
  + Please include in the PIS that participants who are symptomatic can receive treatment but that their data will not be used in the study.

Decision

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

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

This following information will be reviewed, and a final decision made on the application, by Mrs Kate O’Connor

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| **8** | **Ethics ref:** | **14/NTB/155** |
|  | Title: | GAUSS-3: Goal achievement after utilising an anti-PCSK9 antibody in statin intolerant subjects |
|  | Principal Investigator: | Prof Russell Scott |
|  | Sponsor: | Amgen Australia |
|  | Clock Start Date: | 18 September 2014 |

Dr Jinny Willis 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 noted that the 27 page PIS was difficult to understand. While they acknowledged that a lot of information needs to be included, they recommended that the researchers consider what language can be simplified and if any duplication can be removed.
* The Committee asked how long blood will be kept for (R.1.3.2). Dr Willis advised that for future research it will be kept indefinitely but the rest will be analysed and disposed of using standard disposal methods. She noted that once tissue is sent overseas, there is no guarantee that it will be disposed of in a culturally sensitive manner.
* The Committee noted that the acronyms in the plan English summary (A.1.5) should have been spelt out in full. They noted that the opening paragraph of the covering letter provides a good example of a short study title.
* The Committee asked for justification on making patients take medication from which they have already had known side effects, for three months. Dr Willis advised that if people have a documented statin intolerance, they will not need to go through Part A of the study. She explained that the FDA requires objective study data to prove statin intolerance. She subsequently noted that Part A may be shorter if side effects are reported.
* The Committee noted that the Investigator’s Brochure was dated May 2013 and asked if there was a later edition that may change the risk/benefit profile of the study. Dr Willis agreed to confirm this.
* The Committee asked why independent peer review would only be available after the study had started (B.2.2.1). Dr Willis explained that the protocol had been developed overseas so they did not have any input. The Committee asked that independent peer review be provided and recommended using the template on the HDEC website at <http://ethics.health.govt.nz>.
* The Committee noted that the coordinating investigator is on the medical panel for Amgen, the sponsor of the study, and asked if this would be considered a conflict. Dr Willis did not think it would be an issue as long as it is declared.
* Dr Willis advised that no had been selected in error in answer to R.1.9 and ACC equivalent compensation would be provided.
* The Committee asked for clarification on how confidentiality of data would be ensured (R.2.1.1). Dr Willis advised that only people associated with the study will have computer access to the study. Paper files will not be stored in an area that people who come into the study have access to and the building has swipe card access after-hours.
* The Committee asked what procedures were in place to deal with any incidental findings, for example hepatitis or pregnancy (R.4.1). Dr Willis explained that the trial clinicians will be responsible for communicating incidental findings and ensuring that participants have access to help.
* The Committee noted for future reference that cultural issues “may be raised” should have read “should be raised” (P.4.2).
* The Committee advised that the study cannot be terminated by the sponsor purely for commercial reasons *(Ethical Guidelines for Intervention Studies, para 6.65).*
* The Committee asked for the name of the Māori Health Group to who consultation had been submitted. Dr Willis advised that this has been forwarded to the HDEC Secretariat and the contact is Peter Mason from Ngā Kete E Rua who has a longstanding involvement with Ngai Tahu.
* The Committee asked for clarification that the results will be conveyed to participants using lay language (P.2.9).
* The Committee noted that page 5 of the PIS refers to participants maintaining their current diet and exercise regimen and asked whether this meant they could not improve their diet in three years. Dr Willis explained that they want to assess the effects of the medication rather than changes in diet and lifestyle. She thinks that this could be addressed before being randomised to the study. Please reword the PIS to reflect this.
* The Committee noted that the PIS says that atorvastatin is not suitable for patients older than 70 but the inclusion criteria is those under 80. Dr Willis agreed to check this but thinks that it just that there is not good data available in those over 70.
* The Committee requested the following changes to the PIS and consent form:
  + Please make the study title in lay language.
  + Please specify what the two groups are in Part B of the study (page 3 of the PIS).
  + Please simplify the table and remove acronyms (page 6 of the PIS).
  + Please include that questionnaires will be completed using an electronic device (page 7 of the PIS).
  + Please specify how many times blood will be taken during the entire study (page 7 of the PIS).
  + Please remove “there are no known side effects caused by AMG 145” as it is followed by a list of commonly reported side effects (page 8 of the PIS).
  + Please clarify “too much alcohol” (page 12 of the PIS).
  + Please remove the paragraph that medical care considered routine care will not be paid for by Amgen (page 19 of the PIS).
  + Please include a section in the consent form for the person taking consent to sign and date the forms (pages 26 & 27)
  + Please include that this study has received ethical approval from the Northern B Health and Disability Ethics Committee.
  + Please include that the two payments of compensation will be $300.

Decision

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

* Please amend the participant information sheet and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide evidence of independent peer review *(Ethical Guidelines for Intervention Studies, para 5.11)*

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

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| **9** | **Ethics ref:** | **14/NTB/156** |
|  | Title: | Mk3682-011: MK-5172/MK-3682 with MK-8742 or MK-8408 in HCV GT1, GT2 and GT4 Infected Subjects |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Merck Sharp & Dohme (Australia) Pty Limited |
|  | Clock Start Date: | 18 September 2014 |

Professor Ed Gane and Ms Vithika Suri 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 this study is a Merck study of MK-5172 and MK-3682 in combination with MK-8742 or MK-8408. He said that this is the next chapter in Hepatitis C treatment as the treatment is only for four weeks duration and can be used for everyone regardless of their Hepatitis C genotype. He believes that this study will be able to demonstrate that this treatment is highly effective with only four weeks duration as the drugs are so potent.
* The Committee noted that cough and shortness of breath were potential side effects of MK-8742 and asked if this was likely to be cardiac, respiratory or related to anaemia. Professor Gane explained that these side effects were seen when taken in combination with ribavirin which is known to cause coughs. He said that he did not expect to see these side effects in this study.
* Ms Suri confirmed that SCOTT approval had been applied for in parallel with ethical approval. She will forward the outcome when it is received.
* The Committee asked for clarification on the DSMB. Ms Suri explained that while there is not an explicit DSMB, the sponsor has formed a committee with internal monitoring systems in place who would undertake all the processes that a DSMB would usually do. The Committee asked Professor Gane whether he thought there should be a New Zealand representative on the committee and he agreed to clarify with the sponsor whether the DSMB is independent to the sponsor.
* Ms Suri advised that the independent Māori reviewer would be Dr Helen Wihongi from Waitemata DHB (P.4.3.1)
* The Committee noted that health data will be held for 50 years from the date of signing consent (page 19 of the PIS). Ms Suri agreed to clarify this with the sponsor.
* Ms Suri advised that each patient will be given a unique study identifier and when samples are being sent overseas, they will be coded with this identifier.
* The Committee advised that for future reference the first six lines of P.4.1 in relation to the Treaty of Waitangi should not be included in applications.
* The Committee advised that for future applications the second sentence in response to P.4.2 should be amended to read “Informed consent will be sought from Maori participants specifically regarding the storage, testing and destruction of tissue samples and information.”
* The Committee requested the following changes to the PIS and consent form:
  + Please include a lay title on the PIS and consent form.
  + Please review PIS for American spelling.
  + Please include the values of the tokens of appreciation (page 18 of the PIS).
  + Please include name and contact details of a person to contact for more information (page 20 of the PIS and page 5 of the Future Biomedical Research PIS).
  + Please amend the sentence “Should you have any concerns regarding appropriate practice / tikanga….” to “Should you have any concerns regarding appropriate practice / tikanga arising from your participation in the study, you may wish to discuss with a kaumatua or whanau member” (page 4 of the Future Biomedical Research PIS).
  + Please include “you will be randomised to Group A or placed into a treatment group” (page 4 of the PIS) as randomisation only applies to Group A.
  + Please remove reference to study doctor (page 16 of the PIS).
  + Please remove reference to “as required by US Law” (page 20 of the PIS).

Decision

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

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

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

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| **10** | **Ethics ref:** | **14/NTB/157** |
|  | Title: | Mk3682-012: MK-5172/MK-3682 with MK-8742 or MK-8408 in HCV GT1, GT2 and GT3 Infected Subjects. |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Merck Sharp & Dohme (Australia) Pty Limited |
|  | Clock Start Date: | 18 September 2014 |

Professor Ed Gane and Ms Vithika Suri 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 that this study was similar to the MK3682-011 study but was looking at whether this drug combination works specifically on genotype 3, which has typically been the most difficult to treat.
* The Committee noted that the issues for this study were similar to the previous study (14NTB/156) and requested the following changes to the PIS and consent form:
  + Please include a lay title on the PIS and consent form.
  + Please review PIS for American spelling.
  + Please include the values of the tokens of appreciation (page 18 of the PIS).
  + Please include name and contact details of a person to contact for more information (page 21 of the PIS and page 5 of the Future Biomedical Research PIS).
  + Please amend the sentence “Should you have any concerns regarding appropriate practice / tikanga….” to “Should you have any concerns regarding appropriate practice / tikanga arising from your participation in the study, you may wish to discuss with a kaumatua or whanau member.” (page 4 of the Future Biomedical Research PIS).
  + Please include “you will be randomised to Group A or placed into a treatment group” (page 4 of the PIS) as randomisation only applies to Group A.
  + Please remove reference to “as required by US Law” (page 21 of the PIS)

Decision

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

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

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

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Chair noted that the next Northern B meeting will be on Melbourne Cup Day and asked the HDEC Secretariat to check whether it was possible to move the venue.
3. The Chair asked that the yes / no options be removed from the PIS and consent form template on the HDEC website as this is confusing for researchers.
4. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| --- | --- |
| **Meeting date:** | 04 November 2014, 12:00PM |
| **Meeting venue:** | TBD |

The following members tendered apologies for this meeting.

No members tended apologies.

The meeting closed at 4.22pm.