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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 02 September 2014 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Auckland |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
|  | Confirmation of minutes of meeting of 05 August 2014 |
|  | New applications (see over for details) |
|  | i 14/NTB/115  ii 14/NTB/117  iii 14/NTB/118  iv 14/NTB/121  v 14/NTB/122  vi 14/NTB/125  vii 14/NTB/126  viii 14/NTB/127  ix 14/NTB/129  x 14/NTB/130  xi 14/NTB/131  xii 14/NTB/132 |
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| 6.00pm | General business:   * Noting section of agenda |
| 6.35pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Raewyn Sporle | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Kate O'Connor | Non-lay (other) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Paul Tanser | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Ms Kerin Thompson | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Phyllis Huitema | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |

## Welcome

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

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 5 August 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTB/115** |
|  | Title: | The use of pulse oximetry in New Zealand and Australia |
|  | Principal Investigator: | Dr Janine Pilcher |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 21 August 2014 |

Dr Janine Pilcher 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

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

* The study aims to compare ‘pulse oximetry’ verses an arterial blood gas sample, for measuring the amount of oxygen in the blood.
* The Committee agreed the delayed consent was adequately justified. The Committee noted the relatives or guardians were consulted before attaching the non-invasive sensor for measurements, but this was not ‘proxy consent’, rather it was assent combined with delayed consent.
* The Committee noted under 16 year olds were excluded.
* The Committee stated ethnicity information should be collected using the same options used in the New Zealand Census.
* The Committee queried if the Fitzpatrick scale had been validated for use in New Zealand?
* (P.4.3.1) Please advise the Committee of the outcome of the Maori consultation.
* (P.4.2) The Committee queried if the researchers felt the Tikanga Maori booklets would be sufficient to meet the needs of New Zealand participants in Australia, noting the high quality training provided for New Zealand sites.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Pg. 2 of 6 “If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home.” Please change **would** to **may**.
* The Committee queried if participants would know what a ‘gold standard’ was. Please explain in lay language, for example ‘best known measure’.
* Include information about the intention to inform the GP of study involvement in the guardian PIS/CF.

Decision

This application was *approved* by consensus.

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| **2** | **Ethics ref:** | **14/NTB/117** |
|  | Title: | Intramuscular Benzathine Penicillin for GAS Pharyngitis treatment |
|  | Principal Investigator: | Ms Tracy McKee |
|  | Sponsor: | National Hauora Coalition |
|  | Clock Start Date: | 21 August 2014 |

Ms Tracy McKee 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

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

* Ms McKee explained that antibiotic adherence is an ongoing problem that presents a particular challenge in some of the communities that are involved in the rheumatic fever prevention programme.
* The Committee commended the aims and goals of the trial.
* The Committee queried if there had been any consideration of having a control arm for the study. Ms McKee explained there was a control arm, or a ‘business as usual’ arm, that is derived from other schools who have the same treatment options available, and will also have blood tests for comparison.
* Will the comparative group have health information collected? Ms McKee confirmed it would be completely anonymous, and would be consented by the other school’s standard practice consent, which includes information on potentially using data for research. The Committee was satisfied with this approach.
* Ms McKee explained that ethnicity information is collected from the study group, but not from the comparison group, due to the data being anonymous.
* The Committee confirmed that there was a pre-screen process to ensure participants would not be recruited if they did not meet the exclusion criteria, particularly any allergies to penicillin.
* Ms McKee explained that pre and post intervention data will be collected, per school, as an additional measure of study outcomes.
* The Committee noted lollies would not be considered coercive.
* The Committee requested a copy of the child assent form.
* Ms McKee explained that standard practice during treatment involves giving participants a card that explaining the treatment, with additional contact information. Furthermore, verbal discussions covered risks with participants. The Committee felt this process was robust.
* (R.1.7) The Committee queried whether participants would be getting treatment from a registered health professional? Ms McKee confirmed they would.
* The Committee advised Ms McKee registers a Universal Trial Number (UTN).
* Ms McKee confirmed the summary of study results would be in lay language, or communicated verbally by interpreters.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* The Committee noted that in the first statement of the PIS, you don’t ‘stop’ rheumatic fever, as it has not happened yet. Ms McKee explained that this language was used purposely, to be accessible to the patient population. The Committee acknowledged this.
* The Committee commended the use of pictures.
* The Committee commended the use of 0800 numbers, citing the demographics being targeted as participants who would benefit from this decision.
* The Committee requested contact information on the PIS/CF, suggesting this could be for the nurse at the school.
* Include some information about what to do if there are any problems after the injection. For instance ‘after the injection, if you or your child notices anything concerning, please contact (appropriate person)’.
* Include information on the injection site, if appropriate.
* Use short study title on the consent form header.

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 age appropriate assent forms for younger participants (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* The purposes of study registration are to avoid duplication of studies and to foster the publication of key study outcomes. All clinical trials (this includes Phase I to Phase IV trials) should be registered with a World Health Organization (WHO)-approved register. (*Ethical Guidelines for Intervention Studies* *para* 5.42)

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

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| **3** | **Ethics ref:** | **14/NTB/118** |
|  | Title: | Prevalence and impact of genetic muscle disease (MD-Prev) |
|  | Principal Investigator: | Dr Alice Theadom |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 18 August 2014 |

Dr Alice Theadom, Dr Richard Roxborough and Ms Miriam Rodriquez 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 Kate O’Connor declared a conflict of interest. The Committee decided that Ms O’Connor will stay in the room but will not participate in the discussion or decision of the application.

Summary of ethical issues

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

* The Researchers explained that the study aims to identify the frequency and impact of genetic muscle disorders in New Zealand. The Committee queried if there was any existing literature on the prevalence of MD in New Zealand. The Researchers explained that earlier work on this topic was not of a high quality.
* The Committee confirmed that disclosing health information for screening was justified, as it is the only way to identify the patient population. The Committee suggested being clear about how potential participant information was sought.
* The Committee noted that some adults will not be able to consent. Please explain why?
* The Researchers explained that some of adult participants have severe MD which affects the nervous system, reducing competency. There will not be very many of these cases.
* The Researchers justified the subgroup’s involvement because they represent an important subset of people who experience the severe impact of disease. The Committee was satisfied that there was a need to include this group.
* The Committee confirmed that the legal representative would, in all cases, be providing consent for any adults, as a legal guardian. Welfare guardians or advance directives were suitable due to the observational nature of the research.
* The Committee added that participants must be given the opportunity to dissent, in which case they should not be enrolled.
* (R.7.1) Please explain how risks to researchers will be managed. The Researchers explained that risks posed to researchers out in the field were mitigated by having access to crisis team numbers, as well as having an awareness of participants who may have high levels of anxiety or depression. Referrals will not occur unless with the consent of the participants.
* The Researchers further explained that researchers out in the field will have an electronic tracking system which they must check in and out of, which is monitored externally. The Committee was satisfied with the response.
* The Committee confirmed written consent will be obtained before conducting the in-person interview or telephone assessment
* Please explain what the reasoning is behind using data for a larger study.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please review PIS/CFs for correct use of ‘you’ and ‘they’, currently inconsistent.
* The Committee noted that consent form ‘yes/no’ options should only be available if the bullet point is truly optional. Please review and remove the yes/no for those which are not optional.
* Simplify the child assent form language where possible.

Decision

This application was *approved* by consensus.

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| **4** | **Ethics ref:** | **14/NTB/121** |
|  | Title: | Hip Fracture Evaluation with ALternatives of Total HipArthroplasty versus Hemi-Arthroplasty (HEALTH) |
|  | Principal Investigator: | Mr William Farrington |
|  | Sponsor: |  |
|  | Clock Start Date: | 21 August 2014 |

Ms Carol Greene 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

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

* Ms Greene noted the timeframe for the study might take longer as it failed to take into account time to recruit patients.
* The Committee noted this research question was important, particularly as there is currently no consensus on best practice.
* Ms Greene confirmed that all patients that are individually asked to participate and then randomised.
* Ms Greene confirmed that only one surgeon would conduct all procedures. This would ensure data is consistent.
* Ms Greene confirmed that participant data would be potentially identifiable during the study.
* Will there be any local oversight? Ms Greene stated that the head of department would likely be involved in monitoring the study internally.
* The Committee noted the desirability of having monitoring, due to the fact that the surgeon is conducting all of the procedures. Please indicate who the CI selects.
* Please explain the data safety monitoring committee composition. Ms Greene stated she was not sure of the composition, adding it will be based in Canada.
* (R.1.7.1.1) The Committee noted this question should be ticked ‘Yes’. Due to incorrectly filling out the application questions about ACC have not been populated. The Committee noted the study is not sponsored. Please include information on whether the study is for the primary benefit of a sponsor, and if so whether this will impact access to ACC.
* (R.5.4) The Committee noted this question should be ticked ‘Yes’. Please explain the conflict of interest will be mitigated, in particular the consent process.
* The Committee queried if there would be Maori consultation. Ms Greene explained that Maori consultation is the responsibility of the CI.
* Please explain why there is an area for a legal proxy consent on the PIS/CF, where the study aims to only seek consent from adults who are capable of providing informed consent.
* The Committee would like confirmation on the vulnerability of the patient population.
* The Committee recommends reviewing the NEAC guidelines for observational studies, in particular the section on levels of identifiability of data. The Committee noted data is partially de-identified after the study.
* Please explain what travel payments are in place? Ms Greene stated reimbursement in the form of vouchers.
* The Committee requested that ethnicity data is made relevant to a New Zealand context, suggesting using the same categories as the New Zealand Census.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Pg. 4 of 6 ‘during the follow up visits ‘x-rays’ will be taken. Please include, in lay language, an explanation of amount of radiation these involve. Please make it clear what procedures are different or additional from standard practice.
* Please distinguish clearly between risks that are study related and risks that are general and would be part of standard practice.
* Please include a statement regarding the availability of ACC. Note that compensation **may** be available, not will.
* The Committee requested New Zealand statistics for the introduction – currently it is related to American or Canadian participants.
* Include information about how either option (procedure) is considered appropriate for you.
* Please revise and simplify technical language.
* Please review for New Zealand spelling.
* Please include New Zealand as a country who is conducting the study.
* Add a statement about informing GP of study involvement.
* The Committee suggested clarifying what travel expenses are covered, as current wording could be misleading.
* Please include a Maori contact number. The DHB should be able to assist with the appropriate person.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Provide further information on the recruitment process (*Ethical Guidelines for Intervention Studies para 6.2)*
* Provide details of the Data Safety Monitoring Committee’s composition and monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*
* Explain whether any of the participants will not be able to give informed consent, and elaborate on the vulnerability of the participant group *(Ethical Guidelines for Intervention Studies para 5.28*)
* Provide confirmation of internal monitoring contact *(Ethical Guidelines for Intervention Studies para 6.46).*

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

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| **5** | **Ethics ref:** | **14/NTB/122** |
|  | Title: | Generation of patient derived xenografts |
|  | Principal Investigator: | Dr B Lawrence |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 21 August 2014 |

Dr Ben Lawrence, Dr Bill Wilson and Dr Steve Jamieson and Dr Kate Parker 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.

Ms Kerin Thompson declared a potential conflict of interest, and the Committee decided to have Ms Thompson remain in the room but abstain from discussion of the application and the resulting decision.

Summary of ethical issues

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

* The Committee discussed the NET project and its relationship with the project grants.
* The Committee confirmed that the pathology department will retain samples for future diagnostic testing. If there is not enough to take a research sample then no sample will be taken.
* (P.4.6) Please explain why you are not collecting ethnicity data. The Researchers explained there is no relevant clinical question where ethnicity data would be beneficial, adding they are also not looking at germ line data. The Committee queried whether it could be useful to collect ethnicity data as it may help indicate if the samples are representative of New Zealand. The Researchers explained that they were not trying to produce any data that is representative of New Zealand, due to the limited sample size.
* The Committee discussed the blood line member signature on the CF. The Researchers explained that it allows people to sign based on a concept of collective ownership of tissue.
* The Committee confirmed the tissue bank the application and CF references will be Middlemore. The researchers explained the transition phase that Middlemore bank was in. The Committee added that the PIS should at least state that the tissue bank is in Auckland and provide further information once the transition is complete.
* The Committee confirmed 60 participants was feasible.
* The Committee commended the on-going Maori consultation.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* The Committee noted that consent form ‘yes/no’ options should only be there if it is truly optional, please review and remove the yes/no which are not optional. A statement will be appropriate.
* The Committee suggested adding an ACC statement, even in the very unlikely event that ACC would be needed. For instance:
* If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.
* 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.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **14/NTB/125** |
|  | Title: | Wraparound and the Theory of Change |
|  | Principal Investigator: | Ms Grace McNatty |
|  | Sponsor: | Psychology Graduate Research Fund |
|  | Clock Start Date: | 21 August 2014 |

Ms Grace McNatty 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

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

* The Committee noted the difficulty in reviewing without having a researcher present.
* The Committee noted that the children are highly vulnerable, adding there was not a ‘sense of care’ in the application.
* The Committee noted that children may be in CYFS care which raised the issue of who should provide consent. Please address this issue.
* Please explain the relationship between facilitator and team member?
* Explain how the statement ‘your name will not be used unless permission is given to the team leader’ will be implemented, noting this is not on the PIS.
* (A.6.2) states 10 participants, does this mean total or 10 families?
* Please explain what ‘limits of confidentiality’ exist, as mentioned in the application and protocol, yet there is no mention of this in the PIS.
* (P.3.3.1) please clarify what reimbursement is planned, noting the discrepancy of 20 or 5 dollars (of McDonalds vouchers).
* Currently states Maori can have a support person – is this going to be extended to all participants?
* On fidelity survey – please include ethnicity information as it reads in the New Zealand Census.
* The Committee noted that there were two independent people who would review the feedback. This was a good measure to address potential conflicts of interest between researchers and care providers. Please explain any other processes that mitigate conflict of interest between participants and researchers.
* Please explain how risks to researchers are mitigated, as researchers may be required to go to people’s homes.
* Please explain what process and follow up is in place for those participants who indicate they have significant problems, or show signs of distress. Furthermore the potential to raise these issues and referral processes in place should be included in the PIS and assent forms.
* Explain how the recruitment process conflict is mitigated, including who approaches who and how this will be managed.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please explain what ‘wrap around’ is, as it may not be clear to some participants.
* Assent form – please review and make it more inviting / friendly, considering the participant population it is going to.
* Include information for children to inform them that parents will be interviewed.
* Reword confidentiality statement in PIS/CF.
* Please explain participants can withdraw their data at any time.
* Please remove ‘input will be extremely valuable’ as this is overstated and could be coercive.
* Please break down assent statements on the CF further, so each element of the study is outlined.
* Please include opportunity to bring a support person for all participants.
* Please include information about what videoing at home does regarding issues relating to confidentiality.
* Please use terminology consistently ‘this family’, rather than ‘the’ family.
* Add health and disability advocates and HDEC contact information.
* Refers to yes/no questions, however they actually agree or strongly agree.
* Note that the first person and second person use is inconsistent between forms. Please review and consider who the participant is.

Decision

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

* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Please address all potential conflicts of interest and explain how these conflicts will be managed or mitigated *(Ethical Guidelines for Observation Studies 4.18)*

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

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| **7** | **Ethics ref:** | **14/NTB/126** |
|  | Title: | Clinical Study Protocol M13-550 |
|  | Principal Investigator: | Dr Daniel Ching |
|  | Sponsor: | AbbVie Pty Ltd |
|  | Clock Start Date: | 21 August 2014 |

Dr Daniel Ching was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* Dr Ching explained the study is similar to the DARWIN I studies submitted last year.
* Dr Ching confirmed SCOTT is pending.
* (R.3.1.1) what will happen to tissue if patients don’t consent to storage? Dr Ching stated that it will be discarded. The Committee asked that this is made clear, as storage is optional.
* (R.4.1.1) the Committee noted that participants will be informed about any unexpected findings (from blood tests). The Committee asked how this information will be followed up – explain the process is in place. Dr Ching stated that he will help manage findings by referrals and consulting with specialists and discuss the findings with the participants.
* Dr Ching explained how stopping criteria for the whole study would be communicated to participants.
* The Committee requests an independent DSMC.
* The Committee requested further clarity in the PIS that participants will stay on methotrexate and folic acid, as currently it is misleading, potentially indicating they will need to stop their main treatments to participate.
* (P.2.9) please confirm study results that are given to participants will be in lay language. Dr Ching stated he often gave a synopsis but was not sure whether this is in lay language. The Committee explained it was important to have a lay language summary. Dr Ching agreed.
* Dr Ching confirmed the patient card was contactable 24/7. Dr Ching added that participants have his cellphone number as well as his after-hours number re-directing to his home phone.
* The Committee queried the Maori consultation process. Dr Ching expressed difficulties as the process recently changed, but confirmed it was on-going.
* The Committee queried if the researchers planned to record ethnicity data. Dr Ching explained that he did not intend to, as there were only 12 participants. The Committee stated that from the DHB perspective it would be useful to collect ethnicity data, to know the variability in trial participation across ethnicities. This is a suggestion not a requirement.
* The Committee requested future applications had better lay language summaries.
* (P.4.1) please be clear about the benefits, include statistics if possible, or be clear that there is no specific Maori benefit.
* Revert back to HDEC commercial study insurance information.

*Suggested text:*

“Commercially sponsored” intervention studies:

If you were injured as a result of treatment given as part of this study, which is unlikely, you **won’t** be eligible for compensation from ACC. However, compensation would be available from the study’s sponsor, [x], in line with industry guidelines. We can give you a copy of these guidelines if you wish. You would be able to take action through the courts if you disagreed with the amount of compensation provided.

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.

* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please remove the need to withdraw in writing. Pg. 6 phamacokinetic, pg. 3 phamacogenetic, pg.4 of pregnancy and pg. 18 of main PIS.
* Please review information that is not relevant to a New Zealand context (pg.16 Main PIS – as required by US Law) (Phamaco kinetics pg.3 other countries law, references to the EU).
* Please address study title, it is very long. Use lay language.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Provide details of the independent Data Safety Monitoring Committee’s composition and monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*

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

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| **8** | **Ethics ref:** | **14/NTB/127** |
|  | Title: | Clinical Study Protocol M13-538 |
|  | Principal Investigator: | Dr Daniel Ching |
|  | Sponsor: | AbbVie Pty Ltd |
|  | Clock Start Date: | 21 August 2014 |

Dr Daniel Ching was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* Dr Ching confirmed he would follow up unexpected findings
* (P.2.9) please confirm study results that are given to participants will be in lay language. Dr Ching stated he often gave a synopsis but was not sure whether this is in lay language. The Committee explained it was important to have a lay language summary. Dr Ching agreed.
* The Committee queried the Maori consultation process. Dr Ching expressed difficulties as the process recently changed, but confirmed it was on-going.
* The Committee queried if the researchers planned to record ethnicity data. Dr Ching explained that he did not intend to, as there were only 12 participants. The Committee stated that from the DHB perspective it would be useful to collect ethnicity data, to know the variability in trial participation across ethnicities. This is a suggestion not a requirement.
* Dr Ching confirmed the patient card was contactable 24/7. Dr Ching added that participants have his cellphone number as well as his after-hours number re-directing to his home phone. (A.7.3) stated has been declined by international committee. Dr Ching explained this related to an Ethics committee in Australia not wanting to approve a phase II extended follow up. The Committee discussed this issue and concluded that provided there are no additional safety risks and the participants are informed there was no issue in principle.
* The Committee explained that this furthered the need for an independent DSMC.
* The Committee requested the following changes to the Participant Information Sheet and Consent Forms:
* Please remove the need to withdraw in writing.
* Please review information that is not relevant to a New Zealand context.
* Please address study title, it is very long. Use lay language.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Provide details of the independent Data Safety Monitoring Committee’s composition and monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*

This following information will be reviewed, and a final decision made on the application, by Mrs Kerin Thompson and Mrs Raewyn Sporle.

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| **9** | **Ethics ref:** | **14/NTB/129** |
|  | Title: | He Kura: Asthma in Schools - PHASE 1 (Guideline Development) |
|  | Principal Investigator: | Mrs Bernadette Jones |
|  | Sponsor: |  |
|  | Clock Start Date: | 21 August 2014 |

Mrs Bernadette Jones and Dr Tristram Ingham 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

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

* The Committee commended the application and noted the research question was worthwhile.
* Mrs Jones confirmed the University has support services in place.
* Mrs Jones confirmed the Co-ordinating Investigator has responsibility for reporting and data analysis.
* Mrs Jones confirmed the HRC made no suggestions to change their application. This may relate to an earlier HRC application which was not successful, which did have a number of recommendations. These changes were made in tandem with wider community consultation.
* The Committee noted that data generated from the study may be used was ticked no. The researchers explained that there will be a future, RCT, which will perhaps generate data, however with regards to this particular study the idea was that the resulting data would not be made available for other research. The Committee was satisfied with this response.
* Please explain whether assent will be written. The researchers explained that it would be verbal. Prior pilot studies found that it was difficult to seek written assent. It was more robust to speak to children and seek verbal assent.
* The Committee queried if the researchers document the invitation and resulting conversation? The researchers confirmed they do, adding they made it very clear that the children did not need to talk or participate.
* (P.3.1) a letter being sent to parents by the schools. The researcher stated that schools preferred to send out a letter, that the university is conducting research – this includes our contact details, so people can contact us to participate. We are generally guided by the schools and their preferred method.
* The Committee noted that typically any communications going to potential participants would receive HDEC approval before use. The researcher explained that there may be a varied approach across the schools.
* The Committee noted that that there was a need to ensure that any letters or notices were not coercive.
* The Committee suggested having researchers review any communications from schools if possible. The researchers explained that they did prefer to use the PIS/CF. The Committee agreed with the suggestion of drafting a guideline for schools to use that ensured the communications were appropriate.
* Committee queried if Kura Kaupapa will also be targeted? The researchers explained that they are being invited. Maori research institutions in Wanganui will translate the PIS/CF for Kura Kaupapa. The researcher acknowledged that her experience with Kura Kaupapa indicated they were very interested in participating.
* The toolkit will allow schools to use guidelines to help assist with asthma. There is no consistency with asthma guidelines currently.
* The Committee queried if there is a PIS/CF that discusses the focus group. The researcher stated that they offer one or the other. The Committee queried what occurs when a participant wants to take the focus group – do they sign the consent form for the interview? The researcher explained yes.
* The Committee stated the PIS should cover the focus group, and have this as an option on the consent form. This way the document covers both elements of the study. Include potential locations, explain flexibility, who will participate.

Decision

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

* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Please submit a template for communications coming from schools in relation to study participation.

This following information will be reviewed, and a final decision made on the application, by Mrs Kerin Thompson and Miss Tangihaere Macfarlane.

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| **10** | **Ethics ref:** | **14/NTB/130** |
|  | Title: | Beclomethasone dipropionate bioavailability study administered with and without concurrent oral charcoal |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Cipla Limited |
|  | Clock Start Date: | 21 August 2014 |

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

Potential conflicts of interest

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

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

Summary of ethical issues

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

* (R.1.6) the Committee noted that termination cannot be for purely commercial reasons. Researchers responded sponsor would only stop for safety reasons.
* The Committee noted the data is more reasonably considered potentially identifiable, rather than de-identified.
* The Committee noted the short study title is quite wordy, please revise.
* Committee noted the DSMC was good.
* Committee noted peer review was good.

Decision

This application was *approved* by consensus.

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| **11** | **Ethics ref:** | **14/NTB/131** |
|  | Title: | (duplicate) Developing a model of care for the long term follow-up of childhood cancer survivors |
|  | Principal Investigator: | Dr Rob Corbett |
|  | Sponsor: |  |
|  | Clock Start Date: | 21 August 2014 |

Christina Signorelli was not 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.

Christina Signorelli was present by teleconference for discussion of this application:

Summary of ethical issues

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

* Ms Signorelli explained that sending the questionnaires back indicates implied consent, adding some versions of the questionnaire did have an area for consent as requested by some Australian ethics committees. The Committee stated that written consent is desirable and it would be straight forward to obtain as the participants were already sending back a written document. The committee felt there was no justifiable reason to not seek consent in writing.
* The Committee noted there is consent for the interviews, so there is a disparity where the participants are consenting for one element but not the other.
* Ms Signorelli clarified that declining participation is assumed by non-response – the committee noted that a written decline option on original package sent out would reduce the follow up for the sites as well as potentially reducing follow up that may cause distress or additional inconvenience to participants.
* Ms Signorelli agreed they will have consent in writing.
* The Committee asked if the referral specialists in New Zealand were aware of the study and the potential referrals. Ms Signorelli clarified that the referral specialists were not aware of the study but were available and used for similar situations on a daily basis.
* The Committee requested that they make sure participants are able to get medical or psychological follow up in New Zealand as proposed, noting the different referral protocols between New Zealand and Australia that impact accessibility to treatment.
* What is relationship between Australian Co-ordination Centre and New Zealand sites? Ms Signorelli explained that the New Zealand sites are primarily to contact potential participants, by having investigators access their database of eligible patients. It is also to ensure easier contact for participants in New Zealand. Information will be released to Australia. This is contingent upon ethical approval. Committee note that the release of identifiable patient data to Australia is contingent on being in accordance with local DHB policy and that local research office approval must be granted. The committee’s view is that this information is afforded greater protection by having the NZ sites only access this information and send out information from within their NZ organisation. Ms Signorelli confirmed this was possible based on local requirements.
* There are also follow up calls after questionnaires are sent out.
* Ms Signorelli added that the New Zealand investigators also allow us to implement the follow up for emotional or other care.
* Is the New Zealand site funded? Ms Signorelli confirmed it was, by Kids Cancer Alliance.
* What are the funding arrangements and triggers for releasing funding? Ms Signorelli stated there is 100 thousand dollars per year for 3 years for the entire trial, adding there were no direct costs expected from the NZ sites to run the study. All questionnaires or printing are done in Australia. Researcher time is funded.
* The Committee queried if there is a cap on the researcher time that can be billed to Sydney? Ms Signorelli stated there is no cap at the moment but felt that such information would be useful. The committee noted this payment arrangement has ethical implications and in particular when there is no research agreement it leaves many open questions.
* Ms Signorelli confirmed that the New Zealand Co-ordinating Investigator and all other co-investigators are investigators on the HDEC application for each site.
* The Committee queried, beyond identifying the database do New Zealand investigators have any role? Researcher stated only follow up calls and or ‘general tasks’.
* Please explain the process for adopting recommendations that come from consultation.
* Further consideration of impact on Maori or potential benefit for Maori.
* Please peer review PIS/CF and questionnaires in New Zealand for Maori spelling and context before printing.
* PIS states that complaints will be directed to a “Maori DHB’. There is no such organisation, please amend PIS to include appropriate complaints contact.
* The Committee queried why the questionnaire included questions about parents drinking and other lifestyle habits. Ms Signorelli responded that they wanted consistency, referring to other questionnaires that had this information. Furthermore, for analysis purposes, we wanted to see whether these health behaviours informed health outcomes and survivor rates.
* The Committee queried if health behaviours of parents would relate to health behaviours of the children. The researcher confirmed this was one general question – that they have a role to play.
* The Committee suggests including information on why these questions are being asked, and noted that it was clear in the PISCF that they are optional.
* The Committee queried why the clinical director was going to send letters when they weren’t co-investigators on the trial – please elaborate.
* Insurance certificate uploaded pertains to Commonwealth of Australia only. Please provide details of insurance relevant to NZ conduct.
* The Committee noted the PIS/CF was not relevant for a New Zealand patient population.
* (A.1.4) please confirm New Zealand start date.
* (A.1.5) please provide some relevant NZ data to people lost to follow-up.
* A7.1 should indicate = yes as previously declined by NTA.
* (R.5.4) Currently answered ‘No’. The Committee noted this might be incorrect because investigators are from an oncology setting. Because the answer was answered ‘No’ the following conflict of interest questions have not generated. Please answer how the potential conflict of interest between researchers and participants will be mitigated.
* (R.2.5) Please note that health data derived from the study must be stored for a minimum of 10 years according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html). For participants under 16 years old please retain for 10 years after participant turns 16.
* (R.8.1) PIS does not outline questionnaire themes.
* Whole Maori consultation section is poor. Expand on issues, questions on statistics for Maori.
* HRC guidelines state that Maori consultation is appropriate, because there will be Maori participants. The Committee notes some consultation has occurred.
* Please explain what response was to Maori consultation and how recommendations are to be implemented following reviews.
* Has there been any analysis between barriers of accessing long term survivor issues and ethnicity?
* Justify why not obtaining written consent, and are going through implied consent. There is no reason to not seek consent as the responses are being sent back.
* The researcher explained that the study is controlled and centrally co-ordinated in Australia. The NZ sites will perform the study but have the data submitted to Australia.
* The Committee noted that the parents are being invited to provide consent and receive information for young adults aged 16-18 years old. This is problematic for over 16 year olds who may legally consent for themselves. . The parents can be involved in the consent process if the young adults consent to their involvement.
* The interview scripts refer to Australia. There are technical elements in the script that are not explained clearly and in simple language, particularly around new technologies. Please confirm how ‘off script’ researchers will be able to go in order to aid individual understanding
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Add local investigator information.
* Add ACC information, please utilise HDEC template wording.

Decision

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

* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Please address all potential conflicts of interest and explain how these conflicts will be managed or mitigated *(Ethical Guidelines for Observation Studies 4.18)*
* Evidence of free and informed consent by a participant or authorised third party should ordinarily be obtained in writing *(Ethical Guidelines for Observation Studies* 6.26)
* Some studies may involve interviews or questionnaires that are intrusive and may cause distress. In this case, it is appropriate to seek participants’ prior consent by forewarning them of the potentially distressing nature of participation (*Ethical Guidelines for Observation Studies* 6.29)
* Relevant Insurance certificate to be provided.
* Please expand on potential cultural issues and advise how Maori consultation recommendations received to date will be implemented in study.

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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| **12** | **Ethics ref:** | **14/NTB/132** |
|  | Title: | A study to evaluate the use of GS-4774 in combination with TenofovirDisoproxil Fumarate (TDF) in subjects with HBV who are currently not on treatment |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 21 August 2014 |

Ms Kerry Walker and Prof Ed Gane 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

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

* This is a study to determine whether a new vaccine against hepatitis B will help control hepatitis B infection. In this study, the vaccine will be combined with an oral antiviral treatment which is already approved for use in New Zealand
* This method attempts to produce rapid suppression of the virus, allowing earlier stopping of treatment, which is beneficial for the patient.
* The Committee asked whether there is any need to monitor bone density? Prof Gane explained that based on data from patients with hepatitis (rather than HIV) there was no need. The Committee was satisfied with this response.
* Please provide information on the composition of the DSMC. Prof Gane confirmed they are independent of the study team, who would probably be comprised of specialists from various countries. The researcher confirmed that they can get a list of members, or at least a number.
* Committee confirmed Maori consultation is in process.
* The Committee clarified that 20 participants will be recruited from New Zealand.
* (P.3.3.1) Prof Gane confirmed the payment figure in the application is incorrect. The information in the PIS/CF is correct.
* Please include information on returning medications. Prof Gane explained that this information is usually verbally discussed in detail with pharmacist. The Committee was satisfied with this process.
* Please remove the need to revoke consent in writing. This should be able to be done verbally.
* Pg. 20 of application states human tissue will be disposed after analysis however Pg. 21 of main information sheet (third paragraph down) includes text in regard to data and samples being used for future research. Please clarify that future research is optional.
* Prof Gane explained that if participants do not consent for future storage, which is optional, then their samples will be destroyed.
* The Committee noted the PIS currently reads that data and samples ‘may also be used for additional or unanticipated…’. Please remove this from the PIS, as it is not relevant to the main study.
* Is the number on the alert card 24/7 7 days a week accessible? Prof Gane confirmed that it is, and it is also 0800, and after hours it goes to a study doctor.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* The Committee queried whether the wording on the table could be simplified, adding that the table was a good addition.
* Please change (Pg 11) 9% of patients experiencing nausea into a more meaningful number, e.g about 1 in 10 or 9 out of 100
* Middle paragraph, 4th line up, ‘payment for participation’. Please reword ‘you get no legal rights’.
* 4th paragraph down on pg.21 – regarding access to health information until study is over. The Committee noted there is a right to correct health information. Re-write to be clear that participants can access their health information during the study.
* Please include general HDEC information.
* Please include information on informing GP of significant results, but noted that this would not cover drug screening.

Decision

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

* Provide details of the Data Safety Monitoring Committee’s composition and 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*).

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

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee discussed the SPLIT Trial (0.9% Saline vs. Plasma Lyte 148 for Fluid Resuscitation in Intensive Care Trial) complaint. Dr Young was present via teleconference for discussion of this complaint.

* Dr Young confirmed the trial is nearly complete. The study will finish on 10 October 2014.
* Dr Young confirmed there are 1796 patients enrolled.
* The Committee believes the researchers have conducted the trial as it was approved.
* The Committee queried how many are cardiac surgery patients? In Christchurch there are 370 patients of which 90 who are cardiac surgery patients. Some elective, some emergency. Auckland has had 365 enrolled with none as cardiac surgery patients. Wellington had 490 enrolled, with between 20-30% being cardiac surgery patients.
* Dr Young noted all patients at one Auckland site have had information provided before surgery, with 2 out of 600+ opting out before surgery.
* The Committee noted that pre-planned cardiac surgery was something that was managed differently at each site.
* The Committee queried if there is a difference in the methods of identifying people within ICU, i.e. are they all approached in the same way. The researcher confirmed they are.
* Dr Young explained the purpose of the study is to test hospital policy rather than individual patient therapy.
* Dr Young explained the hospital policy dictates the treatment the patient gets.
* The opt out patients only opt out of collection of study data, the treatment is the same regardless of study participation.
* The argument is that all participants are consented, as the study relates to the data, not the treatment. Therefore even if some places did consent prior to being in ICU, it would sometimes be more appropriate to approach them after surgery when they are in a better position to make an informed choice.
* The Committee confirmed that all collected data only enters the study data set if consent is given for use of data.
* The Committee noted that consent should be obtained upfront wherever appropriate and acceptable.
* Dr Young raised the issue of Dr Shaw denying participants of entering into an ethically approved study. Dr Young suggested this was unethical, both to participants as well as potentially undermining the validity of the study. The Committee noted this.

The Committee decided that on-going ethical approval remains valid.

1. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| --- | --- |
| **Meeting date:** | 30 September 2014, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Auckland |

The following members tendered apologies for this meeting.

* Mrs Phyllis Huitema gave tentative apologies.

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 5.35pm