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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 07 June 2016 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 03 May 2016 |
| 12.30pm | New applications (see over for details) |
|  | i 16/NTB/82  ii 16/NTB/86  iii 16/NTB/89  iv 16/NTB/91  v 16/NTB/92  vi 16/NTB/93  vii 16/NTB/94  viii 16/NTB/95  ix 16/NTB/96  x 16/NTB/97  xi 16/NTB/98  xii 16/NTB/99 |
| 5.40pm | General business:   * Noting section of agenda |
| 6.00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2015 | 01/07/2018 | 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 |
| Mrs Kate O'Connor | Lay (ethical/moral reasoning) | 14/12/2015 | 14/12/2018 | Present |
| Dr Nora Lynch | Non-lay (health/disability service provision) | 24/07/2015 | 24/07/2018 | Present |
| Mrs Leesa Russell | Non-lay (intervention studies), Non-lay (observational studies) | 14/12/2015 | 14/12/2018 | Present |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Present |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members.

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 03 May 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/NTB/82** |
|  | Title: | 64294178HPC2001: A Phase 2 study of Different Treatment Combinations of AL-335, odalasvir and simeprevir in subjects with chronic hepatitis C virus infection. |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Janssen Cilag (New Zealand) Ltd |
|  | Clock Start Date: | 19 May 2016 |

Prof Edward Gane and Ms Carolyn Harris 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

1. The study investigates phase II of the phase I study which is currently undertaken at The Researcher’s sites. Phase I study is only in Auckland and Christchurch.
2. The phase II study is much larger with more participating sites. The phase II looks at a larger patient population, and will confirm safety and efficacy of the phase I design.
3. The Committee queried what the registration status of the study drug was. The Researcher(s) explained that he thought it had been submitted for Medsafe approval, but it was not funded. It was submitted for approval for use in combination with other antiviral drugs. The drug has been used in many other countries with oral antivirals.

Summary of ethical issues (resolved)

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

1. The Committee noted the Participant Information Sheet states that it is marketed in many countries, but please add what its status is in New Zealand, and whether its use is an alternative outside of the trial or not.
2. The Committee asked for information around screening and recruitment at multisite studies. The Researcher(s) explained that this may well change, but at the moment, people with Hepatitis are referred from primary to secondary care, from specialists, and most are opting not to get treatment with standard care (interferon and ribavirin). A consequence is that many are waiting for availability of oral treatments.
3. The Researcher(s) explained that research nurses would mention to patients whether an oral study was occurring, that had a curative goal. Once interested, the study personal would contact the patient and give some brief information. If interested, the patient was sent a Participant Information Sheet and would be invited to come for screening.
4. The Researcher(s) explained that with this study, due to there being 8 sites, it would be likely that their treatment site would also have a study site, so in these cases there would not need to be any referrals around New Zealand.
5. The Researcher(s) stated come July the hope is that this treatment will be funded by the government, and the presumption is that once it is funded recruitment will slow greatly, as patients can receive this treatment through PHARMAC funded standard care. After funding is announced it would be possible for the research to move towards genotypes that are not funded by PHARMAC.
6. The Committee noted any advertising needs ethics review prior to use, noting advertising was mentioned in the application but not uploaded.
7. F.1.1 – page 29. The Committee queried whether the study would or would not reduce inequalities. The Researcher(s) stated F.1.2 is actually correct, it won’t reduce inequalities, but will benefit Maori. The Committee noted this response.
8. The Researcher(s) confirmed travel costs reimbursed.

Summary of ethical issues (outstanding)

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

1. R.3.7 – states samples going to Singapore, but Participant Information Sheet states going to Netherlands. Please ensure Participant Information Sheet is correct.
2. B.4.5 – future research of tissue. The Researcher(s) stated this should have stated yes, to future unspecified research.
3. The Committee noted there was confusion around what is optional versus what is mandatory, in terms of use of tissue. The Researcher(s) explained there are safety samples and some PK samples that are mandatory. The extra ones are optional – this is on pharmacokinetic, and general future unspecified research that is not genetic.
4. The Committee noted on page 8 of Participant Information Sheet, states tissue would be used to better understand disease, development of assay etc. The Committee noted this could be future unspecified research? The Researcher(s) stated that they are not sure whether this is development of assays for this treatment combination, or if it were general.
5. Page 16 also states uses for unanticipated studies in relation to study drugs.
6. The Committee requested a clear explanation of what tissue is used for the study and is mandatory, and why and how it relates to the study, and then what is future unspecified research and why. The Committee noted it is just unclear what they are signing up for if they only signed the main form and none of the optional forms.
7. The Committee noted the long list of drugs that are not allowed during participation. The Committee asked how researchers ensure participants don’t receive or use contraband drugs, either from their GP or by their own use. The Researcher(s) explained the screening process, and how it involves reviewing their current medicine use. In some cases an alternative medicine can be found. The participants also have a card that they present, which explains that they are on a study that may interact with other drugs – this helps GPs with their decision-making, and protects participant safety.
8. The Committee asked if all GPs are informed of participation. The Researcher(s) explained that they are informed at screening, and explained that the GP is optional, but that the referring physician will be informed.
9. Add a yes or no for GP to be informed about participation, in Participant Information Sheet. Make it clear that the referring physician will be informed.
10. The Committee queried why there was no independent data safety monitoring committee. The Researcher(s) stated it was a decision of the sponsor. The Researcher(s) stated they would seek more information about the monitoring arrangements of the study. Please also explain if there is anyone from New Zealand on the board.

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

1. Add that they will be given a device and instructions to complete the questionnaires etc.
2. Page 4 – take pills in morning with food – but some days requested to come in fasting. Please explain to the participants on those days, bring pills into the visits and they will be given food to take them after the visit.
3. Page 8 – the request to have participants pay for costs if they have an adverse event. The Committee queried what this was referring to? The Committee noted that participants should not incur a cost by participating so this should be removed, if the event is related to the study.
4. Page 13 – reference to skin biopsy. The Researcher(s) stated this would be a standard of care follow up. The Committee request that it is stated to be unexpected, and with consent if required.
5. Add a yes/no option for receiving the summary of study results.
6. Page 3 of pharmacokinetics, please clarify length of storage and destruction.
7. Review for compensation and or payment on page spare PK component. Remove or clarify.
8. State clearly any subsequent results from the future unspecified research will not be sent back to participants.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Provide details of the Data Safety Monitoring Committee’s composition and monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*
* Provide further information on the study design, *in particular the use of tissue* (*Ethical Guidelines for Intervention Studies para* 5.4)

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

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| **2** | **Ethics ref:** | **16/NTB/86** |
|  | Title: | Holter recording in long QT syndrome |
|  | Principal Investigator: | Dr Kathryn Waddell-Smith |
|  | Sponsor: |  |
|  | Clock Start Date: | 26 May 2016 |

Dr Kathryn Waddell-Smith 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

1. The study investigates methods to diagnose genetic heart diseases that are passed down through family.

Summary of ethical issues (resolved)

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

1. The Committee queried how participants are identified? The Researcher(s) stated people are referred to see the Researchers as Doctors. Clinically, the Researcher(s) would ask patients if they want to be part of this study. The Researcher(s) would, as part of clinical care, be giving them a halter device anyway, but if they participate it would involve the additional study measurements.
2. The Researcher(s) are also recruiting normal children as a control group. These could be brothers and sisters of affected kids, for example, or children on the ward. The Researcher(s) confirmed they would not seek to recruit from a wider population level.
3. The Committee asked are brothers and sisters truly normative as they are related to children with long QT? The Researcher(s) stated it would be a gene negative unaffected group. If they don’t have the genetic mutation they would be a reasonable control.
4. The Committee asked whether the children would have already been genetically screened. The Researcher(s) stated they first use the halter device to monitor heart rhythm. Once they return, they get genetic testing, and are retrospectively genetically tested and assigned to each arm of the study.
5. The Researcher(s) explained that the study has two aims; one is to test how to check if children have long QT, and second is to identify those who are at a higher risk for acute events.
6. The Committee explained at the beginning stage of screening that children would not know whether they were in either the normative or the mutation group. The Researcher(s) confirmed this was correct, though all procedures are the same for both groups. We will not use any readings from the halters to change clinical care.
7. The Committee acknowledged that some participants will be recruited in the clinical context, and that some might not know whether they would be in the group with long QT or not, but that this would not impact the clinical decision making.

Summary of ethical issues (outstanding)

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

1. A.5.1 – The Committee noted there is no study sponsor, although it seems this is collaboration with two charitable funding sources. Please explain the sponsorship status of the study. Because this is part of the PhD study, it could be the university.
2. B.2.2.1 –The Committee note that peer review from within the research team is not best practice, however given the incredibly low risk the study poses this is justifiable.
3. The Committee queried whether the 10 dollars for parking is given twice. The Researcher(s) stated just once.
4. The Committee noted participants are asked to participate and immediately given the halterer. The Committee requested that participants are given some time to consider participation if possible.
5. The Committee noted it would pay to check with families whether there are any cultural needs of the family.

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

1. Please remove the yes or no options at the end unless a true choice is presented. (Adult and older child sheet).
2. Please remove the template instructions, which have been left behind (guardian sheet).
3. Add on the guardian’s one that participants (their children) can’t swim/shower while having the monitor attached.
4. Amend consent form heading of each participant to be clear about whom each is for.
5. Make it clear that this is research (for the older consent).
6. Please add instructions for patients in case there is a sticky dot reaction (adverse event).

Decision

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

* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).

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

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| **3** | **Ethics ref:** | **16/NTB/89 (CLOSED)** |
|  | Title: | Feasibility study of an oral device to promote weight loss |
|  | Principal Investigator: | Prof. Paul Brunton |
|  | Sponsor: |  |
|  | Clock Start Date: | 26 May 2016 |

Prof. Paul Brunton 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

1. This is an open label uncontrolled intervention study of 1200 calorie liquid diet plus an oral magnetic device which is attached to the back 4 teeth to prevent chewing. The aim is to facilitate weight loss of 10% over 4 weeks in participants with BMI >35, aged 20-65 with a healthy mouth and no major contraindication. Similar to wiring jaw but safer as can be unlocked for emergency vomit.
2. The Researcher(s) explained that a prior method worked but was not well tolerated. This new device should not be intrusive at all. The reason why we are conducting this research is to avoid having to conduct bariatric surgery, and provides an alternative to patients who can’t have surgery.
3. Feasibility study N=10. The Researcher(s) explained they are recruited from a list that receives a regular newsletter from the study team.

Summary of ethical issues (resolved)

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

1. The Committee noted participants are to be recruited from existing panel research subjects said to be representative of Dunedin demographic. The Researcher(s) explained with regards to Maori, they have recruited with local community, as well as the established university consultation processes. The Committee asked how well are Maori represented in the recruitment pool. The Researcher(s) noted they don’t know what ethnic range is in the current recruitment method.
2. The Committee and Researcher discussed how participants brush their teeth.
3. The Researcher(s) confirmed they would provide the liquid diet.
4. The Committee queried what would occur if participants dropped out, for example 5 or so, given it is both a tolerability study and the sample size is only 10. The Researcher(s) stated they would plan to keep trying for 10 completed, however if vast majority wanted it removed we would stop the study and re-evaluate it.

Summary of ethical issues (outstanding)

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

1. The Committee noted Question 4 of the device questionnaire reads "Have you found it uncomfortable to eat any foods because of problems with your mouth or the device?" Is this a trick question or just uplifted from the parent questionnaire- the OHIP-14. The Researcher(s) stated they would remove this statement; it is not a trick question.
2. IW-QOL questionnaire also contains Q3 and 4 in Work section that is unanswerable for retirees or homemakers. Suggest adding a N/A option for these groups.
3. R.5.2 The Committee noted that there was no commercial interest declared, but there was a closed meeting – please explain. Who designed the device and who may stand to gain if it is a success and patented (UOA). The Researcher(s) stated this study is just for feasibility, and The Researcher(s) will learn from this study – if it did look to be working we would move to create and protect an intellectual property claim. In this case we would need a larger trial to demonstrate efficacy. The Committee accepted that at this stage the commercial involvement was minor.
4. The Committee requested the Researchers check with the University to see whether they are the appropriate sponsors of the research.
5. Please add a participation card that gives an overview of information, which can be presented to GPs, for example.
6. Please remove name from data collection (questionnaires). Use the study number.
7. The Committee asked what the incidence of obesity in Maori is. A potentially important constellation of numbers for equity.

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

1. Maori health support contact: add Prof John Broughton's title i.e. Assoc Dean Maori and also add phone extension number.
2. The Committee noted that the IW-QOL questionnaire contains a section on sex life. Make sure Participant Information Sheet mentions possibility of sensitive questions.
3. The Committee noted that in 'What will participation involve' section, you must mention the visits during study as well as beginning and end, and clarify what 'monitoring for a year' actually involves. The Committee asked, does this just refer to a call after a year? The Researcher(s) stated yes. The Committee requested that this is made clear.
4. The Committee noted that a picture of the device would be appropriate. The Researcher(s) confirmed they would add pictures of the device on a model.
5. Confidentiality: regarding data storage - more detail on where, how, for how long and if de-identified.
6. Costs: why not offer transport costs, as participants should not have to pay to participate in a study. The Researcher(s) stated they would offer transport costs.
7. ACC statement: word more carefully to inform that while a claim may be lodged, it is always up to ACC to accept or decline. The Researcher(s) noted they would review the wording.
8. Soften statement with regards to how people are recruited.
9. Please make it clear that the researchers provide the food for the liquid diet, at no cost to the participant.
10. The Researcher(s) explained the withdrawal process. The Committee requested that this is made clear for participants.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Amend the questionnaires in line with Committee suggestions.

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Mrs Tangihaere MacFarlane or Secretariat.

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| **4** | **Ethics ref:** | **16/NTB/91** |
|  | Title: | Comparison of the blood levels of two forms of tadalafil 20 mg tablets in healthy male volunteers under fed conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Southern Cross Pharma Pty Ltd |
|  | Clock Start Date: | 26 May 2016 |

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

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

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

1. The Researcher(s) confirmed ethnicity is collected with New Zealand ethnicity collection protocols.

Summary of ethical issues (outstanding)

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

1. The Committee queried the insurance certificate – does this cover New Zealand? The Researcher(s) stated they were quite certain that they did, but would check and confirm.
2. Add statement of ethics approval for advertising.
3. Make it clear in advertising that the study is not for those who suffer from erectile dysfunction.

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

1. The Committee queried whether GP being informed of unexpected results, consent should be sought for non-communicable diseases.

Decision

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

* Confirm the insurance is applicable for New Zealand. (*Ethical Guidelines for Intervention Studies* *chapter 8).*

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

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| **5** | **Ethics ref:** | **16/NTB/92** |
|  | Title: | STAR-120-SIES |
|  | Principal Investigator: | Dr Trevor B Gray |
|  | Sponsor: | AMO Development LLC AMO Milpitas |
|  | Clock Start Date: | 26 May 2016 |

Priya Janakiraman (sponsor) were present by teleconference, with Mr Nick Mathew in attendance 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

1. The study, conducted in a large ophthalmology private practice, seeks surgeon feedback on ease of use and speed of a new laser system for correcting long and short-sighted though otherwise healthy eyes.
2. The main differences compared to existing laser technology are a new machine to sculpt the cornea after flap lifting, a new machine to improve precision of surgery which can talk directly to new software.
3. Everything else is the same as treatment. I.e. the changes are minor, and incremental.

Summary of ethical issues (resolved)

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

1. The Researcher(s) confirmed this is the first in human trial. Participation involves more measurements for the participants than in standard care, such as dilation of the pupil for further measurements.
2. The Committee discussed the recruitment method for the study.
3. The Committee queried any additional risks in relation to the procedure failing. The Researcher(s) noted that 1.5% of cases need a revisit to adjust the vision, explaining that this is easy, at 3 or 6 months, and occurs free of charge in standard of care, as well as in the research.
4. The Committee queried possible pressure on surgeon to push through 20 cases. How many are usually on the list? The Researcher(s) clarified that it was 20 on the machine, without any interruption or problems – not for the surgeon to do 20 in a row. The Committee noted this clarification.
5. The Researcher(s) noted it was not expected to be difficult to recruit or difficult to get that figure in that amount of time.
6. The Researcher(s) stated the risk is identical to the current system, adding they are really researching the surgeon’s use of the machine, not the participants, though some aspects of the new machine would be reviewed by the additional procedures that the participants underwent.
7. The Committee queried why the age range was 21? The Researcher(s) stated this was for physiological reasons - 21 is when generally vision is stable.
8. The Committee queried what data is sent to Abbott? The Researcher(s) stated de-identifiable data would be sent to Abbott – study number, date of birth. No NHI and no names.
9. The Committee queried amount of training involved for surgeon? The Researcher(s) stated they have a day and a half minimum – however this is basically the same machine and there was no expectation of learning problems.
10. The Researcher(s) noted that they had since responded to the Maori standard questions and also had a plan to make the consent process culturally acceptable by having options to speak with cultural advisors.
11. The Committee noted that it is acceptable to recruit those who were already having surgery. The Researcher(s) confirmed they would bring it up only with those who would be eligible.

Summary of ethical issues (outstanding)

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

1. The Committee requested peer review from surgeons in Australia. Please email [HDECS@moh.govt.nz](mailto:HDECS@moh.govt.nz) and request a template, or view <http://ethics.health.govt.nz/>
2. The Researcher(s) confirmed they are recruiting in an Auckland population from patients already coming in for treatment.
3. $5,700 is the usual price for this standard of care intervention.
4. The Committee noted that this is a $5000-dollar reduction in cost for this operation.
5. The Researcher(s) noted the sponsor was happy to remove the charging if that was the HDECs advice. The Committee confirmed that the fee should be waived, as well as the 75-dollar payment. This is because participants should not have to pay to be in research, nor should they be paid to be in research.

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

1. Check pages 2 and 6 for typos and duplications: Replace pseudo anonymised with de-identified.
2. Page 9 ii Add Maori contact details
3. Consent form: remove tick boxes, change 'participation' to 'health info' or similar when talk of confidentiality. The Committee noted that participation is not confidential, rather their data is.
4. Change phrase regarding authorisation of use of medical records to 'my'.
5. Please add a statement in the consent form about releasing photos for use.
6. Can you drive immediately afterward if not had a sedative? See pg. 4 this implies you can. The Researcher(s) stated they couldn’t drive for 4 hours, whether sedated or not.
7. Explain the 21-year-old requirement as a physiological requirement rather than a consent requirement.

Decision

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

* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This following information will be reviewed, and a final decision made on the application, by Mr John Hancock and Dr Nora Lynch.

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| **6** | **Ethics ref:** | **16/NTB/93** |
|  | Title: | STUDY OF AVELUMAB IN PATIENTS WITH LOCALLY ADVANCED ORMETASTATIC UROTHELIAL CANCER |
|  | Principal Investigator: | Dr Peter Fong |
|  | Sponsor: | Pfizer Australia/NewZealand |
|  | Clock Start Date: | 26 May 2016 |

Dr Peter Fong 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

1. The Researcher(s) Explained, immunotherapy has been quite successful in bladder cancer. The Researcher(s) explained that for invasive bladder cancer, after first line chemotherapy, patients don’t have many options remaining.
2. This study aims to bring second line treatment ahead with randomisation. Similar study drugs have been used; but they were introduced later on, and the studies were smaller than the proposed study.

Summary of ethical issues (resolved)

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

1. The Committee noted drug is not available in New Zealand, and not approved for use for this indication. The Researcher(s) stated this drug is not approved for any use, globally.
2. The Committee asked what usual care is. The Researcher(s) stated it is frequent clinical check-up meetings, but no treatment. In some cases repeat of previously given chemotherapy could be given.
3. The Committee queried if it was possible to use historic controls. The Researcher(s) stated it was scientifically weak. The Researcher(s) also noted that there are side effects with the experimental drug – so until the evidence is there, the Researcher(s) need to study it in a robust scientific method before giving it to everyone, and this is best achieved through a randomised controlled trial.
4. The Researcher(s) confirmed travel costs are reimbursed. The Committee requested how much is given. The Researcher(s) stated reasonable travel costs for the duration of the study.
5. The Committee asked what the publication restrictions were. The Researcher(s) stated there is no way that the study won’t be published – even if the results are negative, rather it is to stop sites from publishing individual results. The Researcher(s) confirmed they are standard restrictions.
6. The Researcher(s) noted that the incidence of bladder cancer in Maori was unknown, and further muddled by non-invasive cancer. It would be possible to consider Maori as having higher rates, as they have higher smoking rates, for example – but there is no strong data.

Summary of ethical issues (outstanding)

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

1. The Researcher(s) confirmed that participants in this study would have continued access if they have positive effects. The Committee noted this statement is ambiguous. Please make it either yes or no. Please clarify ongoing access for the Committee.
2. The Committee noted MPS is out of date. The Researcher(s) confirmed it is being updated.
3. Please confirm that the insurance covers product liability, and is also ACC equivalent cover.
4. The Committee asked about the charter and independence of the monitor. The Researcher(s) stated they were not yet sure of the composition. The Committee requested the composition or charter or summary of how they are independent, and whether there is anyone from New Zealand on it. The Researcher(s) confirmed they are comfortable with the proposed composition.
5. The Committee requested the sponsor clarifies the length of tissue storage, in particular the 15 years storage. Please also clarify what is mandatory and what is optional.
6. The Committee queried whether it was necessary to inform GP that participant is involved in optional sub studies, noting that no information that is clinically relevant will be sent back. The Researcher(s) acknowledged this, and stated they would remove it.

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

1. Pg. 3: Clearly indicate regarding transportation/storage of tissue (overseas).
2. Future Unspecified Research consent form: change ‘that you consult with a kaumatua' to 'with a kaumatua or whanau member'.
3. Please state how many doses of the study drug they will give or the duration of the on medication phase in the consent form. All it says is that it will be given 2 weekly and infusion duration. Indicate reimbursements in PICF (i.e. parking and travel time will be compensated).
4. New Zealand spelling and New Zealand numbers on the participant card.
5. Add doses of study drug, if possible.
6. The Researcher(s) queried how the scanning schedule differs if they are not in the standard care arm. The Researcher(s) stated if they were in the standard of care arm they would likely have no scans. Therefore in the experimental arm they have many more scans. The Committee noted this does not communicate clearly in the Participant Information Sheet, and it should also note the minor radiation risk, but quantify it.
7. Please ensure the Participant Information Sheet is correct with regards to the use of tissue, its storage and its destruction.
8. Page 17 – legally acceptable representative – please remove this statement as all will provide their own consent.
9. Add a descriptive lay language title.

Decision

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

* Provide further information on the study design, *in particular* Clarify ongoing access to treatment and use of tissue.(*Ethical Guidelines for Intervention Studies para* 5.4)
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Provide details of the Data Safety Monitoring Committee’s composition and monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*

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

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| **7** | **Ethics ref:** | **16/NTB/94** |
|  | Title: | A study to evaluate the long-term safety and efficacy of intravenous Alphal-Proteinase Inhibitor in adults with emphysema |
|  | Principal Investigator: | Dr Jeffrey Garrett |
|  | Sponsor: | Grifols Worldwide Operations Ltd |
|  | Clock Start Date: | 26 May 2016 |

Dr Jeffrey Garrett 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

1. The study is extension study from a 3-year study. This study seeks more study data, as well as allowing access to study drug for those who were on placebo for the 3 year.

Summary of ethical issues (resolved)

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

1. The Committee asked how the existing participants are doing. The Researcher(s) stated 6 participants so far, due to the extensive study requirements. 6 or 7 patients were not recruited due to not meeting inclusion criteria (lung function to severe).
2. The Researcher(s) explained this is the only treatment for these patients.
3. The Committee asked for confirmation that the participants understood that the trial involved drugs derived from plasma, from participation from the prior study involvement. The Researcher(s) explained that there have not been any adverse events, or cultural concerns to date. One participant may have declined during recruitment, but people understand in that process what participation involves.
4. The Committee queried when participants are told about the extension. The Researcher(s) stated they knew it was a possibility from the beginning. The Researcher(s) explained we would talk to the existing participants again soon.

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

1. Haematology is spelt incorrectly.
2. Add more information on infusion sites.
3. Please provide New Zealand specific numbers and information on the participant card.
4. The Committee queried whether participants can miss transfusions (4 weeks or 10 a year) for any reason, travel or medical, and remain in the study. Noting the strict criteria for withdrawal outlined in the ethics application form. Please make this clearer in the Participant Information Sheet. The Researcher(s) explained there are many sites around the world where treatment could remain.

Decision

This application was *approved* by consensus with non-standard conditions.

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| **8** | **Ethics ref:** | **16/NTB/95** |
|  | Title: | Te Ara Hā: Asthma Self-Management Programme |
|  | Principal Investigator: | Dr Tristram Ingham |
|  | Sponsor: |  |
|  | Clock Start Date: | 26 May 2016 |

Dr Tristram Ingham 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:

1. The researcher explained that population inequity remains in asthma and this needs to be addressed.
2. This study assesses a long-term approach of chronic disease management by empowering Whanau, so that they recognise that asthma is a long-term condition, even though we treat it as an acute episodic condition. This might lead to short term thinking with Whanau.
3. The intervention is validated and comes from Stanford University. The Researcher(s) are assessing it in our New Zealand Maori populations, hoping it improves outcomes in our communities.

Summary of ethical issues (resolved)

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

1. The Researcher(s) explained that they acknowledge the risks of a single blind study, but hope that they can maintain this blinding of outcome assessors. The Researcher(s) noted they could add a note on the questionnaire, so as to let the investigator state whether the blind was holding or not.
2. The Committee asked about recruitment. The Researcher(s) stated it would be prospective recruitment from paediatric centres. The Researcher(s) acknowledged there was provision for retrospective provision of identification of cases from the DHB records in order to recruit further.
3. The Committee ask how prospective recruitment works. The Researcher(s) stated the clinic staff identify potential cases and then give us permission to directly approach the patients, as outsiders from the clinical context.
4. The Committee noted any home visit brings with it safety considerations for the researchers. The Researcher(s) stated that fieldworkers have guidelines developed by the university, which are policies in place given to all field study personal. The Researcher(s) added there are investigator-training manuals.
5. The Researcher(s) confirmed participants are reimbursed for the workshops.
6. The Researcher(s) stated workshops are held in English only.
7. The Committee asked why GPs are not informed about participation. The Researcher(s) stated that GPs stated they don’t want information that is not relevant to what they are doing in terms of their treatment for their patients. The Researcher(s) confirmed they would add it as an option.

Summary of ethical issues (outstanding)

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

1. The Committee requested a copy of the letter of invitation that would be sent to retrospectively invited hospital or clinic patients. The Researcher(s) will submit an outline.
2. The Committee requested a justification for storing identifiable data, as opposed to a de-identified link or coded system, for increased security. The Researcher(s) explained the data storage arrangements. The Committee requested this is separated. The Researcher(s) noted they would contact the university about facilitating better data storage.
3. Add third person perspective for questionnaire, as it is about the children not the adults.
4. The Committee queried when the end date for the study was.
5. Please explain the rationale for questions on c3.15 and c3.16 under family cohesion. What will happen with this information if disclosed? Are there plans for follow up? The Researcher(s) stated the questions come from the New Zealand health survey. The Researcher(s) stated they were considering removing this question. The Committee confirmed that that it should be removed.
6. The Committee queried whether there is a sponsor? The Researcher(s) stated the University of Otago. The Committee agreed, please confirm this in writing to the HDEC.
7. Remove names from the questionnaires and use a study number to maintain confidentiality.

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

1. Add extension number or toll free number for Maori contacts.
2. Add that researchers will be accessing medical records in the Participant Information Sheet rather than just the consent form.
3. The Committee queried whether there was enough information for participants, for example with regards to randomisation. Make it clearer for participants, i.e. that they were allocated by chance, and that there are two distinct groups. Make it clear there is no selection.
4. The Committee queried whether the non-workshop group still receives asthma management information. The Researcher(s) stated before randomisation they are offered a GP review for their asthma. They are also given brochures from asthma foundation. This is likely to be considered best practice, currently.
5. The Committee requested the Participant Information Sheet states what standard support is. The Researcher(s) noted they would also add at the end of the trial they could be given a referral to community workshops.
6. The Committee queried whether it was possible to have home visits as optional, whether they could arrange alternative meeting arrangements. The Researcher(s) stated home best works best for this population. The Researcher(s) stated if they wanted some other place, i.e. library or Marae, they could accommodate this. This is part of Kaupapa Maori. The Committee requested this should be clear in the Participant Information Sheet.
7. Add more information on data confidentiality.
8. Add information on compensation.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Provide further information on the recruitment process (*Ethical Guidelines for Intervention Studies para 6.2)*
* Provide responses to outstanding ethical issues in a cover letter.

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

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| **9** | **Ethics ref:** | **16/NTB/96** |
|  | Title: | A Study of ALN-HBV in Healthy Adult Subjects and Non-cirrhotic Patients with Chronic Hepatitis B Virus |
|  | Principal Investigator: | Prof. Edward Gane |
|  | Sponsor: | PPD Global Limited (New Zealand Branch) |
|  | Clock Start Date: | 25 May 2016 |

Ms Rebecca Hu 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

1. This is a Phase 1/2 first in human safety and tolerability study of a new antiviral drug for Hepatitis B, testing HBV subjects who are already stabilised on a direct-acting antiviral, over an increasing dose range of ALN at the same time.
2. Efficacy in reducing HBV markers is a secondary outcome.
3. The Part A testing of healthy subjects is not included in the New Zealand study.
4. Part B involves repeated small cohorts given a single dose, which is escalated progressively through the cohorts.
5. Minimum of 14 days between cohorts as data monitoring committee looks at safety outcome of previous group.
6. Part C gives multiple doses to each participant. Frequency of dosing varies from 4 doses in total 4 weeks apart to 13 doses at weekly intervals.

Summary of ethical issues (resolved)

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

1. The Committee queried the future use of tissue as being required as part of the study, not with optional components. The Researcher(s) explained their Maori consultation had stated that research that is specified should be involved in the main Participant Information Sheet.
2. The Committee queried if there are methods to consult with Pacific or Asian populations. The Researcher(s) stated there were means for Pacific consultations, but not sure about Asian populations. The Researcher(s) stated they would check with ADHB.
3. The Researcher(s) confirmed the single dose in part B does not preclude further participation in studies or treatment options.

Summary of ethical issues (outstanding)

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

1. The Researcher(s) explained that IF this research (on tissue) is about how this particular drug, for these particular patients, works, it can be in the main PISC. The Committee noted that it should be clearer, but if that is the case, then it can be mandatory.
2. The Committee asked for a full overview with regards to use of tissue and what is mandatory and what is not – both in a cover letter to HDEC and in the Participant Information Sheet. Committee requested researcher/s consider creating an Optional Future Tissue Use form for this study.
3. The Committee did not understand this statement on main consent " Study data including your coded medical information may be used or shared for legitimate study and scientific purposes including, if you do not object, for future use in medical or pharmaceutical research" There is nowhere on this form for participant to register their objection to further use. Please clarify if this relates to use of de-identified data.
4. The Committee requested information on compensation, for instance a variety of scenarios.

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

PISC Part B and C

1. Could do with bolder headings and some section spacing.
2. Please add a lay title.
3. The payment to participants has not been disclosed to us nor is it yet in PISC.
4. Requires participant agree to future use of tissue for further similar drug studies
5. Layout of contacts: suggest use of Emergency call 111 vs. contact researcher might be better defined
6. Page 12 – ‘no further doses of the drug’. However part B is a single dose. Please revise.

Part C

1. Tables of scheduled activities would benefit with the word 'injection" added in header. Currently reads "Scheduled Assessment for Weekly”, “Scheduled Assessment for Biweekly

Optional Pharmacogenomics Consent

1. As data will be delinked overseas and recoded, it would seem participants would not be able to withdraw consent although it is implied that they can. Please clarify. The Researcher(s) stated it is coded, but at ASC we could potentially link and remove.

Decision

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

* Provide further information on the study design, *in particular the use of tissue* (*Ethical Guidelines for Intervention Studies para* 5.4)
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This following information will be reviewed, and a final decision made on the application, by Mr John Hancock and Dr Nora Lynch.

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| **10** | **Ethics ref:** | **16/NTB/97** |
|  | Title: | Sentimag use for sentinel node biopsy |
|  | Principal Investigator: | Dr Ahrin Anna Morrow |
|  | Sponsor: |  |
|  | Clock Start Date: | 26 May 2016 |

Dr Ahrin Anna Morrow and Mr Issac Cranshaw 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

1. The study investigates a very new method, trialled in Europe currently, for detecting sentinel nodes in breast cancer.
2. The Researcher(s) noted this was part of surgery training.
3. The Researcher(s) confirmed sample size was 75 not 50. This was an error.

Summary of ethical issues (resolved)

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

1. The Committee queried whether this question has already been solved. The Researcher(s) stated there were no studies in Australasian context. It will be important for a New Zealand context, to determine that it works.
2. The Researcher(s) explained that a few surgeons in Gisborne have implemented based on the European model, but this study could open it up further for wider use in New Zealand.
3. The Researcher(s) explained a co-investigator has used it twice in clinical care. All ADHB breast surgeons will be using the method, once this application is approved. There are 5 surgeons at Auckland Hospital, who will all receive training.
4. The Researcher(s) explained that from a technical perspective, as far as surgery goes, this intervention works in the same way. The main difference is the solution and the probe.
5. The Researcher(s) confirmed a statistician will be involved in analysis, and was involved with study design.
6. The Committee queried if the Co-ordinating Investigator had supervision and support. The Researcher(s) explained Mr Cranshaw would provide supervision, to supplement the lack of research experience.
7. B.2.1 – The Committee asked when consent would be sought. The Researcher(s) stated one doctor always speaks to the patient (about surgery) in clinical setting, however consent is signed on the day. This is a second failsafe. Therefore, at clinic research will be discussed, however morning of consent would then result in signing the consent form. The Researcher(s) clarified it could be a few weeks between clinic, and the day of surgery.
8. The Committee asked if there was any need to talk in the interim period. The Researcher(s) stated they could have a number to call or an email on the Participant Information Sheet if needs be.
9. The Researcher(s) confirmed that Maori review would part of local review processes at ADHB.
10. The Researcher(s) confirmed they recorded ethnicity as part of New Zealand Census collection methods.
11. The Committee discussed staining and any impacts on quality of life. The Researcher(s) explained there were no subjective reports of staining being an issue, between 120-180 participants. The Researcher(s) added the solution is already used as a contrast for MRI, so it is not new, just how it is being used.

Summary of ethical issues (outstanding)

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

1. The Committee suggested reviewing the HDEC template Participant Information Sheet to model the Participant Information Sheet, particularly around data privacy, length of storage, rights of access etc.
2. R.5.4.1 – Conflict of interests. The Committee noted this is a conflict of interest as there are duel roles – clinician and researcher. The Committee suggested a mitigation plan would be to increase the emphasis on voluntariness at the beginning of the PISC, to make it clear participation is optional. There could also be information around talking with others, GP or family etc. This mitigates the conflict to an extent.
3. The Committee confirmed that ADHB would be the sponsor.
4. The Committee queried the data safety monitoring. The Researcher(s) stated Mr Cranshaw would monitor the data. The Committee requested that this process was formalised, as to what they were looking at, and who was reviewing the data.
5. The Committee noted if the intervention was to occur outside general anaesthetic and a day earlier than stated in the current protocol( as raised by the researcher as a possibility), this would require an amendment. The Researcher(s) acknowledged this.

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

1. The Committee noted that the explanation of the new procedure somewhat undermined the current procedure. Could this language be reviewed? The Researcher(s) noted it could be.
2. Add contact details on investigators.
3. Make it clearer what the alternatives to participation are.
4. Make the main points (exclusion inclusion criteria) more clear.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Clarify for the HDEC when the intervention occurs. The Committee noted that if the dye is injected a day earlier this requires an amended protocol, participant information sheet etc.

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

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| **11** | **Ethics ref:** | **16/NTB/98** |
|  | Title: | SuDDICU-ANZ |
|  | Principal Investigator: | Dr Paul Young |
|  | Sponsor: | The George Institute for Global Health |
|  | Clock Start Date: | 25 May 2016 |

Dr Paul Young and Ms Sally Hurford 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.

Mrs Stephanie Pollard declared a potential conflict of interest, and the Committee decided to have Mrs Pollard stay in the room but not participate in the discussion or the decision of the application.

Summary of Study

1. The study investigates bacteria in the gut of ICU patients, and whether an intervention can reduce bad bacteria.
2. The Researcher(s) explained that there is a reasonable amount of evidence that suggested using SUDD decreased mortality in ICU settings. This research has not occurred in New Zealand before, so this study aims to confirm that the information from the Netherlands applies to the New Zealand context.
3. The Committee queried what was being applied for ethics review today. The Researcher(s) stated approval is sought for the RCT and the ecology study.
4. The Researcher(s) explained that there was a concern that antibiotic resistance could be increased with SUDD. This study aims to A) confirm it reduces mortality rate, but B) it does not increase antibiotic resistance. This will be a concurrent observational study that looks at bacteria in the ICU systems.
5. The Committee noted they would not be reviewing the cost effective aspect, as this was not ready for review yet. The Researcher(s) confirmed that was correct.

Summary of ethical issues (resolved)

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

1. The Researcher(s) explained that the entire care unit is randomised (cluster design). There is only one centre participating in New Zealand. This means from an ethical or moral perspective, SUDDICU in New Zealand would either be entirely observational if they were randomised to current care, however if the ICU gets randomised top SUDD then all mechanical ventilated participants would receive it up until the time that they are extubated. Once awake, they can opt out of using their information if they want.
2. The Committee noted NICU is excluded but children in ICU are not. The Researcher(s) noted number of children in Wellington ICU is very small. The Researcher(s) continued, we would not enrol any children in New Zealand. The Committee requested that the New Zealand protocol is amended.
3. The Committee noted ecology study is use of standard of care data.
4. F.2.4 The Committee queried whether the study adversely impact health and disability service. The Researcher(s) stated there is no data to support that view, it is only a concern to address with this research. There is evidence that it reduces the risk. Our study will support this research.
5. The Committee explained the funding process.
6. The Researcher(s) noted that participants couldn’t provide consent due to their ICU status.
7. The Committee acknowledged the detailed argument made by the researcher with regards to the law and best interests and accepted the argument.
8. The Researcher(s) noted more sites might come on board in New Zealand.
9. The Committee query whether infectious disease groups within the hospital would be consulted. The Researcher(s) confirmed they were consulted prior to funding application and were on board.

Summary of ethical issues (outstanding)

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

1. The Committee requested posters in the ICU to let people know that it is going on.

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

1. Add more detail about the frequency of the applications (every 6 hours).

Decision

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

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

This following information will be reviewed, and a final decision made on the application, by Mrs Leesa Russell and Mrs Mali Erik.

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| **12** | **Ethics ref:** | **16/NTB/99** |
|  | Title: | Study to Improve Adherence to Type 2 Diabetes Oral Medications Through Personalised Multi-Channel Interventions |
|  | Principal Investigator: | Dr Jodie Main |
|  | Sponsor: | PHARMAC |
|  | Clock Start Date: | 26 May 2016 |

Mrs Olivia Anstis, Mr Andrew Beszant and a study nurse 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

1. The Committee noted that in terms of reviewing this study, the HDEC could only review the study going forward from the review date. Any review letter will explicitly state that the study had no ethics review for the period starting in March, as well as the pilot. The Committee also expressed their concern that no ethics review had been sought since March and noted that this could constitute a violation of patient rights, as participants may not have been fully informed, and their health information may have been used inappropriately. The Researcher(s) stated there were roughly 130 participants recruited since March, and the study was still running.
2. This is a controlled intervention study in Type 2 diabetics where 3 different levels of support via Txt, web site information and variable frequency of telephone calls are being trialled to improve medication adherence.
3. The outcomes are changes in patient derived adherence information and change in frequency of collection of medication scripts.
4. The controls are historical prescription data of the participants, and prospective de-identified prescription data from matched controls in the MOH database.
5. The intervention runs 6 months, follow-up out to 12 months.

Summary of ethical issues (resolved)

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

1. The Committee asked how interventions work for those who don’t have Internet access (website, smart phone use). The Researcher(s) explained the website does not form part of the intervention, rather the text and phone calls (and emails) are the intervention. These are the evidence based interventions, adding that all information from the website are in the booklet given to participants.
2. The Committee queried when the calls are made. The Researcher(s) stated they have flexibility for timeframes.
3. The Committee asked why only 6 months data on de-identified controls but 12 months data on participants, adding this might weaken the study. The Researcher(s) stated there is a matched prospective control but no retrospective participant control.
4. Please clarify that data on Australian server is de-identified while raw data retained in New Zealand. The Researcher(s) stated that it was stored by third party but was not identifiable.

Summary of ethical issues (outstanding)

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

1. The Committee described the consent chain: Atlantis who are providing the nurses and psychologists for the study, contact GP and discuss. If GP agrees to participate, and has prior patient authority for healthcare disclosure to 3rd party healthcare provider, Atlantis ask Ministry of Health to interrogate electronic prescription system to identify type 2 diabetics in that practice. GP screens list and authorises Atlantis nurse to cold call and invite participation. Then, verbal consent is given. All enrolment and survey phone calls are scripted, and intervention phone calls are personalised.
2. The Committee asked about the calling method, asking how a participant verifies that the cold-calling nurse is not a market researcher. The Researcher(s) noted that additional information could be sent out to them if they are unsure or they could ring their GP practice to check.
3. The Committee queried why verbal consent is sought at first call, rather than sending the Participant Information Sheet to everyone, opposed to just those who are sceptical. The Committee noted that this method gave no time to consider participation.
4. The Committee noted there is a reasonable burden to comply, and to continue with engagement, given the cold call.
5. The Committee clarified, going forward – when the study is properly approved, the original call would no longer be a consent process, but a recruitment, by which further information was sent to potential participants, who then consented verbally on the phone once they had read the Participant Information Sheet.
6. The Committee asked, for the personalised email and txt messages, who writes them – the nurse who spoke to them or someone else.
7. The Committee asked for a formal plan for working with adverse events, such as mental health emergencies or disclosure of family abuse.
8. The Committee requested clarity around adverse events, case reports and the formal process for management of them.

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

1. Layout would be improved with some headings aka template on HDEC website. Please revise. For example put name/logo of sponsoring organisation at beginning.
2. Include how results will be used i.e. by sponsors MOH - PHARMAC to shape policy.
3. Inform what happens to data if they withdraw midway.
4. The words encrypted and de-identified used several times close together. Explain the difference.
5. Add Maori support contact details.
6. The Committee requested more privacy information.

Decision

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

* The Committee noted that the application required substantial revision, including the consent processes, the recruitment methods, the informed consent documentation and management of adverse events or incidental findings.
* The Committee noted that this study had commenced without ethics approval and that the data collected to date should not be used in the study.
* The Committee noted the importance of this research and the importance of maintaining a continuity of care for those who had already been enrolled. The Committee requested a full plan to manage those 130 participants already recruited for the study without ethics approval. The Committee suggested these individuals maintain the current support and are informed of what has occurred, and are re-consented as well as told that the study they are in does not have ethics approval.
* Because the study should be suspended pending making the necessary adjustments and obtaining ethics approval, it will not be possible to continue collecting outcome measures from these participants in the interim. The Committee noted this may affect the scientific integrity of the study and recommended the Researchers consider restarting the study.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee discussed the article in the agenda, discussing maleficence over autonomy and how New Zealand places a high value on autonomy.
3. The Chair discussed the chairs day meeting on 25 May and the meeting with National Ethics Advisory Committee with regards to the updated guidelines that are being developed.
4. The Committee discussed Te Mata Ira, the Genomics research consultation and the Health Research Strategy and the Therapeutic Products bill.
5. The Chair commended the expedited reviewers for their quality and expediency, and thanked the wider committee for reviewing the Cancer Oncology Group progress reports.
6. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 05 July 2016, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

1. **Problem with Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

The meeting closed at 5.45pm