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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 03 March 2015 |
| **Meeting venue:** | Novotel Ellerslie |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.10pm | Confirmation of minutes of meeting of 03 February 2015 |
| 12.30pm | New applications (see over for details) |
|  | i 15/NTB/32  ii 15/NTB/33  iii 15/NTB/34  iv 15/NTB/35  v 15/NTB/37  vi 15/NTB/38  vii 15/NTB/39  viii 15/NTB/40  ix 15/NTB/41  x 15/NTB/42  xi 15/NTB/43  xii 15/NTB/44 |
| 5.20pm | General business:   * Noting section of agenda |
| 5.20pm | 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.

The Chair thanked Kerin Thompson for her work on the Committee and wished her well, noting that her input will be greatly missed.

The Secretariat agreed to look at providing a protocol template on the HDEC website.

## Confirmation of previous minutes

The minutes of the meeting of 3 February 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/NTB/32** |
|  | Title: | The Juniper Study |
|  | Principal Investigator: | Professor Richard Gearry |
|  | Sponsor: | Quintiles Pty Limited |
|  | Clock Start Date: | 19 February 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.

Dr Paul Tanser declared a potential conflict of interest, and the Committee decided that he would not take part in the discussions.

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 participants can receive the open label treatment as long as the disease is in remission.
* Please confirm if participants need to tell their doctor if they get pregnant while on the 92 week follow up or if this is only if they are receiving active treatment.
* The Committee noted for future reference that the answer to P.4.1 should include more information on the benefit to Māori.
* Please provide text on the restrictions on publication from the Clinical Trial Agreement (B.4.3).
* Please review the NEAC Guidelines and confirm whether stored data when the study is finished is truly de-identified (R.2.4.1). The Committee noted that as all the signed participant consent forms will have the participants’ names, that it is likely to be potentially identifiable.
* Please clarify how any unexpected clinical findings will be communicated to participants, for example pregnancy testing (R.4.1).
* Please confirm if the sponsor or investigator will provide a lay summary of results to participants (P.2.9).
* Please clarify if the New Zealand Census question will be used to collect ethnicity data.

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

* Please include a lay study title on the PIS.
* Please include statement on Māori beliefs on sending blood and tissue overseas and the storage of samples in the PIS (P.4.2).
* Please confirm how participants will be monitored for safety if they do not take part in this study (“What other choices do I have if I do not take part in this study? page 6 of the PIS).
* Please amend “you will be asked to enter the 12-week safety follow up period and continue into Part 2” to “you will be invited to enter the 12-week safety follow up period and continue into Part 2” (page 5 of the main PIS).
* Please remove reference to legally authorised representative (page 17 of the PIS).
* Please include contact numbers for Māori cultural support and HDC advocacy.
* The Committee noted that participants may be asked to provide cerebral spinal fluid as part of the long term monitoring of rare side effects. Please include in the PIS where all samples will be analysed and stored.
* Please provide an approximate figure of what are considered reasonable costs for reimbursement (page 13 of the PIS).
* Please remove reference to participants having to withdraw consent in writing (pregnancy 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 Stephanie Pollard and Mrs Raewyn Sporle.

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| **2** | **Ethics ref:** | **15/NTB/33** |
|  | Title: | Baby Spice CONSENT Study |
|  | Principal Investigator: | Miss Claire Sherring |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 February 2015 |

Miss Claire Sherring and Ms Miriam Rea 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 noted that there is a lack of information on how consent occurs for all clinical trials and found this to be a worthwhile study.

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 how the consent process will work for this study, particularly in relation to the Baby SPICE study. Miss Sherring explained that for the Baby SPICE study, parents will be approached at the bedside. The research nurses will screen children and identify whether they are suitable for the Baby SPICE study. They will then have a chat with parents to see if they interested, leave them with the paperwork and give them time to digest the information. Parents will not be approached while their children are having any procedures and they will be given time to think about the study before the researchers go back to have a full discussion. If parents agree to take part in the Baby SPICE study, then the researchers will ask whether they also want to participate in the consent study.
* Miss Sherring confirmed that parents can consent to taking part in one study, no studies or both studies. She said that most parents give a reason for not wanting to take part in a study so if parents do not agree to the Baby SPICE study, the researchers will assess on an individual basis whether they invite them on to the consent study.
* The Committee asked the researchers if they felt that too much information was being given to parents. Miss Sherring explained that the Baby SPICE study has the option of delayed consent. If consent has been delayed, the researchers will then go back to the parents and have a conversation about the further study.
* Miss Sherring advised that delayed consent happens when parents are not in a position to give consent, for example when parents do not initially come in with the children or the parents are distressed. It is usually a consultant, bedside nurse or research nurse who makes the call for delayed consent.
* The Committee asked if the researchers thought they might obtain consent for the Baby SPICE study but not the consent study. Miss Sheering agreed that it could happen as this happens quite a lot with other studies as there is a limit of information that parents can deal with.
* The Committee noted that the researchers had identified parents as being vulnerable and asked if this would be because they were in a distressing situation or because parents could not give the capacity to consent. Miss Sherring advised that while there may be parents who did not have the capacity to give consent, these parents would not be approached. She said that the vulnerability she had identified came from the situation.
* The Committee asked why participants would not be offered the study results (P.2.8). Miss Sherring explained that as the study will not have an impact on the children’s outcomes as they are trying to make the consent processes more efficient, they did not think it was relevant. The Committee felt that it would be nice for parents to get a summary of results in lay language as a thank you for participating. This does not need to be individual results.
* The Committee asked if the study involved kaupapa Māori research methods (P.4.4). Miss Sherring confirmed that it did not and that the yes answer on the application was selected in error.
* The Committee asked for clarification on the emotional rating tool (R.1.1). Miss Sherring advised that this tool had been advised in conjunction with Australia. As bedside nurses are with the families for up to 12 hours a day, they have more knowledge of the emotional state of the parents than the research nurses and doctors. This will help give research nurses an idea of how the parents are emotionally and whether it is appropriate for them to be approached to be in the study.
* The Committee noted that there is an evaluative component to this study and asked what would happen if parents had negative comments about the research nurses. Miss Sherring advised that the research nurses will read the forms and as a manager she would deal with any negative feedback in the same way as with any other complaints in the PICU.
* The Committee asked for clarification on who the coordinating investigator is as the PIS states that it is Dr John Beca. Miss Sherring confirmed that the research nurses are coordinating this study and agreed to amend the PIS to reflect that she is the PI.
* The Committee congratulated the researchers for initiating a research nurse led study as this kind of research is very important.
* The Committee asked who is responsible for the initiation, management and financing arrangements (A.5.1). Miss Sherring confirmed that it would be her in New Zealand and Debbie Long in Australia.
* The Committee advised that the New Zealand Census question should be used to collect ethnicity data to make it relevant to the New Zealand population

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

* Please remove the ACC compensation clause as it is not relevant to this study.
* Please include more information around bedside nurses monitoring parents’ emotional state so this is not a surprise to parents.
* Please remove references to a sub-study in the PIS because the participant population is different to Baby SPICE.
* Please ensure that a complaints procedure is in place if any issues arise from the feedback. Please indicate that the HDC advocacy number can be used for complaints.
* Please rename “Parent Information Sheet” as “Participant Information Sheet” as parents are the participants. Please review and ensure that it is aimed at parents as participants and not as providing consent for their children.
* Please include a sentence that not taking part in this study will not affect your child’s participation in the Baby SPICE study (page 2 of the PIS).

Decision

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

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

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

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| **3** | **Ethics ref:** | **15/NTB/34** |
|  | Title: | MyHealth e-Body Study |
|  | Principal Investigator: | Dr. Patrick Gladding |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 February 2015 |

Dr Patrick Gladding 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 himself available to discuss the application.
* The Committee noted a worthwhile and interesting study.
* Dr Gladding explained that this is an observational study with a focus on seeing whether genotyping can be used to predict a cardiac event. At the moment samples that come from genotyping are discarded and this study aims to formalise the storage of samples so that they can be audited in the future. There is also an optional biobanking component with a separate consent form.

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 references to the sub-study on pages 1 and 6 and the PIS were confusing. Dr Gladding advised that the sub-study referred to in the main PIS were actually cohort 1 and cohort 2. He agreed to move the references to sub-study.
* The Committee asked whether the devices were used in New Zealand outside the study. Dr Gladding advised that both devices are FDA approved and CE marked but he was not sure if they had been registered on WAND. He said that the Alivcor device was available online and the Health Check pen is on sale through a Canadian company. The Committee asked for confirmation, such as evidence of FDA approval or CE mark to show that these devices are approved for use in New Zealand.
* The Committee noted that there was some confusion in the main PIS about whether blood samples were being collected for the main study or the biobanking component. They said that both PIS appeared to be storing samples for future unspecified research. Dr Gladding explained that they were trying to include wording that would allow for changes in methodology due to advances in technology. The Committee noted that if the researchers want to use samples for as yet unspecified testing, then this consent should be optional.
* Dr Gladding confirmed that Ralph Stewart who provided the peer review is not involved in the study.
* The Committee asked if the funder had reviewed the project. Dr Gladding confirmed that they had not.
* The Committee noted that the NEAC Guidelines outline different criteria for labelling data. R.2.4.1 states that the data stored will be de-identified. The Committee advised that if there is a document that links the study ID to identifiable details and this is archived with the study, then there is the potential for study data to be re-identified. Please review guidelines and confirm what format data will be stored in and provide details of processes in place to mitigate the privacy risks.
* The Committee asked how any unexpected clinically significant finds would be dealt with, for example from the ECG results (R.4.1). The Committee advised that the researcher has a responsibility to ensure that participants get appropriate care or follow up.
* The Committee asked for clarification on the ethical and scientific committee referred to in R.5.4.1. Dr Gladding explained that there is an ethics committee at the hospital who he goes to when ethical issues are found in genetic testing, for example whether it is appropriate to inform patients of their test result. He said that the scientific committee has just been established. The Committee advised that this question referred to whether there was a conflict of interest with an investigator being a treating physician. They were satisfied that there would be no coercion for this study.

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

* Please simplify DC cardio version and ablation (page 2 of the PIS) and molecular analysis (page 3 of the PIS).
* Please include more information on the devices. The Committee recommends a simplified version of the paragraph on page 7 of the protocol.
* Please make it clear that devices will be provided at no cost to the participants.
* Please clarify whether all participants will trace heart rhythms using a device. If something is not relevant to the whole participant population, then separate activities into two groups.
* Please include more information on the saliva, breath, urine or stool samples (page 3 of the PIS).
* Please amend “unlikely to be of relevance to you” to “will not affect your clinical care” (page 3 of the PIS).
* Please remove the reference to participants having to withdraw in writing (page 4 of the PIS).
* Please amend Northern X Committee to Northern B HDEC (page 4 of the PIS).

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Observational Studies, para 6.22).*
* Please provide confirmation that this device would be used in New Zealand even if this study were not taking place.

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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| **4** | **Ethics ref:** | **15/NTB/35** |
|  | Title: | Safety of Tiotropium prescription in COPD |
|  | Principal Investigator: | Dr Richard Beasley |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 19 February 2015 |

Dr Leonie Eastlake 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.
* The Committee noted a well put together application, particularly around addressing the vulnerability of the participant population and consent process.

Summary of ethical issues (resolved)

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

* Dr Leonie Eastlake confirmed that she has submitted an application for Māori consultation to the Regional Advisory Group for Māori at CCDHB. She is still waiting to hear back from them.
* The Committee noted that the title of the PIS refers to the safety of tiotropium but the PIS refers to looking at how often participants use the inhaler. Dr Eastlake explained that if a participant uses their inhaler more than once a day, it is considered over use and this is a safety issue.
* The Committee asked how the risk of conflict of interest would be managed given that some of the investigators may be responsible for participants’ health care. Dr Eastlake advised that two of the investigators listed on the protocol are consultants at CCDHB but they will not approach patients for whose care they are responsible. There are a number of people on the research team who could instead approach participants.
* Dr Eastlake confirmed that all of the doctors listed on the protocol are medical doctors.
* Dr Eastlake confirmed that the New Zealand Census question will be used to collect ethnicity data.

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

* Please include the title from A.1.2 in the PIS as it helps participants understand why they are taking part in the study.
* Please include in the PIS that if participants do not wish to participate that it will not change their routine health care (A.1.6).
* Please include an explanation as to where Whanau Care Services is based.
* Please review the PIS template on the HDEC website and include information on the nature and source of funding for the study, key inclusion and exclusion criteria, any cost or reimbursement provided to the participant and how long any data will be stored.
* Please clarify how long it will take participants to complete the questionnaire.
* Please include risks for participants from taking part in the study (R.4.1.1).
* Please amend “if you wish to have an interpreter please indicate this to research staff” to “an interpreter will be provided” as some people may not feel comfortable asking.
* Please remove the yes/no boxes for those statements on the consent form that are not truly optional.

Decision

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

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

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

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| **5** | **Ethics ref:** | **15/NTB/37** |
|  | Title: | Health and wealth in chronic kidney disease |
|  | Principal Investigator: | Dr Tonya Kara |
|  | Sponsor: | Kidney Health Australia |
|  | Clock Start Date: | 19 February 2015 |

Dr Tonya Kara 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 Study

* The Committee thanked the researcher for attending in person.
* Dr Kara explained that 200 children had been recruited to this study in Australia and the researchers want New Zealand to be involved as they want to look at the disparity in transplant rates.
* Dr Kara advised that they know that chronic illness makes people poor but there is nothing objectively published to show this.

Summary of ethical issues (resolved)

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

* Dr Kara explained that Starship does not look after patients over the age of 15 due to funding constraints.
* Dr Kara confirmed that parents will not be interviewed.
* The Committee advised that parents are also participants in this study as parts of the children’s questionnaires are for parents to complete. Dr Kara advised that in Australia, they found children over 10 were completing the questionnaire. The Committee advised that there needs to be a fuller PIS for children and an assent form.
* The Committee advised that the children’s questionnaire should be grouped into the questions that children can answer.
* The Committee asked if the Weschler IQ testing was part of this study. Dr Kara explained that it would not be done in this study in New Zealand but that it was part of normal clinical care. She said that this study will not have interviews or IQ testing. This was because the testing had different clinical justifications and because these were not ready in time. The Committee advised that as the participants are likely to be the same, this may be able to be submitted as an amendment rather than a separate application.
* Dr Kara advised that she was told to wait until after the HDEC meeting before consulting with Māori. She noted that Dr Helen Wihongi would provide consultation, along with a paediatrician in Dunedin.

Summary of ethical issues (outstanding)

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

* Please provide copies of all questionnaires.

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

* Please provide a PIS and assent form for children. The Committee recommended a pictorial version for six to twelve year olds and another PIS for 12 to 15 year olds.
* Please make it clear that questionnaires will be run again in two years’ and four years’ time.
* Please make it clear that this study is looking at the costs for parents of a child with CKD.
* Please make it clear that parents are being asked to answer questionnaires as well as giving consent for their child.
* Please make it clear that participants have the option to leave an answer blank in the questionnaires but note that as the study is about wealth, answers about family income would be helpful

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).*
* Please provide a copy of all questionnaires.
* Please provide a PIS and assent form for children *(Ethical Guidelines for Observational Studies, para 6.10).*

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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| **6** | **Ethics ref:** | **15/NTB/38** |
|  | Title: | The Bergamot Study |
|  | Principal Investigator: | Professor Richard Gearry |
|  | Sponsor: | Quintiles Pty Limited |
|  | Clock Start Date: | 19 February 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.

Dr Paul Tanser declared a potential conflict of interest, and the Committee decided that he would not take part in the discussions.

Summary of Study

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

* The Committee commended the researchers on the placebo justification document and the submission of the DMC Charter.

Summary of ethical issues (outstanding)

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

* Please confirm what will happen if a participant’s symptoms worsen due to reducing their steroid dose.
* Please confirm if the optional escape to the open label extension at 10 weeks if participants’ symptoms are not under control can happen any sooner if needed (A.1.6)
* Please confirm whether a chest x-ray is considered standard care. If not standard of care, please quantify the radiation used in this x-ray in the PIS.
* For future reference for P.4.1, please provide information on the incidence of Crohn’s Disease in New Zealand. Please elaborate if it is higher for any ethnic group.
* Please clarify how this study will reduce inequalities as the answers to F.1.1 are contradictory.
* Please include in the advertising material that this study has received ethical approval from the Northern B Health and Disability Ethics Committee.
* Please confirm if the trial is registered on a clinical trial registry (B.4.6).
* Please provide text on the restrictions on publication from the Clinical Trial Agreement (B.4.3).
* Please review the NEAC Guidelines and confirm whether data is truly de-identified (R.2.4.1). The Committee noted that as all the signed participant consent forms will have the participant’s names, that the stored data is likely to be potentially identifiable.
* Please clarify how any unexpected clinical findings will be communicated to participants, for example pregnancy testing (R.4.1).
* Please confirm if the sponsor or investigator will provide a lay summary of results to participants (P.2.9).
* Please clarify the purpose of a legally authorised representative on all consent forms. Please confirm that all participants are able to provide consent for themselves.
* Please confirm if the contact number on the patient ID card is monitored 24 hours.
* Please provide an approximate figure of what is considered reasonable reimbursement (P.3.3.1).

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

* Please include a lay study title.
* Please confirm whether participants taking part in no other research studies only refers to other drug trials (page 2 of the PIS)
* Please use a flowchart to outline the information on page 3 of the PIS, including a timeline of where people exit the study.
* Please amend “the study doctor will ask you to visit the study site for follow-up examinations” to “the study doctor will invite you to visit the study site for follow-up”.
* Please clarify what will happen to the results if the participant has a positive HIV or Hepatitis test (page 4 of the PIS).
* Please ensure that the descriptors in the tables on page 10 and 11 are in lay language.
* Please review for American spellings.
* Please clarify where the samples are being sent, stored and for how long for the PK sub-study.
* Please remove reference to participants having to withdraw consent in writing (pregnancy PIS).
* Please explain to participants how the information on questionnaires will be used, for example will it be confidential, will it be fed back to the clinical team.
* Please remove second bullet point on the consent form for the PK sub-study (page 4).

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 Stephanie Pollard and Mrs Raewyn Sporle.

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| **7** | **Ethics ref:** | **15/NTB/39** |
|  | Title: | Effect of Barrier Gel on Buccal Mucosal Graft Harvest Site Morbidity |
|  | Principal Investigator: | Dr Vincent Chong |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 February 2015 |

Dr Vincent Chong 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 Study

* Dr Chong explained that there is no standardised post-operative care for patients undergoing a buccal mucosal graft and that a few nurses had found that Bonjela helped with the pain.
* The Committee commended the researcher for a PIS that was easy to read.

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 main cultural issue for Māori would not be that they could not speak English but that tissue would be harvested (P.4.3).
* Dr Chong advised that the mouthwash contains anaesthetic and is anti-inflammatory. It is hoped that the gel will be more effective as it will last longer.
* Dr Chong confirmed that during the study period, mouthwash or gel can only be used three times per day for three days. The PIS needs to be amended to reflect this.
* Dr Chong advised that a biostatistician had done the power calculations with 21 people needed on each arm. He did not see there being many drop outs as participants have to visit the clinic for a follow up visit.
* Dr Chong advised that pain severity will be graded using a visual analogue scale.
* Dr Chong confirmed that he had contacted the DHB research office who had advised that Māori consultation would be done through Auckland DHB.
* The Committee noted that if data is going to be shared (P.4.4) that participants need to be informed of this in the PIS.
* The Committee advised that health information should be stored for 10 years (R.2.5).
* The Committee asked how the one month and two month questionnaires would be completed. Dr Chong explained that participants would be given a prepaid envelope to post back and he will call them if they do not send it back. This needs to be included in the PIS.
* The Committee advised that it is the responsibility of the investigator to notify participants of any updates (P.2.7).
* The Committee noted that for future reference if a researcher is looking at health information to identify potential participants, that the answer to R.2.1 should be yes.
* The Committee advised that if the surgeon is involved in the informed consent process that they need to be listed as a co-investigator (P.1.3).
* The Committee recommended that the New Zealand Census question is used to collect ethnicity data (P.4.6).

Summary of ethical issues (outstanding)

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

* Please confirm whether an independent data safety monitoring committee will be used (R.1.4).

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

* Please amend “you would be eligible for compensation from ACC” to “you may be eligible for compensation from ACC”.
* Please simplify some terms, eg harvest site morbidity, NSAIDS.
* Please refer to Northern B HDEC.
* Please include information on what is standard care and what is considered experimental.
* Please include that participant’s GPs will be informed about their participation in the study.
* Please include any known risks or if experiencing side effects or allergies to notify researcher.
* Please include any possible benefits from taking part in the study.
* Please include contact details for Māori cultural support and HDC advocacy.
* Please only include one Principal Investigator on 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 the HDEC Secretariat.

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| **8** | **Ethics ref:** | **15/NTB/40** |
|  | Title: | RHB-104-01: Efficacy and Safety of Anti-MAP Therapy in Adult Crohn's Disease |
|  | Principal Investigator: | Professor Richard Gearry |
|  | Sponsor: | RedHill Biopharma Ltd. |
|  | Clock Start Date: | 19 February 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 confirm whether SCOTT approval has been applied for.
* Please clarify the composition of the Data Safety Monitoring Committee. Please clarify how this is independent.
* Please confirm whether there is any provision for transportation or food given the number of study visits.
* The Committee noted that the evidence of favourable peer review was not adequate (B.2.2.1). Please use the template on the HDEC website to provide a peer review.
* Please provide wording around restrictions on publication from the Clinical Trial Agreement trial agreement (B.4.3).
* The Committee advised that as per the NEAC Guidelines, sponsors cannot terminate a study purely for commercial reasons (R.1.6).
* The Committee noted that this is a study of an unapproved medicine that participants are using for 52 weeks, with a lot of side effects and were concerned that only $5m insurance has been provided (R.1.11). Please confirm if this is per participant or for the whole trial. Please confirm if you think this amount is adequate and equivalent to what would be available through ACC.
* Please confirm that a lay summary of results will be provided to participants (P.2.9).
* Please provide an approximate figure of what is considered reasonable reimbursement (P.3.3.1).
* Please confirm whether the New Zealand Census question will be used to collect ethnicity data.
* Please confirm if the phone number on the patient alert card is a 24 hour monitored number.
* Please include the study ID on the patient alert card to allow the sponsor to identify participants in an emergency.

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

* Please include a lay study title in the PIS.
* Please remove reference to notifying government health authorities as this is not relevant to New Zealand (page 8 of the PIS).
* Please remove bullet point that the study can be stopped for commercial interests (page 10 of the PIS).
* Please remove “as required by US law” (page 11 of the PIS).
* Please include that this study has received approval from the Northern B HDEC (page 12 of the PIS).
* Please remove the reference to the National Statement as this is not relevant to New Zealand (page 12 of the PIS).
* Please provide definitions for acronyms as a lay person would not understand these.
* Please include in the PIS that participants’ GPs will be informed about their participation in the study. The Committee recommends this is included under section 16 on page 10 of the PIS.
* Please include contact numbers under the who to contact section (page 12 and 13 of the PIS).
* Please remove yes / no boxes for those statements that are not truly optional in consent form.
* Please include bullet points on optional colonoscopy and blood and biopsy samples as a separate optional section on the consent form.

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please confirm whether insurance is considered adequate for this study *(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 Mali Erick and Ms Kerin Thompson.

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| **9** | **Ethics ref:** | **15/NTB/41** |
|  | Title: | TV48108-COPD-10045 |
|  | Principal Investigator: | Dr Michael Epton |
|  | Sponsor: | PPD |
|  | Clock Start Date: | 19 February 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 Study

* The Committee commended the researchers for an excellent plain English summary on A.1.5 which was one of the best they had read.

Summary of ethical issues (outstanding)

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

* Please explicitly state what the restrictions on publication are as in the Clinical Trial Agreement (B.4.3).
* Please note that as per the NEAC Guidelines, studies cannot be terminated purely for commercial reasons (R.1.6).
* Please clarify the extended reporting period in the insurance certificate and confirm whether this is equivalent to ACC compensation.
* Please provide an updated CI indemnity.
* Please review NEAC guidelines and confirm whether stored data is truly de-identified as there will be a document linking the data (R.2.4.1)
* Please address the risk of a conflict of interest due to an investigator being a participant’s treating physician (R.5.4.1).
* Please confirm if participants will be provided with a summary of the study results in lay language (P.2.9).
* Please confirm if the phone number on the study card is monitored 24 hours.
* Please confirm if the New Zealand Census question will be used to collect ethnicity data (P.4.6).
* Please provide outcome of Māori consultation.
* For future reference for P.4.1, please include information on the incidence of COPD in Māori.

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

* Please make lay title specific to this study as it is currently too generic.
* Please include in the PIS that participants need to be a current smoker or former smoker.
* Please provide information on what will happen to participants if their condition gets worse because they have stopped taking their medication (page 4 of the PIS).
* Please include whether ipratropium bromide is standard of care in New Zealand.
* Please include that salbutomol is standard care in New Zealand.
* Please include any risk from ipratropium bromide (page 11 of the PIS).
* Please include the risks of withholding COPD medication.
* Please review PIS for American spellings.
* Please clarify whether HIV and Hepatitis results or results from drugs of abuse testing will be going to participant’s GP (page 4 of the PIS).
* Please underline statement that Māori Protocol (Tikanga) wil not be able to be followed when samples are destroyed (page 5 of the PIS).
* Please review ordering in the PIS as it does not flow logically.
* Please provide more information about the meal that will be provided.
* Please provide more information on how much time the participant will need to stay in the clinic , who will pay for accommodation and in what circumstances can people not go home.
* Please confirm if rescue medication can be used in the seven day period between treatment visits.
* Please correct typo on page 10 of the PIS “thinking abnormal”.
* Given that participants are advised not to drive or operate heavy machinery, please include whether participants can drive home, will need to get someone to drive them or they will be given taxi vouchers.
* Please remove reference to providing a reason for withdrawing as this is not required (page 15 of the PIS).
* Please clarify total payment for completing the study (page 15 of the PIS).
* Please add contact details for Māori health support (page 16 of the PIS).
* Please remove references
* Please clarify whether interpreters will be provided.
* Please include a statement that withdrawing from the study will not affect participants’ health care.

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 confirm whether insurance is of ACC equivalence Please confirm whether insurance is considered adequate for this study *(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 Ms Kerin Thompson and Mrs Mali Erick.

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| **10** | **Ethics ref:** | **15/NTB/42** |
|  | Title: | FUTuRE Fertility |
|  | Principal Investigator: | Dr Tristan Pettit |
|  | Sponsor: | University of New South Wales |
|  | Clock Start Date: | 19 February 2015 |

Dr Tristan Pettit 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 congratulated the researcher on the NHMRC funding.
* Dr Pettit advised that this study is constructing a registry of cancer patients under the age of 25 who are seeking fertility preservation (FP). It will consist of all cancer patients aged 13 to 25 and 0 to 12 year olds who are referred to FP services. The aim of this is to create locally relevant knowledge.

Summary of ethical issues (resolved)

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

* The Committee asked under what circumstances will identifiable information be given to other researchers (B.4.4.1). Dr Pettit advised that any information sent to other relevant linked databases and any publication of patient information will be de-identified.
* The Committee asked why information is only being kept for 10 years rather than 10 years from when the youngest participant turns 16 (potentially 26 years) (R.2.5). Dr Pettit explained that while they are collecting prospective long term data, the dataset only has a five year duration due to working within the limitations of the Australian study. Dr Pettit advised that once the project is completed, they would look at creating a separate New Zealand database. Please include in the PIS that this is a project which will end after five years.
* The Committee asked if this was a feasibility study. Dr Pettit explained that New Zealand is only looking at themes one and two but if they can successfully run the database, after 12 months they will consider running the third and fourth themes. They are not looking to roll out the third and fourth themes just yet as they don’t want the service to be over prescribed and underfunded.
* The Committee noted that the non-participation form seems a little burdensome if people do not want to participate in the study.
* The Committee advised that revocation of consent does not have to be in writing.
* Dr Pettit advised that they will be putting an application to the Māori Review Group at Canterbury DHB.
* The Committee asked if all participants would be based in Canterbury. Dr Pettit advised that Paediatric Oncology in Christchurch takes patients up to the age of 17 in the South Island and Wellington. They are also in contact with the Auckland Paediatric Oncology team who will also be involved.

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

* Please review the language in the PIS for seven year olds as this may be too advanced.
* Please review language in PIS for 12 to 15 year old PIS, for example it talks about having a baby which might concern a 12 year old boy.
* Please provide an assent form for participants under 16 years.
* Please remove reference to not losing any benefits in the PIS for adolescents.
* Please include HDEC contact details for all PIS.
* Please review PIS for adolescents as it refers to “you” and then “patients”.
* Please provide an 0800 or mobile number which participants can text for any questions. Please also provide the same for Māori health support.
* Please make it clear that for the purpose of the PIS, that the definition of an AYA is aged from 12 to 15, rather than 12 to 24 years (as per the study dictionary).

Decision

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

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

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

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| **11** | **Ethics ref:** | **15/NTB/43** |
|  | Title: | 5% Aciclovir or a 5% aciclovir/Honevo combination as a treatment for cold sores |
|  | Principal Investigator: | Dr Irene Braithwaite |
|  | Sponsor: | Honeylab |
|  | Clock Start Date: | 19 February 2015 |

Dr Alex Semprini, Dr Evan Tan 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 thanked the researchers for making themselves available to discuss the study.

Summary of ethical issues (resolved)

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

* The Committee asked if the researchers had previous experience in using pharmacists to recruit to trials. The researcher explained that while MRINZ has used research institutes and GPs for recruitment, this was the first study in which they had used pharmacists. The Committee noted that they understood the reasoning as the standard treatment for cold sores would be available from pharmacists.
* The Committee asked how the pharmacists would be chosen to find participants. The researcher explained that it would be a combination of those who are interested and have approached MRINZ or the sponsor or vice versa. He said that they have spoken with the Pharmacy Guild. Ideally the pharmacists will have had some experience in research.
* The researcher advised that they were hoping to run the study in Wellington, Christchurch, Auckland and possibly Tauranga.
* The Committee noted that while the risks for this study were small they were not zero. They recommended the inclusion of a small independent DSMB. The researcher advised that they had a group of people who may be part of the institute who review safety events on an ongoing basis but this was not formalised. The Committee reiterated that given this was the first study in which the researchers had used pharmacists to recruit to a study that an independent DSMB would be useful. This could look at dropout rates, recruitment and the quality of data coming out of pharmacy after about 50 to 100 participants had been recruited.
* The researcher advised that SCOTT approval was still pending.
* The Committee advised that as per the NEAC Guidelines, studies cannot be terminated purely for commercial interests and asked that this is clarified with the sponsors (R.1.6).
* The researcher confirmed that the New Zealand Census question will be used to collect ethnicity data (P.4.6).
* The researcher confirmed that the study was open label because it is hard to blind honey. He agreed that there is no way that a patient could not know that they are receiving the honey treatment although they might be unaware if they are receiving standard treatment. The researcher advised that in previous studies they have had one investigator who is blinded to what the participant receives and the rest of the study staff know what the subject is getting. He noted that the data will go to the biostatistician blinded.
* The Committee noted that as there is soft endpoint for study, it is worth noting as a limitation of the study.
* The researcher confirmed that the pharmacist will be responsible for the eligibility assessment and they will complete the questionnaire.
* The researcher confirmed that pharmacists will give participants the summary PIS, ask them to sign the consent form and then send them away with a full PIS. The Committee were concerned that participants would be signing a consent form without having all of the information available. However, they noted that the summary PIS contained most of the information and that only a little more information needed to be provided, including information on restrictions around taking other medication. The Committee suggested including the more detailed information on the treatments as a supplementary document and reiterated that participants should be provided with all relevant information before providing consent.

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 noted the document provided on Māori consultation and asked that an outline of the process used for consultation be provided.

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

* Please include Māori health support contact details (page 7 of the PIS). For participant accessibility this should be an 0800 number or a mobile number which participants can text.
* Please combine the summary and main 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 Ms Tangihaere Macfarlane and Dr Paul Tanser.

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| --- | --- | --- |
| **12** | **Ethics ref:** | **15/NTB/44** |
|  | Title: | Why do Australian women have better breast cancer survival ratios than NZ women? |
|  | Principal Investigator: | Dr Rachael Flanagan |
|  | Sponsor: | NZ Breast Cancer Foundation |
|  | Clock Start Date: | 19 February 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 Study

* The Committee commended the researcher on a much improved application.
* The Committee noted that researcher was now only going to look at the cancer registry and data already collected rather than collecting any more. This eliminated the need for a lifestyle questionnaire and the need for patient contact.

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 noted that the Auckland Breast Cancer Register website states that only de-identified information is ever extracted from the register. Please confirm how clinical notes will be matched if data is de-identified.

Decision

This application was *approved* by consensus.

## 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:

|  |  |
| --- | --- |
| **Meeting date:** | 07 April 2015, 08:00 AM |
| **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 5.15pm.