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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 02 June 2015 |
| **Meeting venue:** | Novotel Ellerslie |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
|  | Confirmation of minutes of meeting of 7 April 2015 |
| 12.30pm | New applications (see over for details) |
|  | i 15/NTB/88  ii 15/NTB/90  iii 15/NTB/91  iv 15/NTB/92  v 15/NTB/93  vi 15/NTB/94  vii 15/NTB/95  viii 15/NTB/96  ix 15/NTB/97  x 15/NTB/98  xi 15/NTB/99 |
| 4.45pm | General business:   * Noting section of agenda |
| 4.50pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Raewyn Sporle | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | 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 | Apologies |
| 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 12.20pm and welcomed Committee members, noting that apologies had been received from Ms Kerin Thompson.

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 7 April 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/NTB/88** |
|  | Title: | Improving the breast cancer journey for women with experience of mental illness |
|  | Principal Investigator: | Dr Ruth Cunningham |
|  | Sponsor: |  |
|  | Clock Start Date: | 21 May 2015 |

Dr Debbie Peterson 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 thanked the researcher for making herself available and for an interesting application.

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 participants may be interviewed in their homes and asked whether there was a protocol for keeping interviewers safe. Dr Peterson explained that in a previous project in peoples’ homes, the interviewers made sure that co-workers were aware of where they were going and called them when the interview was finished. This study will use the same protocol.
* The Committee commended the researcher on the Lotteries funding and recommended asking the University Research Office to come on board as sponsor
* The Committee advised that the advertisements for recruitment should be sent to the HDEC Secretariat.
* Dr Peterson explained that the research proposal had been submitted online to the Maori Research Committee at Otago University. The Committee will discuss the application and let the researchers know if any further information is required.
* Dr Peterson advised that participants will be asked at the interview if they want a summary of results at the end of the study.
* The Committee asked if the researcher thought that there would be any participants who would be unable to give informed consent due to their mental illness. Dr Peterson thought that this was unlikely as in her previous experiences of people with mental illness, she seldom encounters people who are unable to provide consent. Participants usually volunteer for these types of studies and these women will have gone through many health procedures and are used to providing consent. Dr Peterson advised that if she comes across a participant who is unable to give consent, they will be excluded from the study.
* The Committee asked if there were any mechanisms in place to ensure that there were some Maori participants given the higher levels of breast cancer and mental illness among Maori. Dr Peterson advised that they will do their best using their contacts but this may be difficult as the sample will be so small. She also said that they will take advice on recruitment from the Maori consultation.
* The Committee discussed whether the researchers anticipated any issues with the information that paranoid schizophrenics may give but agreed that as this was a qualitative study, it would be part of the lived experience.

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

* Please include university logo on PIS.
* Please make it clear that there will be no change in treatment for participants. Please reword to explain that this may result in better experiences or outcome for future patients.
* Please include what types of questions will be asked (as outlined in interview schedule) to give participants a better idea of what the interview entails.
* Please make it is clear in the inclusion criteria that women need to have had a diagnosis of mental illness prior to breast cancer being diagnosed.
* Please include Northern B HDEC.
* Please include that interviews may take place in a participant’s home.
* Please include a list of support contacts in PIS.
* Please remove ACC statement.
* Please include contact details for Maori health support.
* Please include that participants can have a support person with them at the interviews.
* Please review consent form template on the HDEC website and ensure relevant statements are included as bullet points on the consent form.
* Please include where the information will be stored and for how long.

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 an HDEC advisor.

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| **2** | **Ethics ref:** | **15/NTB/90** |
|  | Title: | M14-198 - A Phase 2, Multicenter, Open-Label Extension(OLE) Study with ABT-122 in Active Psoriatic Arthritis Subjects Who Have Completed a Preceding Study M14-197 Phase 2 Randomized Controlled Trial |
|  | Principal Investigator: | Dr Douglas White |
|  | Sponsor: | AbbVie Pty Ltd |
|  | Clock Start Date: | 21 May 2015 |

Ms Denise Darlington 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 thanked the researcher for making herself available to discuss the study.
* Ms Darlington explained that this is an extension to a study that was submitted at the previous Northern B HDEC meeting.

Summary of ethical issues (resolved)

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

* The Committee noted the length of the PIS and asked if participants would have a good level of knowledge of their disease. She explained that participants will already have been on the initial study and will have an understanding of study requirements and their disease. Participants will be at the more severe end of Psoriatic Arthritis population and will have been attending clinics for some time.
* The Committee noted that this study was taking place in 11 countries and asked whether this study was dependent on all of the other countries obtaining ethical approval. Ms Darlington advised that the study to which this one is a follow up is already underway in a number of countries.
* The Committee noted that there were 110 participants worldwide which did not appear to be many. Ms Darlington explained that the initial study is for 220 participants and she had asked the sponsors why this number was low in comparison. She said that the figure of 110 had been worked out on the statistical analysis needed for the primary endpoint but that all eligible people could move onto this extension phase.
* The Committee noted that patients would already be on methotrexate and asked if this would be withheld during this study. Ms Darlington advised that if patients needed to add extra drugs, then the study drug was clearly not working. If a patient’s disease was not controlled they would be given the option of coming off the study. The Committee asked if patients would need to come off the study to receive rescue treatment. Ms Darlington advised that they would discuss this with the sponsor but she thought that as the sponsor was keen to keep people on, participants would be allowed to continue on the study but would be marked down as a non-responder.
* The Committee asked for clarification on the answer to B.4.4 that data generated in this study will be made available for use in future research. Ms Darlington explained that this would be for any future studies that may take place with this compound and would provide information if needed to support extra studies.
* The Committee recommended reviewing the NEAC Guidelines for Intervention Studies to consider whether data is de-identified. The Committee advised that if there is a document from which the researchers can link to identify participants, then data is potentially identifiable.
* The Committee noted that samples will eventually be stored with the sponsor (R.3.8.1) but there was no reference in the PIS to onward storage and where it will be long-term.
* Ms Darlington confirmed that study results will be available in lay language for participants.
* Ms Darlington confirmed that separate SCOTT review had been applied for this study. The Committee noted that this can be used as evidence of peer review.
* Ms Darlington confirmed that participants will be given a patient alert card.
* Ms Darlington explained that there is a future sub-study and not taking part in the sub-study will not exclude participants from taking part in the main study.
* Ms Darlington advised that she was planning to submit the documents this week for Maori consultation.
* The Committee noted for future applications that references to Article 3 of the Treaty are inappropriate and it would be more appropriate to include data on the prevalence of Psoriatic Arthritis in Maori.

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 why study documents would be retained for 20 years and asked how this related to GCP (as per the answer to P.2.5 of the application). Ms Darlington agreed to check with the sponsor.
* The Committee asked for clarification on the statement “AbbVie Limited agrees to pay all necessary reasonable medical expenses necessary to treat such injury provided you have (1) not contributed to the injury and (2) you have followed the directions of the study doctor” (page 12 of the PIS). Ms Darlington explained that they will treat each situation on a case by case basis. The Committee were concerned that this does not meet the requirements of ACC equivalent compensation which is no fault. The Committee asked that the standard compensation wording for commercial studies be included in the PIS. Ms Darlington agreed to discuss this with the sponsor.

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

* Please include a lay study title.
* Please consider numbering each heading on the PIS.
* Please highlight that storage of samples will be overseas.
* Please include list of prohibited medications and reassurance that this will be discussed and participants will always receive medication that in best interest.
* Please remove duplication.
* Please review for New Zealand English spellings.
* Please remove reference to withdrawal in writing (page 15 of the PIS and in optional skin biopsy PIS).
* Please include if it is acceptable for participants to receive flu vaccinations.
* Please include how questionnaires will be completed. Ms Darlington confirmed this will be on an electronic tablet.
* Please include an approximation of how long questionnaires will take to complete.

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).*
* Please provide confirmation from the sponsor that ACC equivalent compensation is available *(Ethical Guidelines for Intervention Studies, para 8.1-8.5).*

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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| **3** | **Ethics ref:** | **15/NTB/91** |
|  | Title: | FOLEY CATHETER STUDY |
|  | Principal Investigator: | Dr Suheelan Kulasegaran |
|  | Sponsor: |  |
|  | Clock Start Date: | 21 May 2015 |

Dr Suheelan Kulasegaran 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 thanked the researcher for attending in person.
* Dr Kulasegaran explained that an ileus is a common complication after surgery for patients with colorectal cancer. This can cause swelling and blockage of the bowel. This study will look at whether inserting a Foley catheter during surgery will reduce the swelling. Dr Kulasegaran advised that a similar study had commenced in the United States but was abandoned due to lack of staff. He said that researchers do not currently know how many patients get blockages but the co-investigators think the Foley catheter will make a big difference.

Summary of ethical issues (resolved)

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

* The Committee queried whether the study will be blinded. Dr Kulasegaran explained that he and the surgeon will know whether the catheter will be inserted, with the surgeons finding out on the day of surgery. Patients will be told that they may or may not have a catheter inserted.
* The Committee recommended that the manager of the researcher’s Head of Department is invited to be sponsor for this study.
* The Committee noted that the incidence of complications ranged from 3% to 93% and asked why this range was so large. Dr K explained that the 93% figure included minor complications such as minor skin irritations.
* The Committee noted that the researcher had answered that data would be de-identified (R.2.4) and advised that if there is a linking document, it is likely to be potentially identifiable.
* Dr Kulasegaran explained that he had discussed the study with a Maori advisor at North Shore Hospital who advised that if the procedure is done on Maori or Pacific people that there would need to be someone on site. This advisor would be happy to be this person.
* The Committee noted that the peer review had queried whether the study was powered correctly. Dr Kulasegaran explained that he had used power calculations and was comfortable with the sample size.
* Dr Kulasegaran advised that the 20 hours difference in the groups was in the first movement into the bag. If this was done, it would reduce the amount of time before a patient could eat.
* The Committee asked if there were any examples in surgery when a catheter would not be inserted. Dr K could not think of any examples but agreed to include a statement in the PIS that a catheter will not be inserted if the surgeon does not believe it is in a participant’s best interests.
* The Committee asked for clarification on the answer to P.4.1. Dr K explained that they know that the incidence of colorectal cancer is lower in Maori but the incidence is increasing quicker than in other populations. The Committee noted that the answer to F.1.1 should therefore have been yes.
* The Committee recommended showing participants a Foley catheter during the informed consent process.
* Dr Kulasegaran advised that baseline ethnicity data will be collected and no had been answered in error on the application.

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

* Please define technical terms.
* Please include a lay study title.
* Please review for spelling.
* Please include more information on the reinsertion of the catheter.
* Please include the ACC compensation clause from the PIS template available on the HDEC website.
* Please include a diagram showing where the catheter will be inserted.
* Please include that reasonable travel costs (page 3 of the PIS).
* Please remove repetition on confidentiality clause on page 4 of the PIS.
* Please clarify what would happen if someone withdrew from the study, i.e. they can withdraw and not have data collected or ask for the catheter to be removed.
* Please include any potential risks for participants.
* Please amend to Northern B Health and Disability Ethics Committee.
* Please include matched version numbers for PIS and consent form and make it into one document so that the consent form follows on from 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 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 Raewyn Sporle.

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| **4** | **Ethics ref:** | **15/NTB/92** |
|  | Title: | AIRVO use following hospitalisation for COPD |
|  | Principal Investigator: | Prof Richard Beasley |
|  | Sponsor: | Fisher and Paykel Healthcare |
|  | Clock Start Date: | 21 May 2015 |

Dr Janine Pilcher 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 (resolved)

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

* Dr Pilcher explained that the AIRVO machines are mainly used in clinic settings, including hospitals in Wellington, the Hutt Valley, Palmerston North and Hawke’s Bay. Some patients also use the machines at home.
* Dr Pilcher explained that the AIRVO machine goes under the nose and around the ear and is worn like nasal prongs. However the material is softer, they are delivering something different and they may be more comfortable than nasal prongs.
* Dr Pilcher explained that Maori consultation will be applied for when the researchers have made the changes requested by the HDEC.
* The Committee asked what would happen if the AIRVO stops working outside business hours as the contact number for participants is only available during business hours. Dr Pilcher explained that they did not want to offer a 24 hour line as they do not have resourcing but they would advise patients to stop using the device until they could contact a researcher. Patients on home oxygen would be advised to go back to their usual oxygen and patients who were only on AIRVO would be advised to stop until they could call the researchers.
* Dr Pilcher advised that the most common problem would be the machine running out of water and if this happened an alarm would go off and the machine would stop working.
* Dr Pilcher advised that the researchers would encourage family to be present during the home visits for training.
* Dr Pilcher noted that the machine had been used in healthy participants with reported minor incidents of headaches. She said that Fisher and Paykel had not reported any major events. The Committee advised that this needs to be included the PIS.
* The Committee noted that there were two concurrent data safety monitoring processes (the researchers and Fisher and Paykel) and asked if they would be talking to each other. Dr Pilcher explained that her and two other researchers are at a registrar level clinically but she has a very supportive head of department who works at a consultant level and they would consult regularly. If there were any concerns with the trial, this would be reported to Fisher and Paykel. Under the conditions of MRINZ’s contract with Fisher and Paykel, they can stop the study if there are any safety concerns.
* The Committee asked if it was possible to include an 0800 number or cellphone number for whanau support. Dr Pilcher advised that this is a CCDHB number and she will see if there is also an email address.
* Dr Pilcher explained that this study would not involve a complete replacement from oxygen to AIRVO as it was too difficult to get AIRVO for 16 hours, which is the amount of time patients on home are prescribed oxygen.

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

* Please include a picture of the device in the PIS.
* Please include information under a heading “what will happen if I do not take part”.
* Please change New Zealand Ethics Committee to Northern B Health and Disability Ethics Committee.
* Please make it clear that participants will continue to get oxygen but it will just be by a different machine.
* Please make it clear that some oxygen delivery will be done through normal route and some will be supplemented by AIRVO.
* Please make it clear that participants should continue to have oxygen if there are problems with the AIRVO.
* Please include a statement in the PIS and a consent statement that participants will be asked to give consent to access spirometry results from their medical records.

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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| **5** | **Ethics ref:** | **15/NTB/93** |
|  | Title: | 5% Aciclovir or Honevo as a treatment for cold sores |
|  | Principal Investigator: | Dr Irene Braithwaite |
|  | Sponsor: | HoneyLab |
|  | Clock Start Date: | 21 May 2015 |

Dr Alex Semprini 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

* Dr Semprini explained that this is essentially the same study that was reviewed by the Committee earlier in the year, with the main change being to the investigational product.

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 clarification on the data safety monitoring committee. Dr explained that there are two consultants within Wellington Hospital who have reviewed the protocol. After 100 patients have been recruited, they will give them the safety information and SAEs and how the study is going generally and they will generate reports from there.
* Dr Semprini advised that SCOTT review was underway and was looking at new investigational product. He did not expect any issues as the same formulation had been used for other studies.
* The Committee asked for clarification on the recruitment process. Dr Semprini explained that there will be notes on the pharmacy shelf where coldsore products are available advising customers that there is a trial taking place and to discuss it with the pharmacist if they are interested. The pharmacists will also tell potential participants about the study when they go to buy coldsore products. If a person says yes, there will be a suitable area within the pharmacy where the trial can be discussed. The pharmacist can then go through the PIS and answer any questions the participant may have. Pharmacists will be given pre-randomised packs which will be given sequentially to participants.
* The Committee asked what would stop participants from taking the study treatment and other coldsore treatments. Dr Semprini advised that they would be relying on participants not to and to report it in the study diary and in the final phone call at the end of the study.
* Dr Semprini advised that an organisation in Auckland will conduct the final phone call at the end of the study. This was because they found in a previous acne study that there was too much information recorded in the study diaries and the idea was to keep this information to a minimum and collect the information at the end of the study.
* The Committee commended the researcher for condensing the PIS, while still including key information, based on previous Committee feedback.
* Dr Semprini advised that he had spoken to the Maori Pharmacists Association and local universities as they had struggled to find a national contact number for Maori support that encompasses every iwi. He said he had discussed it with Te Ora, a health network charitable trust in Taranaki who had agreed to provide support and contact on an as needed basis. The plan was to include their contact details in the PIS and the Committee agreed this was acceptable.

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

* Please consider grouping information in the PIS under key headings. Please refer to the PIS and consent form template on the HDEC website for recommended headings.
* Please make the checklist on page 1 bigger so it is easier to read.
* Please include Te Ora contact details.

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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| **6** | **Ethics ref:** | **15/NTB/94** |
|  | Title: | Comparison study of clobetasone butyrate cream applied to the skin in healthy male and female volunteers |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Ego Pharmaceuticals Pty Ltd |
|  | Clock Start Date: | 21 May 2015 |

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

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

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

* Mrs Folland confirmed that the study timetable will be given to potential participants at the information readings.
* Mrs Folland confirmed that blood samples will only be collected for screening purposes.
* Mrs Folland advised that the reference to proceeding to page 13 (page 10 of the PIS) should have read proceed to page 11.
* Mrs Folland confirmed that Maori consultation was underway.
* Mrs Folland explained that skin blanching will be done by a chromometer and then those results will be passed on to the statistician to compile results.
* The Committee noted that the answer to P.4.1 should have referred to instances of inflammatory skin diseases in Maori. Mrs Folland explained that this study would have no benefit to Maori and the Committee noted that the answer to P.4.1 should therefore have been no.

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

* Please include that there will be a bed available for study participants.
* Please remove yes / no boxes for those statements that are no truly optional.
* Please include that samples will be applied to 16 sites on the subjects’ arms (eight each arm) and the size of the samples.
* Please include that participants will not have access to the study cream when the study ends.
* Please include a cellphone number or 0800 number for A3 Kaitiaki Ltd.
* Please amend Northern A HDEC to Northern B HDEC.
* Please review for American spellings, for example computerized.

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 an HDEC advisor.

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| **7** | **Ethics ref:** | **15/NTB/95** |
|  | Title: | GS-5745 for the Treatment of Moderately to Severely Active Crohn's Disease (GS-US-395-1663) |
|  | Principal Investigator: | Prof. Richard Gearry |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 21 May 2015 |

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

* Please clarify if there are other treatments available for this patient population and if not, please address how the potential vulnerability of participants will be addressed.
* If there are other treatments involved for participants, please clarify if patients can continue to access medication during the study. Please clarify if it is likely that patients will need prohibited medication during the study and what will happen if they do need it.
* Please note that A.1.5 and B.1.1 should include plain English summaries.
* Please add to the PIS that incidental findings will be notified, for example Hepatitis C and HIV. Please advise if participants’ GPs will be informed of incidental findings (R.4.1.1)
* Please clarify the timeframe for consent as it is not clear whether the participants will be providing consent on the same day they are given information (P.2.1).
* Please provide data on incidence of Crohn’s Disease in Maori (P.4.1).
* Please clarify the need for a legally authorised representative and witness on the consent form and remove if this is not applicable to this study.

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

* Please review for New Zealand English.
* Please include abbreviations in full e.g. HBV and HCV (page 3 of the PIS).
* Please include Maori health support contact details (page 5 of the PIS).
* Please include if there is an option to refuse to answer specific questions in the questionnaires (page 10 of the PIS).
* Please remove the requirement to withdraw consent in writing (page 15 of the PIS).
* Please remove as required by US law (page 15 of the PIS).
* Please include information on where samples will be stored.
* Please include an acknowledgement of the cultural issues that may arise for Maori from transportation of samples and potential future use of tissue.
* Please make it clear that the study drug will not be available at the end of the study.
* Point 10, page 17 of the consent form is an incomplete statement.
* Please remove the requirement to withdraw in writing from all participant information sheets.

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).*
* Please clarify the use of a legally authorised representative *(Ethical Guidelines for*

*Intervention Studies, para 6.22).*

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

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| **8** | **Ethics ref:** | **15/NTB/96** |
|  | Title: | RCT of the efficacy and safety of an ICS/LABA reliever therapy regimen in asthma |
|  | Principal Investigator: | Prof Richard Beasley |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 21 May 2015 |

Professor Richard Beasley, Dr Janine Pilcher and Mr Mark Holliday 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 Study

* The Committee commended the researchers for a very clear PIS.

Summary of ethical issues (resolved)

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

* Mr Holliday explained that up to $50 reimbursement of travel expenses will be provided (P.3.3.1). The information sheets are site specific and will be updated on a site by site basis (as per page 11 of the PIS)
* The Committee commended the researchers on their consultation with Maori.
* The Committee noted that the study was sponsored by MRINZ and funded by AstraZeneca. They asked for confirmation on who would have control of the data and who would perform the analysis. Mr Holliday confirmed that while the sponsor will control the database, MRINZ will perform the analysis along with a statistician.
* The Committee noted that blood sample results could be removed from analysis if participants requested (R.3.12) and asked if this could actually be done. Mr Holliday believed so as the researchers will have access to the dataset across all of the sites. The Committee noted that other studies commonly had a statement that any samples collected up until the point of withdrawal will be used. Please outline in the PIS what the limitations are around withdrawal.
* The Committee asked if the researchers would be contacting GPs to do any eligibility checks. Mr Holliday advised that the majority of inclusion and exclusion criteria would be captured at the first visit.
* Mr Holliday confirmed that they will submit advertisements to the HDEC if it is considered an appropriate recruitment tool once the sites are up and running.

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

* Please amend typo “for their asthma” to “for your asthma” (page of the PIS).
* Please include information on why it would be helpful for participants to attend the unscheduled visit if they are withdrawing from the study. Please make it clear that the withdrawal does not have to be in writing (page 13 of the PIS).
* Please make it clear that participants should not share inhalers.
* GP letter – Please add a statement of HDEC approval and HDEC reference number.

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:** | **15/NTB/97** |
|  | Title: | BI 695500 versus rituximab immunotherapy treatment in participants with low tumour burden follicular lymphoma |
|  | Principal Investigator: | Dr David Simpson |
|  | Sponsor: | Quintiles Pty Limited |
|  | Clock Start Date: | 21 May 2015 |

Dr David Simpson 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

* Dr Similar explained that this study is a comparison of a biosimilar drug to rituximab which is used in the treatment of all B cell malignancies. Participants with Follicular Lymphoma whose disease is classified as low tumour burden will receive four doses of either rituximab or the study drug, at weekly intervals. This patient population would not normally receive treatment so they will not be missing out on a known treatment that is effective.

Summary of ethical issues (resolved)

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

* Dr Simpson explained that rituximab is not funded for patients with low tumour burden and they would need to pay for the treatment themselves at this stage, at approximately $5,000 per dose. The aim is to get a biosimilar drug that would be a cheaper option. Dr Simpson noted that not many people actually pay for rituximab as if their disease advances, treatment is provided for free.
* The Committee queried the answer to A.1.6 that the study drug may not be available on prescription after the study. Dr Simpson explained that this study is a pre-Medsafe submission.
* The Committee commended the lay study title.
* The Committee noted that this study was taking place in 20 other countries but that ethical approval had not been received. Dr Simpson advised that there are often a number of legal issues with biosimilar drugs.
* The Committee noted that participants would be given doses for four weeks and then would be reviewed at 30 weeks. They asked what would happen between four and 30 weeks as this was a large gap for people with cancer. Dr Simpson advised that patients would normally be followed up clinically and if there was clinical evidence of disease progression, a CT scan would be performed. The rationale is that they do not want CT scans to be given too frequently. Please make it clear in the PIS, that participants will receive standard clinical care in the gap between participating in the study and the follow up.
* The Committee noted that the NEAC guidelines state that clinical trials cannot be stopped for commercial reasons only (R.1.1.6).
* The Committee noted that as per the NEAC guidelines, if there is a document linking the participants back to their participant number that data is likely to be potentially identifiable (R.2.4). Dr Simpson explained that the data given to the sponsor would be de-identified as they could not identify the data and would need to come back to the researchers to identify any participants. The Committee noted that the data is potentially identifiable to researchers which means that the researchers need to ensure that the right level of data protection is maintained.
* Dr Simpson advised that patients will be recruited through clinics.
* The Committee noted that there is no mention of the optional future unspecified research in the PIS and consent form (as per the answer to B.4.5.2).
* The Committee asked that the standard wording on compensation for commercially sponsored trials is included under “what happens if something goes wrong?” (page 12 of the 18) as it is currently confusing for participants. This wording is available on the PIS and consent form template on the HDEC website.
* The Committee noted that answers to P.4.1 do not need to reference the Treaty. It is more appropriate to reference the incidence of the disease in Maori.
* The Committee noted that the answer to F.1.2 on reducing inequalities could have been an increased access and improved availability of treatments for Maori, Pacific people and other New Zealanders.
* The Committee asked how many patients were likely to need further lymph node or bone marrow biopsies at screening. Dr Simpson advised that those whose original diagnosis was a number of years ago were unlikely to be interested in the study. He was expecting participating to have had a recent diagnosis and a recent biopsy.
* The Committee queried the answer to B.4.6 that this study was not registered on ClinicalTrials.gov. Dr Simpson said that it was his understanding that this was now registered.

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

* Please include the short lay title on the second page on the cover page of the PIS.
* Please review for New Zealand spelling.
* Please review for consistent font.
* Please include that the study doctor will discuss current medications and that there may be some that participants are unable to continue with while on this study.
* Please clearly indicate that this does not affect participation in the main study.
* Please remove analogy of flipping a coin for randomisation.
* Please include information from P.4.2 on Maori cultural issues on page 8 of the PIS.
* Please include that the effects of the study drug on humans are not yet “fully known”. Please include information on how many people have received the study drug to provide context (page 8 of the PIS).
* Please provide more information on the status of rituximab in New Zealand.
* Please include whether participants can have a flu vaccination.
* Please make it clear that participants cannot take part in other clinical trials (page 7 of the PIS).
* Please make the PIS specific to New Zealand, for example remove reference to PET scan if it is not going to happen.
* Please include that participants’ GPs will be notified.
* Please include how any incidental findings will be managed.
* Please provide separate section in participant information sheet and consent form for optional biomarker research.

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 Kate O’Connor.

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| **10** | **Ethics ref:** | **15/NTB/98** |
|  | Title: | The CENTERA Study |
|  | Principal Investigator: | Dr Mark Webster |
|  | Sponsor: | Edwards Life Sciences |
|  | Clock Start Date: | 21 May 2015 |

Mrs Robin Clarke and Ms Nicole Sommerville 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 Study

* The Committee acknowledged a well put together application.
* The Committee noted that the peer review gave them full confidence in the application.

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 clarification on what European countries would be taking part in the study. Mrs Clarke advised that it was the UK, the Netherlands, Denmark, Germany, Switzerland and Ireland.
* The Committee queried the researcher’s answer of no to P.4.3 on whether formal consultation with Maori had taken place. Mrs Clarke advised that she thought this referred to when the protocol was being developed. The Committee agreed that the answer should have been yes.

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

* Please include Maori cultural support contact details, preferably an 0800 or cell phone number.
* Please clarify what withdrawing from the study means i.e. that the device will not be removed, that future data will be removed and what further follow up will involve (page 5 of the PIS)
* Please remove yes / no box on consent form on images being sent to sponsor as this is not 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).*

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| **11** | **Ethics ref:** | **15/NTB/99** |
|  | Title: | Effect of Nitrates on Bone Density |
|  | Principal Investigator: | A/Prof Mark Bolland |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 21 May 2015 |

A/Prof Mark Bolland 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 (resolved)

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

* The Committee noted that the researcher had selected yes to data being used for future research. A/Prof Bolland explained that anonymised data will be used to inform future studies but they have no plans for this at present. The data will only be used as an anonymised dataset for secondary analysis.
* A/Prof Bolland explained that paper records will be stored in a manila file, then stored on site for about two or three years after the study ends. This will be sent to a site where they are stored securely and destroyed at the end of 10 years.
* The Committee queried the answer to F.3.1 that participants will have access to the intervention at the end of the study. A/Prof Bolland explained that nitrates are available on prescription so people will have access to them but at present it is not known if nitrates will be effective. This needs to be included in the PIS.
* The Committee queried the answer to A.1.6 that many women are taking some form of treatment and asked what the treatment was. A/Prof Bolland explained that recommended treatment for people with osteoporosis is bisphosphonate. While there is no evidence of it for treatment of osteopenia, many doctors still prescribe it.
* A/Prof Bolland confirmed that people who were taking supplements could still take part in this study.
* The Committee asked how many people would have to be screened to find participants with the right level of bone density. A/Prof Bolland thought it would be around 500.
* A/Prof advised that they may identify people with osteoporosis during the screening. Researchers will give them advice about what they should do and recommend discussions with their GP, along with providing a scan to their GP.
* The Committee asked if the invite letters would only be sent from the electoral role. A/Prof confirmed that it would be and that they have used this method before. He was expecting to send the letter to around 20,000 people to get the required study numbers.
* The Committee asked if the study had a Facebook page or website that people could get information from. A/Prof Bolland said there was not but the researchers would be available to answer questions.
* The Committee asked what was the mechanism for nitroglycerine in osteoporosis. A/Prof Bolland explained that nitrous oxide was thought to act directly on bone cells in the skeleton.
* A/Prof Bolland explained that Maori consultation had been done through the university as part of the HRC application.

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

* Please change Northern A HDEC to Northern B HDEC (page 2 of the PIS).
* Please include more information on what will happen to participants and what is expected of them.
* Please remove that the study is free as being a risk.
* Please amend “costs of bus travel will be reimbursed” to “costs of public transport will be reimbursed” (page 2 of the PIS).
* Please include where blood samples will be stored (page 4 of the PIS).
* Please include Maori support contact details (page 4 of the PIS).
* Please review the consent form template on the HDEC website and include statements which are relevant to this study.
* Please add “This does not mean that your claim will be automatically accepted” after “just as you would be if you were injured in an accident at work or at home” (page 3 of the PIS).
* Please include on invite letter that this is an HDEC approved study.

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:** | 07 July 2015, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Auckland |

The following members tendered apologies for this meeting.

Mrs Phyllis Huitema

The meeting closed at 4.50pm.