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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 07 April 2015 |
| **Meeting venue:** | Novotel Ellerslie |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.15pm | Confirmation of minutes of meeting of 03 March 2015 |
|  | New applications (see over for details) |
| 12.30pm | i 15/NTB/49  ii 15/NTB/52  iii 15/NTB/53  iv 15/NTB/54  v 15/NTB/55  vi 15/NTB/56  vii 15/NTB/57  viii 15/NTB/58  ix 15/NTB/59  x 15/NTB/60  xi 15/NTB/61  xii 15/NTB/62 |
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| 5.40-6.00pm | General business:   * Noting section of agenda |
| 6.00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Raewyn Sporle | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Kate O'Connor | Non-lay (other) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Paul Tanser | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Dr Patries Herst |  |  |  | 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 | Apologies |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Mrs Phyllis Huitema.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Dr Patries Herst confirmed their eligibility, and was co-opted by the Chair as members of the Committee for the duration of the meeting.

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 3 March 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/NTB/49** |
|  | Title: | KIWI |
|  | Principal Investigator: | Dr David Simpson |
|  | Sponsor: | Waitemata District Health Board |
|  | Clock Start Date: | 19 March 2015 |

Ms Elizabeth Thatcher and Dr David Simpson were present in person for discussion of this application.

Potential conflicts of interest

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

Ms Stephanie Pollard declared a potential conflict of interest. The Committee decided to have Ms Pollard stay in the room, participate in discussion and take part in the decision.

Summary of Study

* The study investigates a treatment regime for patients with multiple myeloma. Current practice involves a combination of three drugs. The treatment approach in this study follows an approach that is commonly used in New Zealand, except that carfilzomib replaces bortezomib.
* Earlier studies suggest that the study drug may be more effective for patient survival, in combination with current treatment.
* The Committee asked if there been a head to head drug trial with current treatment versus study drug. Researchers confirmed there had, explaining that preliminary data from other studies suggests the drug does provide a benefit but has not yet been proven to be more effective than current standard of care. The combination in this trial is different to the head to head study and involves a different intervention window.
* The researchers explained that there are a number of new drugs that are available for treatment. The study drug is similar to standard practice drugs but may have more benefits – for instance the ability to be dosed at higher amounts without safety or tolerability issues.
* The study aims to generate efficacy data.
* Study drug is not approved for use in New Zealand.

Summary of ethical issues (resolved)

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

* Committee noted survey and questionnaires were used in this study (pain scale). Please note for future applications (r.2.3.1.)
* Data more likely to be potentially identifiable. Please see (*Ethical Guidelines for Intervention Studies para 7.2*) for more information on levels of data confidentiality.
* Researchers confirmed that ethnicity data is being collected using the New Zealand Census format.
* The researchers confirmed a SCOTT application has been submitted.
* Please provide information on the data safety monitoring board. The researchers stated that there is no independent or official DSMB, explaining that the study involved drugs that had been studied at this dosage and in these combinations.
* The Committee suggested that an independent individual was recruited to help review safety data. This person could be someone from another DHB. The researchers added that they have a local biostatistician who would assist in reviewing the data. The Committee was satisfied that the biostatistician could assist with safety data review.
* The researchers explained that they aimed to keep participants informed with toxicity information updates, noting it was important to give participants the right amount of information.
* P.4.6 – ticked no. Researcher explained this was an error.

Summary of ethical issues (outstanding)

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

* The Committee asked how the drug company became involved in the study. The researchers explained that they approached the company to provide the study drug in the place of the standard practice drug.
* The Committee noted that its role was to determine whether a study was primarily for the benefit of a sponsor or manufacturer. The Committee queried whether the researchers felt that the company would be the primary benefactor of this study, noting that the company would benefit if the trial supported the company having the drug approved for use in New Zealand.

The researcher made the following points:

* if we were able to provide a better treatment it would be a good thing for patients, adding it is the patients who would benefit from this trial.
* the study was the Co-ordinating investigator’s idea and that he approached the company to see whether they would be interested in supplying the study drug.
* the study is not a registration study for the company, nor is it part of their study strategy for the company.
* the database was the owned by the investigators, not the company. The analysis will be conducted by the researchers.
* the trial would benefit New Zealand tax payer as they would not have to pay for the treatment drugs for participants.
* The Committee asked if the company will have access to the raw data or be able to undertake their own analyses Researchers explained that toxicity and response will be shared with the company, as well as being published. Researchers stated they will share the information widely so it can be best utilised.
* The Committee queried whether the company will be given access to the participant’s health information/medical records. The researchers explained that this would only be for audit reasons or regulatory reasons. The committee noted that as the company is not the sponsor they do not therefore have right of sponsor audit. A regulatory inspection is unlikely but that researchers would have to accommodate this if it occurred.
* The Committee asked the researchers what agreements are written in the contract with the company with respect to use of participants health information and trial data? The researchers could not accurately recall.
* The Committee requested more clarification on access to patient data and study data in relation to the company.

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

* Please add section on what happens when the study ends. Has pharma company committed to providing Kyprolis at end of study?
* Committee suggested that the interpreter box is added at the front and top of the PIS/CF.
* The Committee commended the drug interaction information.
* The Committee commended the explanation of the AEs.
* Noted discrepancy between application and PIS about how’ everything’ or ‘mostly everything’ is standard of care. The researcher explained that the ECHO would be additional to standard care but only due to the study drug being used. The researcher will clarify this in PIS.
* Thalidomide (and resulting pregnancy risks) – please highlight more information in PIS. The researcher explained that standard care involved registration on a pregnancy prevention programme and a significant amount of information (verbal) regarding pregnancy risks and thalidomide is given to all patients receiving this drug. The committee suggested including information in the PIS stating that these risks will be discussed in some detail with participants as per standards and noting the serious implications of receiving thalidomide while pregnant..
* Page 11 includes an incomplete sentence (3rd para) “cost to you if you..”
* Page 11 under what benefits lists carfilzomib, cyclophosphamide and dexamethasone but not thalidomide.
* Page 12- refers to access by pharma company of participants medical records. Please clarify/remove. This access is not considered appropriate given that pharma company are not sponsor.
* Consent form refers to version 23 Feb whilst footer refers to version 7 Feb , please reconcile
* Please add that samples will be destroyed at end of study and not stored not sent overseas.

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*).
* Please make the case that the study is not for the commercial benefit of the drug company and explain what data sharing arrangements are in place.

This following information will be reviewed, and a final decision made on the application, by Ms Kate O Connor and Ms Raewyn Sporle.

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| **2** | **Ethics ref:** | **15/NTB/52** |
|  | Title: | Proton Pump Inhibitors vs. Histamine-2 REceptor Blockers for Ulcer Prophylaxis Therapy in the Intensive Care Unit (PEPTIC) |
|  | Principal Investigator: | dr paul young |
|  | Sponsor: | MRINZ |
|  | Clock Start Date: | 19 March 2015 |

Dr Paul Young 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.

Summary of Study

* The committee commended the clarity of the application.
* International studies indicate that 2.5% of those admitted to ICU develop stress ulcers.
* Across Australia and New Zealand the figure is around 1.5%.

Summary of ethical issues (resolved)

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

* The Committee asked if either treatment was experimental. Dr Young explained both are standard of care treatments.
* The Committee asked if any other patient population could be recruited to test the hypothesis. Dr Young confirmed that this patient group was the only eligible group for this study.
* Please explain the comparative treatments and explain how they are in equipoise. Dr Young explained that each treatment has been used for decades. At the moment the use of these medicines seems dictated by idiosyncratic treatment choices. Research data (prevalence data on what happens in a day across intensive care units) shows that treatments seem to use it based on historical use. It appears that the choices for treatment are not on patient specific practice. We aim to analyse the idiosyncratic uses to see what benefits each has.
* The study does not aim to dictate what treatment the patient receives. Hospitals will be randomised to using one or other treatments but Dr Young confirmed that doctors will be able to choose either treatment for an individual patient if the choice is deemed to be in their best interest.
* Default choice of treatment is currently random across sites in New Zealand and Australia.
* 75% of intensive care units use proton pump and 25% use histamine receptor blockers.
* Are all intensive care specialists in equipoise over using one over other? Dr Young confirmed.
* The Committee asked what medical reasons may warrant one treatment over another. Dr Young explained that there are not many medical reasons but treatment providers may choose a certain treatment over another for non-medical reasons.
* The study will not dictate treatment for individuals outside of what is best for them.
* Committee noted that ethically the project is sound.
* HDEC noted legal advice for this study has been sought by Dr Young. Please explain what advice was received. Dr Young explained it is very difficult research context with no certainty – advice received is that for a study like this, provided that we are acting reasonably and that our practice is in accordance with the code, then it is reasonable for us to proceed with it. Dr Young explained that the legal view received was that it was not very different from standard of care, apart from the standardisation of reviewing.
* The Committee noted the Health and Disability Commissioner had been consulted. Please explain their advice. Dr Young explained the HDC stated the researchers should be assured because no one has complained and noted the difficulty of the situation.
* Dr Young explained that he felt the code was being followed and that the trial was being conducted legally.
* Committee asked if it was possible of conducting an audit where you assessed data to see outcomes. Dr Young explained it is slightly different as we are randomising centres to balance all other factors. The Committee accepted this explanation.
* The study will provide information but not seek informed consent.
* Dr Young confirmed those who opt out will not look at their clinical records however the plan was to include their data in the aggregate information from databases.
* The HDEC queried whether it was possible to add another step where data of those who opt out is removed. Dr Young explained that the data review will occur at the end of the study rather than day by day. It could be possible to include a list of hospital numbers of all those who opted out to be manually removed from the analysis.
* Dr Young stated he would remove all data from those who opt out, including data from databases.
* The Committee asked about the mortality rate in ICU. Dr Young stated it was 15-20%. Dr Young explained that if we can’t use this information it introduces systematic bias – it is vital to include these participants in the study otherwise the results are meaningless.
* The Committee asked about asking family or kin for data use in cases of death. Dr Young explained that they were not doing this as causes confusion and stress. The Committee accepted this justification.
* Dr Young explained that in a prior study using similar design, of 2081 study participants only 16 did not want their data included.
* Dr Young explained that CCDHB Maori review was ongoing.

The Committee requested the following changes to the Information Sheet

* Change word prophylaxis to prevention.
* Emphasise that no treatment or procedures are undertaken specifically as part of this research that wouldn’t have occurred otherwise.

Decision

This application was *approved* by consensus.

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| **3** | **Ethics ref:** | **15/NTB/53** |
|  | Title: | KETAMINE FOR DEPRESSION |
|  | Principal Investigator: | DR Suresh Muthukumaraswamy |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 March 2015 |

Dr Suresh Muthukumaraswamy and Dr Rob Kid were present in person and 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 study investigates low doses of ketamine for treatment of depression. Small blinded and open label trials.
* The study will compare Ketamine against another anaesthetic (active placebo) which is not suspected to have an antidepressant effect.
* Ketamine effects are very quick. Participants will notice effects immediately rather than in a couple of weeks, as is standard for regular antidepressant treatments.
* Researchers noted slight error in protocol regarding a decimal point - .2 rather than .02. for drug dose.
* The Committee congratulated the researchers on their royal society funding.

Summary of ethical issues (resolved)

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

* The Committee thanked the researchers for the independent scientific review. The Committee noted some important issues were raised, including the short duration of study (4 weeks total). The Committee acknowledged that the half-life of the drugs is very short (couple of hours).
* The Committee asked if the researchers have considered long term follow up? The researchers explained that it was not required. The participants would go back to their standard of care – the researchers will be liaising with the participants treating doctor.
* The Committee noted for stopping anti-depressants you usually have to taper off them. What process is in place for participants who will be coming off their standard treatment? Researchers explained that decreasing dosage slowly will be done for those who are on anti-depressants. Sound management of withdrawing from standard of care will occur for this study by liaising with the participants treating clinician, in all cases. Researchers confirmed that it would not be an abrupt halting of treatment. HDEC requested that this is made clear in PIS.
* The Committee queried if coming off of current treatment may influence the testing – both physiological and on the participant questionnaires. Researchers explained the half-life of fluoxetine, which is likely the most common standard of care drug, would mean that the drug would not be present by the time they are undergoing testing for the study. Furthermore there will be no discontinuation effects from coming off the standard care treatment as these are only present on acute withdrawal. Because participants are slowly tapered off they will not have discontinuation effects.
* The Committee requested information on the healthy participants. The researchers explained they were aiming to recruit 40 participants with depression and 20 healthy controls.
* The researchers explained that the 20 control participants are only recruited to optimise technical procedures. They will not be studied and will only be given ketamine to check that the testing is picking up the correct signals and to ensure the independent variables look correct.
* The Committee asked whether it would be useful to study the effects of ketamine on the healthy individuals. The researchers explained that a prior study conducted by the CI showed healthy individuals showed increase happiness after taking ketamine.
* The Committee asked if smokers were excluded because they had addictive personalities. Researchers explained smoking impacts the measures and imaging.
* Please explain where healthy volunteers are recruited from – what screening occurs? The Committee noted that the study drug was known to be a recreational drug. The researchers explained that advertising was conducted at the university. The researchers explained that the potential participants have same drug tests (to check for current drug use) as well as requiring a meeting with psychiatrist for screening.
* P.3.2.1 – The researchers confirmed consent is sought from all patients. Committee queried why consent was sought from consenting physician? The researchers explained that the physician can inform researcher that the participant is competent to provide informed consent, rather than providing informed consent on their behalf.
* Committee queried how quickly participants can recommence their standard treatment. Researcher explained treatment provider will be responsible for this, adding that all patients referred from treatment providers, who will be working closely with researchers to ensure safe and monitored transmissions between study and standard of care.
* (P.4.3) No need to engage with Maori, please explain? The researchers confirmed this was an error and have spoken with Helen Wihongi.
* Please explain the 5DECS questionnaire. The researchers explained it has been validated. It is used to explore alternated states of consciousness. Researchers confirmed it was validated in English. The committee suggested that the analysis plans for all questionnaire data should be covered in protocol.

Summary of ethical issues (outstanding)

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

* The Committee noted that this ‘testing the equipment and procedures’ pilot component was not clear at all from the PIS or the application. Please make it clear that this first part was feasibility (with healthy volunteers). The Committee stated the study should be considered as part A and B (part A with healthy then B with depression). The committee requested significant overhaul of the PIS.
* The Committee noted that the Researcher Office may be the sponsor (a.5.1). Check with the RO update HDEC in a cover letter if the study is a sponsored study.

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

* Rewrite PIS for healthy participants. Please see HDEC template at <http://ethics.health.govt.nz/home>
* Suggested using ‘up to X participants‘ rather than X participants. This gives the researcher flexibility in recruitment.
* For the healthy participants, on first page – i.e. won’t affect the care you receive. Change to future care. Make it clear it means care in the study, not the care they are receiving as presumably they are not receiving care, being health controls.
* Number pages, add footer, version number and date etc.
* The depressed population PIS is far too brief. Noted pg.2 on depressed PIS – please include lay language. Have more detailed description of what the study is on and what will happen to participants (clearly outlined – perhaps a flow chart). See HDEC template for guidance. For example how many study visits, what happens in each visit.
* Change picture of MRI from the front. Researcher stated they would add a picture from the actual MRI machine used in the study.
* Explain the noise from MRI as this can be very scary.
* Add cultural statement – You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Maori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However it is acknowledged that individuals have the right to choose.
* Pg.3 – medications used – currently misleading as ketamine has only been approved at higher doses and for an anaesthetic not as an antidepressant.
* The researchers confirmed that after the study there will be no access to ketamine. Please make this clear in the PIS.
* ‘Likely you will find your mood is elevated’ – this is leading. Please remove.
* Explain how the data is de-identified, who can access health information and more information on blood samples. Consider using parts of the application. (b.2.1, r.2.3, r.3.7. r.3.10 f.2.1).
* Add complications for ketamine use (for both PIS). Side effects too. Highlight any populations who should not use ketamine.
* The researchers confirmed they can arrange a taxi if needed and would pay for taxi fares. Please include this information in PIS.
* Confirmed tissue samples not being sent overseas. Committee noted CF suggests tissue is being sent overseas – please remove this.

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 who the sponsor of the study is, if any.

This following information will be reviewed, and a final decision made on the application, by Dr Patries Herst and Ms Raewyn Sporle.

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| **4** | **Ethics ref:** | **15/NTB/54** |
|  | Title: | Acupuncture in addition to usual care for chronic low back pain: A feasibility study |
|  | Principal Investigator: | Ms Lizhou Liu |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 March 2015 |

Ms Lizhou Liu and her Supervisor Dr Margot Skinner 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.

* The researchers confirmed all researchers are covered with professional liability insurance.
* The Committee queried how pain is quantified before and after the acupuncture procedure. The researchers explained that the pain will be a subjective response using the standard visual analogue scale (VAS). This is standard practice for physiotherapists.
* Please explain why there is no placebo group? The researchers explained that all 3 groups will have acupuncture. The focus of the study is about which time period is the optimal period to administer rather than looking at acupuncture verses no acupuncture. The comparison is about frequency and duration of treatment.
* (R.1.4) The Committee queried why there is no external member of the DSMC. The researchers explained that one of the members internally is an international member. One of the members is well versed in safety reporting.
* The Committee noted that the lack of independence weakens the power of the study. The Committee suggested adding an external member (acupuncturist) for the study. Note this is not a requirement.
* The Committee queried what compensation is provided for participants. The researchers explained that bus fares are reimbursed.
* Committee queried why the researchers are only recruiting those who can speak in Chinese or English? Researchers explained it is because CI only speaks these languages and will be the primary interaction point with participants.

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

* The Committee noted there are possible injuries, such as infection. Please make it clear that infections can occur (pg.3).
* Include line drawing of anatomical site to see exactly where the needles are being placed.
* Add some information on inclusion and exclusion criteria.
* Add a brief paragraph on the potential mechanism whereby acupuncture therapy functions. This can be either from Chinese philosophy or modern New Zealand.
* Please clarify that after the study or if withdrawing from the study the treatment is no longer free (pg.3).
* On ‘why we are doing this study’ (pg.1) – please simplify this section. Study design not required.
* On ACC section – add ‘If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.’
* Please add statement that participants may receive no benefit.
* Add page number, version number and date.
* Please add Maori contact details and include and 0800 number for Maori support, if possible.
* ‘what would your participation involve’ – please reformat the current paragraph as it is very long.

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*).

This following information will be reviewed, and a final decision made on the application, by Dr Paul Tanser and Ms Mali Erik.

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| **5** | **Ethics ref:** | **15/NTB/55** |
|  | Title: | Comparison of Fluid Restriction with Urea for inpatient management of SIADH |
|  | Principal Investigator: | Dr Sonakshi Sharma |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 March 2015 |

Dr Sonakshi Sharma was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

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

* The Committee noted that Urea has been used with SIADH for a decade and a half. Please explain the reason for the study. Dr Sharma explained that although it has been used internationally for quite some time many clinicians in New Zealand do not know about it as a treatment for SIADH, adding there were no RCTs to clearly show the benefit. The Committee agreed it was a useful study.
* Dr Sharma noted Urea tastes very bitter. To mask this they will use orange juice, adding that they will be careful not to give any patients with diabetes any sugar.
* Data more likely to be potentially identifiable. Please see (*Ethical Guidelines for Intervention Studies para 7.2*) for more information on levels of data confidentiality.
* Please explain the internal data monitoring. Dr Sharma explained researchers will check patients don’t become too dry from fluid restriction. They will check participant’s kidney function and blood pressure. Urea levels will be monitored for those who are in the treatment arm, which is an additional blood test.
* Dr Sharma explained that it will be CI and a research nurse who will be monitoring safety data.
* The Committee suggested recruiting an independent monitor to review data to alert the researchers to any trend that would be adverse to the wellbeing of the participants.
* Dr Sharma explained they could recruit a registrar to review data and assist with analysis. The Committee felt this would be a good idea.
* Dr Sharma confirmed published data will not be identifiable.
* The Committee asked whether ethnicity data would be collected using the same categories as the New Zealand Census. Dr Sharma said she would seek guidance on the ethnicity collection methods.

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

* The Committee suggested adding why blood sodium may be low and why this is important to wellbeing – in the PIS. Expand on side effects of urea for example - bitter taste, nausea etc.
* On CF – please review the tick boxes and remove those that are not truly optional.
* Explain what Urea is, as well as explaining that we all have urea in us. Explain why it has been chosen as supplementary treatment for SIDAH.
* Add ‘testing’ to bloods.
* Add Maori health contact details.
* Please explain to participants why rising urea is a risk. Researcher explained it would be a risk for those at risk of kidney function – expand on this.
* Withdrawal procedures for participants – please explain this further.

Decision

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

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| **6** | **Ethics ref:** | **15/NTB/56** |
|  | Title: | Electronic Cigarettes and Nicotine Content |
|  | Principal Investigator: | Randolph Grace |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 March 2015 |

Randolph Grace (CI) and Meagan Tucker 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 study application was interesting and easy to read.

Summary of ethical issues (resolved)

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

* The Committee discussed how participants would get devices outside of the study. The researchers explained the actual devices are legal to sell in New Zealand but you can’t purchase fluid cartridges with nicotine in them - however you can import them.
* Researchers noted those without credit cards can’t access nicotine cartridges ordinarily.
* The Committee queried whether questionnaire question could be reworded (handle or manipulate changed to play with). Researchers noted the wording comes from a validated questionnaire so it is important to refrain from changing it. Researchers added they could make it clear verbally for participants.
* Please explain mechanisms in place for supporting smokers to quit, if they so choose, after the study. The researchers explained that they will provide participants with, a debriefing information sheet which has support information and resources available to seek further help and information.
* The Committee explained when Maori consultation is appropriate and stressed the importance of Maori consultation, particularly for this study.

Summary of ethical issues (outstanding)

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

* Please tone down the number of ‘frees’ and remove the capital letters in the advertisement as it is borderline inducement.
* (A.5.1) regarding the sponsor. The Committee noted that funding comes from tobacco research fund – please check with the university or the research office and confirm that they are not the sponsor for the study.
* The Committee queried if the study will recruit Maori? The researchers confirmed they would. HDEC suggest talking to university about consultation. Researcher agreed they will approach their Maori research advisor.
* Appendix C question 8 – please explain what a ‘ritual’ is for participants. i.e. preparation and lighting up.

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

* Add that safety information about use and charging of device will occur in person.
* Please refer to HDEC template PIS and incorporate more information in the current PIS based on the template suggestions regarding information that should be included. Example – HDC contacts, HDEC contact information, information on abstaining from smoking for 12 hours prior to study visit, compensation etc.

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 advertising to reduce inducement and or coercion.
* Clarify whether there is a sponsor for the study.
* Confirm that the study will undergo Maori consultation prior to commencing.

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

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| **7** | **Ethics ref:** | **15/NTB/57** (CLOSED) |
|  | Title: | “A study comparing how fast the trial drug GS-9857 is cleared from the body, in healthy adults and in adults with severely reduced kidney function”. |
|  | Principal Investigator: | Dr Richard Robson |
|  | Sponsor: | Gilead Science, Inc. |
|  | Clock Start Date: | 19 March 2015 |

Dr Richard Robson and Mr Chris Taylor 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.

This application was *provisionally approved* by consensus.

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| **8** | **Ethics ref:** | **15/NTB/58** |
|  | Title: | A Phase 2 Study to Investigate the Safety,Tolerability and Efficacy of ABT-122 in Subjects with Active Psoriatic Arthritis Who Have an InadequateResponse to Methotrexate |
|  | Principal Investigator: | Dr Douglas White |
|  | Sponsor: | AbbVie Pty Ltd |
|  | Clock Start Date: | 19 March 2015 |

Douglass White (CI), Denise Darlington and Rachel Campbell 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

* Committee commended the application.

Summary of ethical issues (resolved)

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

* The Committee queried if a SCOTT application had been submitted. Researchers confirmed the protocol would be submitted to SCOTT.
* (B.4.5.2) The Committee queried whether this referred to the optional biological samples. The researchers confirmed it did.
* The researchers confirmed Maori consultation will occur at all 4 sites.
* The researchers confirmed that insurance is held by investigators.
* The Committee noted that (A.1.5) asks for a lay language summary. The information provided is not in lay language.
* The Committee queried if it was likely that patients who are already receiving treatment would be recruited, who would have to wash out of current treatments? Researchers explained that it is unlikely but if they do encounter any patients of this nature they will be offered participation.
* Please explain how rescue treatments work if participants are on placebo arm. Will these patients get worse? Researchers explained that most background medications will be able to continue to be taken as treatment. Only some treatments are required to be stopped.
* The researchers explained there is a helpline provided that is used to help participants identify risks and can provide information to researchers about when a participant should be withdrawn for health reasons.
* Please explain the policy with respect to flu vaccines in New Zealand. The researchers stated they are encouraging potential participants to get flu vaccines, explaining that only live vaccines were contraindicated for trial. Please make this clear in PISCF.
* Please explain the consent process, in particular for the multiple optional studies. The researchers explained that the main PIS/CF is given to participants to consider. Then more time to consider optional components, adding that the optional studies will be discussed during screening and will be covered together.
* The researchers confirmed that no FUR tests occurring during screening.
* The researchers confirmed 24/7 contact number on emergency card.
* The Committee queried who can unblind the participants? The researchers explained that the CI has access to the codes for New Zealand participants. The Committee asked how the codes held. Does CI not need to defer to sponsor to break code? The researchers explained that it is all done via website which is PIN and sign in protected.

Summary of ethical issues (outstanding)

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

* (P.4.1) and (P.4.2) The Committee noted that treaty references are inappropriate and irrelevant, adding that cultural issues have not been identified. These relate to taking storing and transporting human tissue. Please re-address these questions in a cover letter.
* (P.4.6) Ethnicity data – how are you collecting this information? Researchers explained that they will only collected ethnicities listed as Maori or Caucasian. Committee noted Caucasian is a race not an ethnicity. Please use the same format as the New Zealand Census.
* The Committee stated that it does not accept that the study can enrol someone who passes screening but is not enrolled into main study due to ‘competitive recruitment’. The Committee advises that if you screen someone and they are eligible they should be included in the study and the close of recruitment should be closely managed accordingly

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

* The Committee stated that withdrawal does not need to be in writing and can be verbal. Please amend.
* The Committee suggests giving the patient information sheet to a lay person to read and give feedback, noting the drug titles are confusing.
* Please review jargon and ensure there are plain English explanations.
* Committee requested that ‘optional’ is in capitals
* PIS is very long – please review and remove duplication.
* Please include information about where study is happening (internationally).
* The Committee noted duplication on optional PIS’s. Please review and consider consolidating information but leaving differing options clear.
* Review all PIS for new Zealand audience rather than US.
* HIV and Hepatitis is not reportable by law in New Zealand - please remove.
* The Committee queried whether TB requires mandatory reporting? The researchers stated that internal procedure was to report TB but not necessarily reportable. The Committee requested that the PIS be explicit about what happens if positive result for TB is identified.
* Please add radiation exposure levels from x-ray.
* Remove referral to US law Pg.17.
* Pregnancy information sheet – please review for consistency i.e. ‘taking part in a study’ – they are not participating they are pregnant partners. Review researcher declaration.
* Noted participants can likely participate in research (for instance qualitative) but not drug studies – please make this 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*).
* Please address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed (*Ethical Guidelines for Intervention Studies* *para 4.7*).

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

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| **9** | **Ethics ref:** | **15/NTB/59** |
|  | Title: | MENZACS |
|  | Principal Investigator: | Associate Professor Malcolm Legget |
|  | Sponsor: | Heart Foundation of New Zealand |
|  | Clock Start Date: | 19 March 2015 |

Malcolm Legget (CI) and Sarah Masson (PC) 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 researcher introduced the study, explaining the wide range of consultation with stakeholders including the establishment of a Maori review committee.
* The research will study treatments for coronary heart disease which is one of the largest killers in New Zealand. There is a genetic factor involved in heart disease. New technology has evolved to a level where we can start to assess how genes play a role in development of diseases and potential treatments.
* Study will address a variety of factors such as genetics, lifestyle, environment and ethnicity.
* 4000 patients who have had recent heart attack and 3000 controls in Auckland, Middlemore and Christchurch hospitals.
* The study presents a fantastic opportunity to gather very comprehensive data that has not been able to be gathered on this scale before.
* The study will start as a pilot with plans to roll it out further.
* Commended the answers to questions (P.4.1) and (P.4.2).

Summary of ethical issues (resolved)

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

* (P.4.2) suggests that participants can have their samples returned after 10 years – is this an error? Researchers confirmed it was an error.
* The Committee queried why they are storing samples for 20 years. Researchers explained new questions will emerge over time. Noted we will be following individuals anonymously for outcomes in the study.
* The Committee asked where tissue is stored. Researchers stated North Island samples in Auckland and South Island samples in Christchurch.
* The researchers confirmed they are using New Zealand Census questions as ethnicity measure.

Summary of ethical issues (outstanding)

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

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

* Pg.1 first paragraph, add ‘without giving a reason’ to being able to withdraw.
* Add sentence like ‘if you decide to take part now you will be asked to sign a consent form which is X pages long, You will be given a patient information sheet and consent form to take home’.
* Amend to clearly distinguish between future research and future **unspecified** research.
* Pg.2 what will my blood samples be used for. The Committee queried if this consent mean future use of tissue? Researcher explained that it would be for related studies but future use, adding there is an opt out in the consent form for using stored samples for future studies that have ethical approval but are not part of this study. The Committee noted that currently it is not clear enough. Please review the tickboxes and remove yes/no if they are not truly optional. Please make it clear what participants are consenting to.

Decision

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

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| **10** | **Ethics ref:** | **15/NTB/60** |
|  | Title: | M13-740: A Study of ABT-494 for the Induction and Remission for Subjects with Crohn's Disease who are an Inadequate Responder or Intolerant to Anti-TNF Therapy. |
|  | Principal Investigator: | Assoc. Prof Richard Gearry |
|  | Sponsor: | AbbVie Ltd |
|  | Clock Start Date: | 19 March 2015 |

Assoc. Prof Richard Gearry was not 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 are as follows.

* The Committee noted that MPS membership has expired. Please submit renewed MPS.
* Please confirm patient contact card phone number is contactable 24 hours a day 7 days a week.
* On the questionnaire – please let participants know to either circle or underline answers. Currently unclear.
* Please explain why absolute confidentiality can’t be guaranteed?
* Is SCOTT pending?
* Please confirm flu vaccine can be given to participants.

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

* Section 10 pg.9: should tissue be stored for 10 years? Please confirm
* Section 14 pg.10: The Committee noted that the study should not be terminated for commercial reasons. Please remove this statement.
* Pg.10 remove reference to US law.
* Review and remove US spelling.
* Pg.3: you will be paid periodically – please clarify what this means for participants.
* Compensation section – make it clear that ACC is not available.
* For the genomic sub study PIS – please add where samples are stored.
* For the sub studies – please make it explicitly clear that these are optional.
* Section 19 – Note that in New Zealand they are HDECs not HREC. Please also specify that it is the NTB HDEC.
* Please add lay language title.
* The committee noted that withdrawal doesn’t have to be in writing. Please remove this information and explain that participants can withdraw verbally.
* Add information about tissue going overseas.
* Add information explaining that the drug is not available after study completion.
* Make it clear that information will be sent to the GP.
* On the genetic PIS – part 2 – please state ethics committee not IRB.
* Pregnant partner information sheet please amend to HDEC not HREC.
* The Committee noted that hepatitis is not reportable in New Zealand. Please remove this information.
* Quantify radiation of x-ray procedures for participants.
* Statement pg.9 under what will happen to my test samples – ‘to avoid problems’ please remove. Add ‘we invite your family/whanau’.

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*).
* Address outstanding ethical issues in a coversheet.
* Provide updated MPS certificate.

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

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| **11** | **Ethics ref:** | **15/NTB/61** (CLOSED) |
|  | Title: | A study comparing how fast the trial drug GS-9883 is cleared from the body, in healthy adults and in adults with reduced kidney function. |
|  | Principal Investigator: | Dr Richard Robson |
|  | Sponsor: | Gilead Science, Inc. |
|  | Clock Start Date: | 19 March 2015 |

Dr Richard Robson and Mr Chris Taylor 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.

Decision

This application was *provisionally approved* by consensus.

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| **12** | **Ethics ref:** | **15/NTB/62** |
|  | Title: | Pharmacokinetics and safety of ABT-493 and ABT-530 in renal impairment |
|  | Principal Investigator: | Dr Michael Collins |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 March 2015 |

Michael Collins (CI) and Margaret Joppa (PC) 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

* Two experimental drugs for participants who have normal to poor renal function. Single dose. 13 participants expected in New Zealand.
* Safety data has been reviewed from animals, pre-clinical studies and healthy person studies.

Summary of ethical issues (resolved)

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

* The researchers confirmed that the genetic study is not optional.
* The Committee queried why the genetic sub study is not optional? The researchers explained it was a sponsor decision in order to cover all aspects of renal disease.
* The Committee requires information on the genetic study to be in the main PIS because it is not optional.
* The researchers confirmed they would work on incorporating the New Zealand Census questions as their ethnicity data collection method.

Summary of ethical issues (outstanding)

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

* Please ensure the patient contact card has a number that is contactable 24 hours 7 days a week.
* Please explain the leaflet – is this used in conjunction with PIS? The researchers explained it was as they are recruiting through renal clinics. The flyer provides a talking point between physician and patient. The researchers are not directly involved in recruitment. If people are interested and want further information sheet they are given PIS by their treating physician.
* Please add HDEC approval statement – approved by NTB – to the leaflet. Please note this is NOT a therapeutic trial.
* (B.4.4) indicates that trial data may be used for future research. The Committee asked if the researchers had an idea what this research might be. The researchers stated it may refer to pharmacogenomic studies. The Committee asked the researchers to clarify what this actually refers to and then include info in PIS if participant data is going to be used in any future research – if data being used in future research is optional please make this clear and have it as a bullet point on the CF.
* (R.1.2) states that incidental findings and health information will be sent to GP. Please add information in the PIS for participants with regard to intention of notifying GP. Add whether there are limitations on what you will or won’t tell GP (hepatitis, HIV, drug and alcohol findings for example) – and explain how any incidental findings will be communicated.

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

* Please add ‘the decision not to participate will not affect current medical care’ (pg.1).
* Purpose of research (pg.2) please capitalise ‘and’ to make it clear that it is two drugs for each person, combined. Same for title – add ‘combined with’ for clarity.
* Pg.7 and pg.9 contains repetition of allergic reaction and drug interaction. The Committee suggests making it clear what is specific for this drug, for that drug and then both drugs have been known to do X (for drug interactions).
* Can you say exactly where tissue is going (pg.10)? Researchers confirmed tissueis stored in US. Please add this information. Confirm if samples going Singapore include for completeness.
* The Committee note withdrawal of participation doesn’t need to be in writing.
* Please add separate Maori contact rather than a general service. Researcher explained that the person usually providing this service has requested that their number is not listed directly – the researchers will follow up and insure that the general number is appropriate and accessible. HDEC suggests contacting <http://www.healthpoint.co.nz/public/other/waitemata-dhb-maori-health-services-he-kamaka/>
* Remove US law (pg.2 and pg.11).
* Table on pg.3 – simplify terms used – currently overly complex.
* Check whole PIS for US spelling.
* Pregnancy PIS (pg.9) the wording could be improved, for instance the form is used to seek partner consent to use data – they are not a participant for the trial.
* Insurance section – look at HDEC template for wording when a trial is commercially sponsored.
* Suggest change discuss ..(pg.1) ‘with someone such as a kaumatua or whanau member’. Please change to (pg.10) ‘if you wish to have whanau support present **and or** have a karakia’.
* Reimbursement section – actual expenses – please clarify that it is per visit.

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 leaflet / advertising.

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

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The HDEC will add Te Ara Tika document pages to the next agenda.
3. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| --- | --- |
| **Meeting date:** | 05 May 2015, 08:00 AM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Auckland |

The following members tendered apologies for this meeting.

None stated.

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 5.00pm