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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 04 August 2015 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Auckland |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 07 July 2015 |
| 12.30pm | New applications (see over for details) |
|  | i 15/NTB/126  ii 15/NTB/129  iii 15/NTB/130  iv 15/NTB/131  v 15/NTB/133  vi 15/NTB/136  vii 15/NTB/137  viii 15/NTB/138  ix 15/NTB/139 |
|  | General business:   * Noting section of agenda |
| 4.30pm | 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 Stephanie Pollard | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Paul Tanser | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Ms Kerin Thompson | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Apologies |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Phyllis Huitema | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Kate O'Connor | Non-lay (other) | 01/07/2012 | 01/07/2015 | Present |
| Ms Shamim Chagani | Non-lay (NTA CO-OPT) | 01/07/2012 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 12.06pm and welcomed Committee members, noting that apologies had been received from Ms Kerin Thompson.

The Chair thanked Dr Paul Tanser for his time on the Committee. Dr Tanser said that he enjoyed his time on the Committee and hoped his training and experience had helped the other Committee members. Dr Tanser talked about his experience on the New Zealand ethics committees and the Canadian ethics committees.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Ms Shamim Chagani confirmed her eligibility, and was co-opted by the Chair as member 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 7 July 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/NTB/126** |
|  | Title: | Defining thresholds of neonatal hyperglycaemia associated with adverse short- and long-term outcomes. |
|  | Principal Investigator: | Dr Kathryn Williamson |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 23 July 2015 |

Dr Kate Williamson and Dr Jane Alsweiler 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 commended the peer review.
2. The Committee noted the study is retrospective and observational.

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 consent is generally obtained when identifiable data is used for secondary purposes to what it was collected for (clinical practice verses research). The Committee noted that the study data will be identifiable at the onset but then is coded with a link. The Researcher(s) explained that once the data points are brought together the link is no longer required.
2. The Committee requested an explanation for not seeking consent to use data. The Researcher(s) stated that they are looking at 900 patients, going back to 2005. It takes a lot of time and effort to try and find people. We would also not be able to find some of them – for this kind of study we need to analyse all of the data to have the study be both worthwhile and generate valid results. Seeking informed consent would bias the data if we did not include the most vulnerable i.e. sickest children, who may be the hardest to track down, or may have died. The Researcher(s) also cited the undue stress that would be caused if those parents who had children who died were approached for this purely retrospective observational study.
3. The Committee queried if there is any disadvantage to the patients (babies). The Researcher(s) stated no, only general risk of confidentiality, however the laptops are password protected, and even then – the data is NHI protected.
4. The Committee noted confidentiality measures were well thought out.
5. The Committee noted that the researchers had made a case that seeking consent would be impractical, would bias the study, would cause undue stress and noted the use of the data did not pose risk to the patient population. This meets NEAC guidelines for use of health information without consent for research purposes.

Decision

This application was *approved* by consensus.

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| **2** | **Ethics ref:** | **15/NTB/129** |
|  | Title: | Effect of dexamethasone on acute phase response to zoledronic acid |
|  | Principal Investigator: | Professor Ian Reid |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 July 2015 |

Professor Ian Reid was not present 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 stated this study is an important study.

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 if the participants need to wait at the site after the infusion or can they leave shortly after. If they do how long do they need to wait before it is safe to leave, and how is this determined?
2. Please explain if participants will receive any Koha for participation.
3. The Committee queried what normal practice is for these participants and how study participation differed from normal practice.
4. The Committee queried how researchers would manage participant safety, noting the lack of formal data safety monitoring. Please explain the informal or internal safety-monitoring arrangements. The Committee noted that the study drug has a very low risk profile and understands it has been in use for a long time.
5. The Committee noted that the study was for a PhD and queried whether the University would be the sponsor – please check with the University and inform HDEC of the sponsored status of the study.

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

1. Please add Maori support contact information.
2. Please review the ACC information in the current HDEC template. Replace current ACC wording.
3. The Committee queried whether the family was appropriate to help explain the risks and benefits, noting that while family should be consulted about participation they should not be expected to explain risk benefit ratios (page 4). Please use HDEC template wording that is more about discussion with family about participation, not about risk assessment.
4. Please check the telephone number for Professor Reid – it currently differs between the Participant Information Sheet and the Consent Form.
5. (R.1.1) This information is not currently in the information sheet. The blood pressure measurement is also not included – please add.
6. Add how long it will take (roughly) for the completion of the questionnaires.
7. (R.6.1) Will this be part of the consent form? Or will this recruitment for other studies be separate from this study. Please clarify for the Committee and for the participants.
8. Explain ‘blinding’ in lay language.
9. Page 2 of consent form – consent about storing study data for later use – please explain whether this is optional and what exactly this is. Can patients choose not to participate in this part of the study? The Committee noted it should be optional.
10. Add information on the right to withdraw at any time at the start of the Participant Information Sheet – please review HDEC wording on the template Participant Information Sheet.
11. Please include some basic inclusion exclusion criteria from page 21 of the application – (F.2.1).
12. (F.3.1) Please include information about access to the drug after the study ends.

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*).
* All payments, reimbursements and health services provided to study participants must be disclosed to an ethics committee (Ethical Guidelines for Intervention Studies para 6.36)
* Provide details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies para 6.50).*
* Clarify if the study has a sponsor who will be responsible for the initiation, management and funding of the project.

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

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| **3** | **Ethics ref:** | **15/NTB/130** |
|  | Title: | A study of dose schedules for pamidronate infusions in the management of chronic non-specific low back pain |
|  | Principal Investigator: | Dr Saad Anis |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 July 2015 |

Ms Beveridge and Dr Jones 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 Committee complimented the lay language explanation of the study design in the application.

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 that participants must be fluent English speakers (pg.1 ‘How are those outside the trial usually receiving the trial drug?’) The Researcher(s) explained that there is a lot of telephone follow up for the study, so they need people who can speak English. If they felt that a person needed the study drug for standard treatment they would give them the study drug but would not enroll them into the study. Treatment does not require English speakers but study participation does.
2. The Researcher(s) confirmed there was no association with the drug company providing the experimental drugs.
3. (A.6.2) 60 people from New Zealand. The Researcher(s) confirmed the whole sample will be from Bay of Plenty area.
4. (P.4.3) The Researcher(s) confirmed this questions answer was a typo.
5. The Researcher(s) confirmed Maori consultation has occurred. The response was positive.
6. The Researcher(s) confirmed that the treatment is given in the public sector, not private.

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 whether the study drug funded for treatment of lower back pain. The Researcher(s) responded they are not sure about the funding status, adding they use it for chronic pain as part of standard care. This use is based on literature; this study aims to generate evidence to support such uses. The Committee requested clarification of the study drug funding and approval status. Please include this information in the Participant Information Sheet.
2. (F.2.1) Please explain the exclusion criteria of those ‘pending a compensation claim’? The Researcher(s) stated that it was to avoid those potential participants who were working with ACC in a case assessment. This exclusion criterion was for legal reasons, primarily to avoid negatively affecting the person’s case with ACC.
3. The Committee asked that the exclusion criteria about invasive dental procedures. is changed to only exclude unhealed procedures. The Committee noted there are guidelines available for dealing with osteonecrosis.
4. The Committee queried what dosing schedule is currently used? The Researcher(s) stated they are mixing and matching. The Committee noted that it would be useful to explain in the Participant Information Sheet that currently there is no certainty which schedule is better and that both are currently used in the Bay of Plenty area. This will reassure participants that the arms are in equipoise.
5. The Committee queried if participants are randomized? The Researcher(s) confirmed that they are. The Researcher(s) elaborated that the dose schedule will also be based on the participant location. The Committee noted that this is a mixed model of both randomization and self-selection and explained that this is not beneficial to the study design because it introduces bias. The Committee queried if a biostatistician has been involved. The Researcher(s) noted the CI has been involved with study design.
6. The Committee suggested involving a statistician who would be able to provide a robust study design.
7. Please submit the evidence of scientific review. The Committee noted it is pending.
8. The Committee queried if the blood tests could identify incidental findings? The Researcher(s) confirmed that it was possible. The Researcher(s) confirmed general biochemistry panels were taken.

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

1. Please use HDEC template for ACC wording
2. Please consider using the HDEC template consent form.
3. Explain privacy more fully under ‘what are my rights’. Don’t refer to ‘BOP’ etc. Use lay language.
4. Add page numbers and footer.
5. Add information about intention to notify GP of study involvement.
6. The Committee noted that multiple blood tests are not adequately covered. Add more information – how many, how often, what were they for, add information on where they are stored and how they will be destroyed etc. See HDEC template for more information on the kind of information to include for use of human tissue for research.
7. The Committee stated that it would be important to include what occurs if anything is identified from these tests (incidental findings) i.e. onward referrals.
8. Please add contacts for Maori support persons.
9. Add dose range(s) of study drug.

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 Future Unspecified Researcher information on the study design, *in particular the randomisation plans* (*Ethical Guidelines for Intervention Studies para* 5.4), including biostatistical advice/clarification of study design
* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).

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

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| **4** | **Ethics ref:** | **15/NTB/131** |
|  | Title: | Efficacy and Safety of RTH258 versus Aflibercept |
|  | Principal Investigator: | Dr Sarah Welch |
|  | Sponsor: | Alcon Laboratories (Australia) Pty Ltd |
|  | Clock Start Date: | 23 July 2015 |

Ms May Mendoza (Primary contact) and Dr Sarah Welch (CI) 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 Afibercept is standard treatment (but not gold standard). The Researcher(s) confirmed the dosage of the control arm would be standard treatment levels.
2. The Committee queried if most participants would be over 50 years old. The Researchers(s) confirmed they would be as this is the common age group for this disease, if not older.
3. The Committee noted that the application states that there are no ethical issues. Have you considered that there are any ethical issues? The Researcher(s) stated that their understanding was that the study drug was beneficial for participants and could be better than current standard of care. The Researcher(s) added that there are the standard risks involved with using an experimental drug. The Committee noted there are other risks – for instance that you are recruiting your own patients, conflict of interest, power imbalances and using human tissue. The use of tissue has both cultural and ethical issues. Use of health data and confidentiality, including steps taken to respect privacy, are also ethical issues related to the study.
4. The Committee noted the application stated R.1.5 indicates that the study only involves data and only involves usual care. The Committee noted this is incorrect. The Researcher(s) agreed it was a mistake.

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.1.6) The Committee noted the answer stops halfway – please reflect on all of the criteria for terminating the study. Submit this information to HDEC in a cover letter.
2. (R.2.4) The Committee queried whether the long-term storage is de-identified or potentially identifiable? Please provide information in a cover letter.
3. (P.4.3) Are you expecting any Maori participants? The Researcher(s) noted it is very unlikely. The disease is very rare for Pacific Islanders or Maori. The Committee noted that if there is a possibility of Maori participants then formal Maori consultation is required, as per the Health Research Council Guidelines for Research Involving Maori.
4. The Committee requested that the plain English study explanation in the application is in lay language. The current application answer is too technical. Please re-answer this question in the cover letter.
5. The Committee queried why there is no collection of ethnicity data. The Researcher(s) explained that treatment response is the same across all ethnicities internationally. The Committee noted it is not difficult to collect ethnicity information – this kind of information is useful in terms of prevalence, participation in research on a general level etc. The Committee noted that the Participant Information Sheet ‘questions participants on race’ – this is not a construct that is used in New Zealand. The Committee suggests using the New Zealand Census criteria.
6. (B.1.4.1) The Committee queried if people have access to study drug after the trial ends? The Researcher(s) stated it depends on the sponsor. The Committee noted the application states participants would benefit if they show a benefit on the study drug. The Committee explained that this should be clarified with the sponsor and made very clear in the Participant Information Sheet.
7. The Committee noted there are no formal data safety monitoring arrangements – please explain what is in place? The Researcher(s) explained the sponsor must clarify this for us. The Committee requests what committee is governing the trial, looking for trends etc. and safety information. Not just the on-site monitoring of the data.
8. (P.3.3.1) Please explain ‘out of pocket expenses’ – make sure these are explained clearly for participants.
9. (P.4.1) Please expand on this answer to the Committee in a cover letter.
10. (P.4.2) Please expand on this answer to the Committee in a cover letter.

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

1. The Committee queried why there was so much about pregnancy avoidance, noting the patient population. The Researcher(s) stated even if someone was over 50 would be able to become pregnant we would suggest two forms of birth control, but acknowledged that it was unlikely in this patient population. The Committee suggested changing the Participant Information Sheet to state ‘we would discuss pregnancy with you if it is applicable to you’.
2. Remove reference to US law (page 2).
3. The Committee noted Participant Information Sheet references Australia – remove these. Please also remove mention of the ‘National Statement’.
4. Add lay language study title.
5. Remove technical explanations. Revise and resubmit a new version with lay language.
6. Page 13 references study samples. You must include information about what happens to the samples, including that samples are going overseas, in the Participant Information Sheet.
7. Page 15 states in bold about seeking independent legal advice prior to seeking compensation. Please remove this statement.
8. Termination should not be made solely in commercial interests of the sponsor (page 15), as per the National Ethics Advisory Committee Guidelines for Intervention Studies. Remove this statement.
9. Amend to NTB HDEC rather than NTA.
10. Please increase the size of the font.
11. Please remove the ‘flipping the coin’ reference. Instead please explain what randomization is and why it is important for clinical trials.
12. Add Maori health support contact details.
13. Page 9 – please clarify what kind of medical attention should be sought, i.e. study doctor or GP or 111. The Researcher(s) noted they have the information of the study doctor on the Participant Information Sheet.
14. Please explain how much blood is taken in mls.
15. Make it clear if the fluorescence test is going to occur at New Zealand sites.
16. Please use ACC statement from HDEC template.

Decision

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

* 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*).
* 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 plan *(Ethical Guidelines for Intervention Studies para 6.50).*
* Please provide criteria for study termination. (*Ethical Guidelines for Intervention Studies* *para 6.64*).
* Address outstanding ethical issues in a cover letter.

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

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| **5** | **Ethics ref:** | **15/NTB/133** |
|  | Title: | Tart cherry concentrate in gout |
|  | Principal Investigator: | Professor Lisa Stamp |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 July 2015 |

Professor Lisa Stamp 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 Study

1. The Committee noted the study is HRC funded.

Summary of ethical issues (outstanding)

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

1. (P.3.3.1) Is a 10-dollar petrol voucher fair and reasonable given the time and inconvenience of study participation? Please explain the level of compensation.
2. (P.4.2) The Committee noted taking and storing of tissue is a culturally relevant feature of the study.
3. The Committee noted the study intervention is very low risk but queried the DSMC arrangements or general safety monitoring plans. Please explain the arrangements to monitor safety information and trends within the study data.
4. The Committee suggested following up with research office who may be the sponsor. Please inform the HDEC whether the research office is the sponsor of the study.
5. Please address the peer review comment about the quality of the study product.

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

1. Please make the future unspecified research Participant Information Sheet has all the required information. Please see the guidelines by the Ministry of Health at <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>
2. Include risk information about high blood sugar level (this information is in the application but not in the Participant Information Sheet).
3. Please use the HDEC template Participant Information Sheet for the consent form.
4. Please use the HDEC template Participant Information Sheet ACC statement.
5. Please refer to the NTB HDEC rather than the Central HDEC
6. No information about option for karakia for destruction. Please add.
7. Insufficient information about what happens to human tissue. View HDEC template and HDEC informed consent checklist and update with more information - <http://ethics.health.govt.nz/>
8. Version control of documentation – please review for consistency.
9. Please include the consent form as part of the information sheet. Submitting them separately causes administrative issues.
10. Please put HDEC wording about the study being voluntary and include right to withdraw, up front.
11. Please include information explaining that participants may continue to take their regular medication.

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 ensure the optional Participant Information Sheet and Consent Form for the use of tissue for future unspecified research meets the guideline requirements (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).

This following information will be reviewed, and a final decision made on the application, by Ms Shamim Chagani and Ms Tangihaere MacFarlane.

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| **6** | **Ethics ref:** | **15/NTB/136** |
|  | Title: | Study of NP202 Treatment after a Heart Attack |
|  | Principal Investigator: | Dr Gerard Devlin |
|  | Sponsor: | Armaron Bio Pty Ltd |
|  | Clock Start Date: | 23 July 2015 |

Dr Dennis Friedlander (Co-investigator) and Mrs Liz Low (Primary Contact) 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 Committee queried what ‘remodeling’ involves. The Researcher(s) explained that part of the heart muscle dies. Once this part (in the left ventricle) dies we remodel it. It is an effort to positively impact how it heals. Scar tissue is created instead of new heart muscle. The exact size and how this tissue stretches effects clinical outcomes.

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 if the new medicine was to improve the healing process. The Researcher(s) confirmed it was.
2. The Committee queried what standard treatment is. The Researcher(s) explained that treatments that currently affect healing or remodeling are not available. There is no comparative alternative treatment.
3. The Researcher(s) confirmed that participants would receive all standard treatments available to them, as well as study drug or placebo.

Summary of ethical issues (outstanding)

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

1. (P.4.2) The Committee noted cultural issues would likely be raised in Maori consultation. (P.4.3.1). The Committee queried whether there had been any feedback from Te Puna Oranga.

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

1. The Researcher(s) explained that the PK sub-study is currently unclear who will be taking part. Usually sponsor approaches a small number of sites to participate in this part of the study. Currently we are unsure. The Committee queried if it is determined to be at New Zealand sites, will it be optional? The Researcher(s) confirmed it would be.
2. The Committee stated it is currently not clearly optional. This will need to be made clearer.
3. The Committee felt that terming the study drug a ‘treatment’ assumed efficacy. Please reword to have ‘experimental’ prior to treatment, to better communicate the status of the drug.
4. Page 7 – The Committee noted that the study couldn’t be terminated purely for commercial reasons as per the National Ethics Committee Guidelines for Intervention Studies. Please remove this statement.
5. Page 9 – will there be any follow up on mothers who become pregnant during the study. The Researcher(s) confirmed that if this occurs we would follow up urgently and carefully. This will be avoided at all costs as the study involves an experimental treatment. The Committee requested that information about what occurs if you become pregnant during the study is involved. Modify the wording to show that it will be necessary for follow up but will only occur with permission.
6. Add that study data will be used for future research in both information sheet and consent form. Explain the level of identifiably of this data.
7. Please change word from race to ethnicity (under screening visit).
8. Page 3 – please remove the term ‘flip of a coin’. Instead please explain what randomization is and why it occurs.
9. Page 11 – ‘all records will be destroyed after 15 years’. Please amend to at least 16 years.

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 Ms Kate O’Connor and Mrs Mali Erik.

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| **7** | **Ethics ref:** | **15/NTB/137** |
|  | Title: | IntraPeritoneal therapy for Ovarian Cancer with Carboplatin (iPocc) |
|  | Principal Investigator: | Associate Professor Peter H Sykes |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 July 2015 |

Dr David Gibbs 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 Committee commended the lay language in the application

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 comfortable the researchers were using Intravenous and Intraperitoneal. The Researcher(s) stated that both were standard care options, adding they are comfortable with the study procedures.
2. The Committee queried what the internal Data Safety Monitoring arrangements would involve. The Researcher(s) stated that essentially it is a standard of care study, so although it is a randomized study, both treatment arms are well within what we do routinely. In terms of adverse events we are not expecting anything outside of what we see day to day. There will only be essentially two, or on occasions three, investigators who will be delivering the care. We will know what patients are experiencing due to close monitoring.
3. The Committee queried whether you will be assessing safety information on a case by case basis? The Researcher(s) confirmed yes – only 10 patients at most in New Zealand. It will be easy to monitor.
4. The Researcher(s) stated the study is not sponsored by any particular pharmaceutical company.
5. The Researcher(s) stated the only ethical issue for this study is the process of consent that is occurring at a time when women are experiencing a diagnosis of cancer and will require major surgery. It is a standard feature of conducting studies in this context – it must be managed well but is unavoidable. The Researcher(s) added that both clinicians are experienced and are familiar with recruitment for research.
6. The Researcher(s) confirmed that this kind of cancer is one of the only kinds where there is lower prevalence in Maori. The Committee queried whether this was correct. The Researcher(s) stated that as a cohort when compared with Pakeha women that Maori women have a lower rate, and that ethnicity does not affect mortality.
7. The Researcher(s) confirmed no local Data Safety Monitoring Committee.
8. The Researcher(s) confirmed there is no single standard of care used at our sites. There are 3 regiments that most women with ovarian cancer would be offered. All contain Paclitaxel. There are various schedules that can be used with these combinations, and either are IV or IP. This is a reflection of international standards.

Summary of ethical issues (outstanding)

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

1. This trial will test simply the route of administration that should provide some interesting information. The Committee felt that the study was in equipoise but the Participant Information Sheet suggests that IP is best. Please reconsider the wording on the Participant Information Sheet and ensure you describe the various treatment options and the uncertainty that exists, hence the reason for the trial.
2. The Committee queried process for tissue. The Researcher(s) explained that the slides will be sent to Japan. The Committee requested Future Unspecified Researcher information on use of tissue is included in Participant Information Sheet. I.e. its surplus from general practice.
3. Explain what tissue will be used, what you are doing, where it is going etc. and how it is destroyed. See HDEC informed consent checklist for guidance <http://ethics.health.govt.nz/>
4. The Committee requested evidence of the peer review that has occurred. The Researcher(s) stated he could provide this.

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

1. Page 7 – please refer to the HDEC website template Participant Information Sheet and change words on ACC.
2. Please make the introduction paragraph more patient friendly. It is currently written as if it is a protocol introduction. Please soften the wording.
3. Check for New Zealand English (currently some American language).
4. Explain what ‘removal of the port’ means.
5. Add that GP will be informed of study participation. Also remove the yes/no option from the consent form as informing the GP is not truly optional.

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 provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).

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

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| **8** | **Ethics ref:** | **15/NTB/138** |
|  | Title: | The Suction Study |
|  | Principal Investigator: | Mrs Eileen Gilder |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 July 2015 |

Mrs Eileen Gilder 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 Committee commended the study.

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 that suction occurs during standard practice, adding it is not completely risk free. For one, it is not pleasant and can be painful.
2. The Committee queried how often suction occurs? The Researcher(s) stated it varies hugely. Ideally it should not be more than every four hours, though some patients will need it more than that – it is one of those things where we don’t really know what frequency is best or whether it is actually necessary.
3. The Committee queried if suction is something that is specifically asked for by doctors in ICU. The Researcher(s) stated that at the phase of treatment we are looking at – no, we are not sure that there is any need for suction. It occurs but we are not sure that it is actually the best thing to do for these patients.
4. The Committee queried if the researchers have talked with anesthetists in the unit about this study. The Researcher(s) confirmed they had, adding they are happy with the proposed study.
5. The Committee queried whether describing the suction as painful and distressing in the participant information sheet may bias the reported experience as painful and distressing.
6. The Committee requested basic outline of consent process. The Researcher(s) stated they have 6 staff. The researchers screen the list of potentially eligible participants, go and see them on the ward, and talk to them about the study. They explain who we are and explain the research they are doing, answering any questions etc. They leave the Participant Information Sheet with them and their family. They come back later and talk to them again.
7. The researchers acknowledge it is a busy and potentially stressful time for patients. If the patient looks overwhelmed the researchers would not approach them. The Researcher(s) confirmed it was generally same day consent, sometimes overnight.
8. The Committee query, hypothetically, is there any risk of not giving suction? The Researcher(s) stated – we don’t know, in theory there could be a risk of infection, however the particular study group is only in the unit for a very short time. The risk really is minimal in that time frame. Perhaps after 24 hours there would be a risk – we would want to perform suction for longer stay patients.
9. The Committee query how risk is assessed i.e. length of ventilation / ICU period. The Researcher(s) explained that there are data points that are used to assess risk.

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 talking to DHB Research Office to confirm whether they are the sponsor.
2. The Researcher(s) explained Maori consultation occurs after HDEC approval is received.
3. The Committee queried if it is safe having no DSMC. The Researcher(s) stated monitoring is live, real time, by bedsides. Participant numbers are not big – our approach is pragmatic – patients are monitored on a 1-1 basis.
4. The Committee explained that line of questioning was more about general trends of the study – not necessarily the one on one monitoring, but whether someone independent can assess the safety data of the study and review for more generic safety trends.
5. The Committee clarified the individual level assessment is appropriate and so is the higher-level analysis – it is more about the on-going assessment during the trial, across the various participants, preferably independent. This could be an expert colleague. Please talk to research office about accommodating this request.
6. How will the envelopes work for randomization? The Researcher(s) explained when patient has their surgery we will talk to bedside nurse about their study involvement. The Researcher(s) confirmed there are no delays to treatment due to this process.
7. The Researcher(s) stated ideally we would prefer that people had no suction at all. There are safety parameters where suction may be required.
8. The Researcher(s) confirmed that they are seeking statistical advice for powering and conducting non-inferiority studies, particularly how to incorporate the data in cases where suction is required for someone on the no-suction arm, due to clinical reasons.

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

1. Please increase font size
2. Please use current HDEC template wording – ACC.
3. Please add HDEC approval wording and contact details from HDEC template <http://ethics.health.govt.nz/>
4. Add withdrawal statement – see HDEC template. Explain that withdrawal has stages i.e. after the intervention can withdraw data etc.
5. Review wording ‘study will be stopped’ rather than treatment.
6. Differentiate between artificial airway and suction. Be clear that all participants receive artificial airway.
7. The Committee requested randomization is described – both what it is and why it is important for studies. Remove ‘tossing a coin’ analogy.

Decision

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

* Provide details of the internal Data Safety Monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*
* 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 provide evidence of guidance on the non-inferiority and use of data (*Ethical Guidelines for Intervention Studies* Appendix 1).

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

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| **9** | **Ethics ref:** | **15/NTB/139** |
|  | Title: | TERRANOVA |
|  | Principal Investigator: | Dr Paul Dawkins |
|  | Sponsor: | AstraZeneca Limited |
|  | Clock Start Date: | 23 July 2015 |

Dr Paul Dawkins and Catherine Howie 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 Committee noted plain English summary was not easy to read. Please take this into account for future applications.
2. (P.2.8) The Researcher(s) confirmed a lay language summary would be provided to participants if they request it.
3. The Committee requested information on the consent process, in particular on the term ‘ample time to consider’. The Researcher(s) stated we want to give patients as much time as they need. The aim is that they should not feel any pressure to participate. The Researcher(s) confirmed that consent is never on the same day. The potential participant will always take it away for reflection. We would not enroll anyone we thought didn’t have enough time to consider.
4. The Committee noted that a consent flip chart is helpful – ‘Teranova flip chart’. The Committee queried how this is used? The Researcher(s) explained that it was something that the company has given us as an option – we were not planning on using it routinely. It is a bit like giving a presentation. If we were to use it would be in conjunction with the Participant Information Sheet rather than instead of.
5. The Researcher(s) explained that if incidental findings are found we will follow up appropriately by the clinicians.
6. The Committee requested that posters are submitted to HDEC for review prior to use.
7. The Researcher(s) explained that Maori consultation occurs at each site prior to the study beginning.

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 request that Future Unspecified Research is separated out from the Participant Information Sheet into an optional, separate Participant Information Sheet.
2. The Committee noted that clinical trial agreements are not available to HDEC (regarding publication restrictions), are there any undue restrictions in this agreement? The Researcher(s) explained that the restrictions relate to intellectual property concerns from the sponsor. Sponsor states that Co-ordinating investigator can write publications provided that the sponsor can review them prior to submission.
3. The Committee noted that the withdrawal form is not required. Patients do not need to complete a withdraw form – they can do so verbally. There is no obligation to complete this form. The Committee noted the researchers could use it but it would be optional.
4. Review the various levels of withdrawal options and make the form both optional and fit for purpose i.e. review tick boxes to be 3 exclusive levels. They are not OR options.
5. Optional use is fine. Make it clear that verbal withdrawal is an option too.
6. The Researcher(s) confirmed the contact number is 24/7 for study doctor on patient alert card.
7. (P.4.2) Storage of tissue is a potential cultural issue.
8. Please highlight the journey of the tissue – by bolding the existing wording.
9. Ensure Maori health support details are included.

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

1. Add short lay language title.
2. (P.4.2) References sputum samples – is this in the Participant Information Sheet? The Researcher(s) stated there would be sputum samples. The Committee requested clarification in the Participant Information Sheet as a type of tissue collected for this study ‘in the event of an infection’.
3. Page 14 about termination of the study – NEAC guidelines state a study can’t be stopped for commercial reasons. Please remove that statement.
4. Add information about management of incidental findings.
5. ‘Your study doctor has decided to withdraw you’ – please clarify what this means for participants. The current language used is problematic, makes it unclear what are the doctor is stopping – all contact, or just treatment 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*).
* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).

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

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee discussed the definition of a sponsor and suggested whether the SOP should involve a review of the term, noting that most studies should be identified sponsored. HDEC needs to have a national view on the term and whether the HDEC accepts ‘investigator led studies’, as there are often local level responsibilities that are important to recognize. The HDEC secretariat noted that they are reviewing the SOP and are also considering the national view of sponsors, adding the topic was on the agenda for Chairs day in July.
3. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| --- | --- |
| **Meeting date:** | 01 September 2015, 08:00 AM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Auckland |

The following members tendered apologies for this meeting.

* Mrs Stephanie Pollard
* Ms Raewyn Sporle

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 4.30pm