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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 02 May 2017 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm  12:10pm | Confirmation of minutes of meeting of 04 April 2017  General Business |
| 12:30pm | New applications (see over for details) |
|  | i 17/NTB/65  ii 17/NTB/66  iii 17/NTB/68  iv 17/NTB/70  v 17/NTB/71  vi 17/NTB/72  vii 17/NTB/76  viii 17/NTB/77 |
| 4:00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2015 | 01/07/2018 | Present |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Phyllis Huitema | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Apologies |
| Mrs Kate O'Connor | Lay (ethical/moral reasoning) | 14/12/2015 | 14/12/2018 | Present |
| Dr Nora Lynch | Non-lay (health/disability service provision) | 24/07/2015 | 24/07/2018 | Present |
| Mrs Leesa Russell | Non-lay (intervention studies), Non-lay (observational studies) | 14/12/2015 | 14/12/2018 | Present |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Mrs Phyllis Huitema.

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 4 April 2017 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **17/NTB/65** |
|  | Title: | People's experiences in the year after having tests for a Cardiac Inherited Disease. |
|  | Principal Investigator: | Ms Claire O'Donovan |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 20 April 2017 |

Ms Claire O’Donovan and Associate Professor Elizabeth Broadbent were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates the burden on families of Cardiac Inherited Disease (CID) and children’s and caregiver’s experiences of CID.
2. Participants will be given a questionnaire when they attend a clinic in Auckland or Waikato. Participants and their families will complete three other questionnaires either online or through the post.
3. The questionnaires will be completed by parents and the children. They will focus on the children’s depression and anxiety symptoms and the parent’s perception of their child’s quality of life.

Summary of ethical issues (resolved)

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

1. The Committee asked about the efficacy of the medication for CID. The Researcher explained that medication is effective but there are issues with compliance. To be effective compliance must be very high and different groups, such as teenagers, have notably poor compliance.
2. The Committee noted that children in the study will be seven years old or more and asked who would complete the questionnaire. The Researcher explained that children will complete the anxiety and depression questionnaire and that the parents will complete the quality of life assessment with the child.
3. The Committee asked what would happen if a parent who does not have CID brought a child to the clinic. The Researchers explained that both parents are tested in the event of CID diagnosis and so they will be familiar with the clinic and the condition.
4. The Committee asked what would happen if children are unable to complete a questionnaire on their own, as parents cannot assist without biasing results. The Researcher explained that they will assist the children with understanding the questions.
5. The Committee were concerned that a sensitive questionnaire was to be completed in a public space. The Researchers agreed and explained that there will be opportunity to take the questionnaire home and mail it in.
6. The Committee asked how long participation will last. The Researcher explained 1.5 years and that there will be opportunity for consent sought for ongoing participation from those who turn 16 during this time.
7. The Committee asked why the Researcher was not seeking participant’s consent for their GP to be informed that they are in the study. The Researcher explained that they will not inform the GP unless significant risk factors are identified
8. The Committee queried what would happen if significant risk factors were identified. The Researcher explained that they will check with participants in the first instance before informing GPs.
9. The Committee asked if the Researcher had a safety protocol for entering homes. The Researcher confirmed that they did.
10. The Committee stated that the Māori consultation included a request that some questions be reworded and asked if this had happened. The Researcher confirmed that they had changed some of the wordings to be more appropriate.

Summary of ethical issues (outstanding)

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

1. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
2. The Committee requested that a participant information sheet and consent form be created for children down to 6 years old.
3. Please provide the clinic poster for review.

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

1. Please check that each information sheet is clear about what who and what it is for.
2. Please provide a PIS and consent form for young children
3. Please include an area on the assent forms for the children to record their assent.
4. Please remove the statement that the questionnaire must be done on the day.
5. Please emphasise that participants can take the initial questionnaire home to complete.
6. Please make it clear in the information sheet that there are circumstances in which the a participant’s GP will be informed.
7. The Committee requested that the protocol be updated so that patients are informed that they may be approached for research participation when they attend their appointment.
8. Please include that the Researcher is a PhD student.
9. Please replace the term ward with a more appropriate term.
10. The Committee asked what age groups would be completing the questionnaires. The Researcher explained that ages 8 to 18 will complete the questionnaires. The Committee suggested the Participant Information Sheet be amended to reflect that children are defined as under 18.

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 an assent form that is suitable for younger participants.
* Please provide the recruitment poster for review.

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

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| **2** | **Ethics ref:** | **17/NTB/66** |
|  | Title: | Recovery of movement and sensation after stroke |
|  | Principal Investigator: | Associate Professor Cathy Stinear |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 20 April 2017 |

Associate Professor Cathy Stinear, Ms Marie-Claire Smith, and Mr Ben Chong were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates how patients with weakness or sensory loss recover after a stroke.
2. Up to 80 adults will be recruited and observed for 6 months post-stroke.
3. Patients who cannot provide informed consent will not be approached for participation.

Summary of ethical issues (resolved)

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

1. The Committee queried the rationale for the study. The Researcher explained that there had been previous research in this area and this had stimulated the interest for further study.
2. The Committee asked how screening for participants would work. The Researcher explained that in depth assessment would be performed by clinicians in order to assess suitability. Independent clinical judgement will inform recruitment, not researcher judgement.
3. The Committee noted that ADHB therapists will be directed to record information that is not normally collected and queried what would happen if therapists failed to comply. The Researcher explained that this information is not essential and they have strategies in place to help ensure that the information is collected.

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 asked how consent would be recorded from participants who could not sign. The Researcher explained that they would have someone else sign on behalf of the patient. The Committee stated that this was not acceptable as it was close to proxy consent and requested that patients be allowed to simply make a mark.
2. The Committee noted that the participant information sheet implies some therapeutic benefit from study participation and that this may be considered coercive and asked that this section be rewritten to explain that the project is research and there may not be any direct benefit from participation.
3. The Committee noted that four of the six grant reports were critical or had concerns. Please explain how these concerns have been addressed.

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

1. Please add claustrophobia to the risks section in relation to MRI
2. Please explain that this is research and that there may be no direct benefit.
3. Please make room for participants to either sign or make a mark to indicate their consent.
4. Please remove the signature block for other people signing on behalf of participants.
5. Please include that participants will get appropriate support in the case of incidental findings from the MRI scan.
6. Please change the HDEC reference to correctly state the name of the reviewing committee and the study reference.
7. Please add pregnancy to the exclusion section.
8. Please acknowledge the tapu of the head.
9. Please consider adding a picture of each procedure or test to help explain what will happen.
10. Please standardise the contact details across the information sheets and consent forms.
11. Please add contact details for the HDEC secretariat.
12. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. 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 *provisionally approved* by consensus, subject to the following information being received.

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please explain how the questions and concerns raised by the grant reviewers were addressed.

This following information will be reviewed, and a final decision made on the application, by Ms Tangihere Macfarlane and Dr Nora Lynch.

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| **3** | **Ethics ref:** | **17/NTB/68** |
|  | Title: | Fish oil in gout |
|  | Principal Investigator: | Professor Lisa Stamp |
|  | Sponsor: |  |
|  | Clock Start Date: | 20 April 2017 |

Professor Lisa Stamp was unable to attend for discussion of this application.

Potential conflicts of interest

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

Dr Nora Lynch declared a conflict of interest related to this application. It was decided that she could remain and participate in the discussion

Summary of Study

1. The study investigates the effects of fish oil on gout symptoms and serum urate levels.
2. 40 participants will be recruited and randomised to receive fish oil or a no fish oil comparator for 6 months.

Summary of ethical issues (resolved)

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

1. The Committee noted that the aim of the project is unclear and that the project reads as a safety study but could also be understood as a therapeutic trial.

Summary of ethical issues (outstanding)

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

1. Please clarify if the study has a sponsor and who the sponsor is.
2. Please explain how Māori cultural beliefs about use of tissue will be respected.
3. The Committee stated it is unclear if standard care is being withheld from participants as the researchers say they are withholding standard care but the exclusions section of the PIS explains that participants are ineligible for standard care as they are subclinical.If standard care is being withheld from some participants for up to 6 months eg not escalating urate lowering therapy to reach target urate of < 0.36mmol/l, please explain why this is justified.
4. Please explain the purpose of the rescue plan.
5. The Committee noted that, depending on the design of the project, SCOTT review may or may not be required. The Committee requested the researcher seek formal assurance that SCOTT review is not required and provide this documentation.
6. Please provide details of the Data Safety Monitoring plans or formal safety protocol for the study. *(Ethical Guidelines for Intervention Studies para 6.50).*
7. Please explain how side effects will be managed.
8. If SCOTT review is not required please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1)
9. The Committee stated that the final questionnaire on palatability is not sufficient and that the researchers must use a validated scale.

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

1. The Committee requested a separate participant information sheet and consent form be created for Future Unspecified Research (FUR.) All information relating to FUR needs to be separate from the main study information sheet. Likewise a second consent form should be used for consent for FUR.
2. Please clarify where bloods will be sent for testing, which bloods will be kept and which destroyed, and when tissue will be sent for FUR.
3. .Please explain that there will be no karakia when disposing of tissue sent overseas.
4. Please remove or clarify the statement about withdrawal and ongoing use of tissue.
5. Please remove the sentence that begins “I really hope.” from the recruitment letter.
6. Please explain how assessment of tophi number and size can be performed on telephone interviews.
7. Please explain that some participants may not have their urate lowering therapy increased at the usual rate during the study

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)
* Please clarify if SCOTT review is required and provide formal documentation of this.
* Please provide details about the study sponsor.
* Please clarify ambiguities relating to standard care and the study design.
* Please use a validated palatability scale.
* Please provide details of the Data Safety Monitoring plans or formal safety protocol for the study. *(Ethical Guidelines for Intervention Studies para 6.50).*
* Please explain what procedures are in place to manage side effects.

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

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| **4** | **Ethics ref:** | **17/NTB/70** |
|  | Title: | The SANTA Trial: Shoulder Arthroplasty Necessitating Tranexamic Acid |
|  | Principal Investigator: | Dr Ryan Gao |
|  | Sponsor: |  |
|  | Clock Start Date: | 20 April 2017 |

Dr Ryan Gao was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates the superiority of oral versus intravenous administration of tranexamic acid (TXA), a drug to prevent bleeding, in a population of patients undergoing shoulder replacement surgery.
2. 80 participants will be recruited and randomised to either receive oral or intravenous TXA before surgery. Both doctors and participants will be blinded to which form a patient has received.
3. To date no study has been done to determine the superiority of either method of administration in shoulder replacement surgery, with the decision being at the surgeon’s discretion.

Summary of ethical issues (resolved)

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

1. The Committee asked if a statistician had been involved with the study design. The Researcher explained that a co-investigator is a statistician and had helped design the project.
2. The Committee noted the application mentions that practice may be changed if one method is shown to be superior and asked if the project is an equivalence study. The Researcher explained that it is a superiority study.
3. The Committee asked about the safety and termination procedures for the study. The Researcher explained that they will stop if safety concerns are raised or if superiority is demonstrated during the course of Data Safety Monitoring Committee review.
4. The Committee asked how blinding will be maintained. The Researcher explained that all patients will receive an IV and tablet; one will be a placebo and the other the study drug.

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 asked that an update on the recruitment for the data safety committee or the details of the committee. *(Ethical Guidelines for Intervention Studies para 6.50).*
2. Please use Statistics New Zealand's ethnicity classifications when collecting ethnicity data to ensure the options available are suitable for New Zealand participants. These classifications are: New Zealand European, Maori, Samoan, Cook Islands Maori, Tongan, Niuean, Chinese, Indian, Other (such as Dutch, Japanese, Tokelauan)
3. The Committee requested that a lay summary of the project be provided to participants on completion, not an academic journal article.
4. The Committee asked if colourblindness is screened for as part of standard care. The Researcher explained that it is not. The Committee suggested that a colourblindness test be included as part of the study and that the PIS be updated to explain that standard care does not normally involve a colour vision assessment.
5. Please provide evidence of favourable independent peer review of the study protocol.The Committee recommended that the Researcher seek peer review from an academic orthopaedic surgeon. (*Ethical Guidelines for Intervention Studies* Appendix 1)
6. Please include the plans for analysis and specify what the primary outcome measure is, in the study protocol.

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

1. Add that a colourblindness assessment is not part of standard care.
2. Please include that there is no data on the benefits or risks of oral TXAin shoulder replacement.
3. Please make it clear that all participants will receive active treatment.
4. Please describe what forms the placebo will take.
5. Please ensure that the exclusions section matches the exclusions listed in the study protocol.
6. Please remove all tick boxes from the consent form except for those choices where answering no would not exclude a participant from the study.
7. Please include that participant’s GPs will be informed of their participation.
8. Please make sure that paragraph one of the PIS does not imply a direct benefit to participants from their participation.

Decision

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

* Please use Statistics New Zealand's ethnicity classifications when collecting ethnicity data to ensure the options available are suitable for New Zealand participants. These classifications are: New Zealand European, Maori, Samoan, Cook Islands Maori, Tongan, Niuean, Chinese, Indian, Other (such as Dutch, Japanese, Tokelauan)
* 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 details of the Data Safety Monitoring plans and the status of the data safety monitoring committee. *(Ethical Guidelines for Intervention Studies para 6.50).*
* Please provide evidence of favourable independent peer review of the study protocol. The Committee recommended that the Researcher seek peer review from an academic orthopaedic surgeon. (*Ethical Guidelines for Intervention Studies* Appendix 1)
* Please submit a revised protocol that specifies the primary outcome and includes plans for data analysis.

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

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| **5** | **Ethics ref:** | **17/NTB/71** |
|  | Title: | Staphylococcus aureus prevalence |
|  | Principal Investigator: | Dr Ayesha Verrall |
|  | Sponsor: |  |
|  | Clock Start Date: | 20 April 2017 |

Dr Ayesha Verrall 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 study investigates the prevalence of staphylococcus aureus in different populations in Wellington.
2. School children will be recruited from eczema or allergy clinical outpatients at Wellington Hospital or from volunteers from two intermediate schools.

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 asked that the Researchers provide the procedures for when the bacterium is detected.
2. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
3. The Committee stated that samples are potentially identifiable as they are linked to NHI and therefore they can be withdrawn by participants.
4. The Committee asked what the medical obligations are to check for MRSA . Please explain the processes around this.
5. Please provide suitable PIS/CF forms for medical students who are being tested.
6. The Committee were concerned about the possibility of coercion to participate if intermediate school students had been or might be taught in the future by the co-researcher. This could be avoided by only recruiting from classes he has not and will not teach.

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

1. Please include that the researcher will access health records in the PIS.
2. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whānau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
3. Please check the statement about the pain associated with swabbing for appropriateness.
4. Please add Māori cultural contact, HDEC, and Health and Disability Commissioner contact details.

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 suitable consent and assent forms for medical students and 3 to 5 year olds respectively.
* Please explain the procedures around identifying participants who are carriers and what will happen to make sure they are not a risk to others.
* Please explain the medical obligations around a positive MRSA swab.

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

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| **6** | **Ethics ref:** | **17/NTB/72** |
|  | Title: | PEARL-CF |
|  | Principal Investigator: | Professor Andrew S Day |
|  | Sponsor: | University of Otago Christchurch |
|  | Clock Start Date: | 20 April 2017 |

Professor Andrew S Day 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 study is a double blind, randomised controlled trial that compares the effects of probiotics on intestinal bacteria and inflammation in children with cystic fibrosis.
2. Approximately 14 participants will be recruited in New Zealand.

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 asked that it be clarified if children who are breast fed will be excluded from the study. If they are then please clarify in the PIS and if not then please clarify how they will be managed.
2. The Committee stated that withdrawal of consent does not need to be in writing.
3. Please provide a separate future unspecified research (FUR) information sheet and consent form and remove all mention of FUR from the main PIS/CF.
4. Please clarify if samples can be withdrawn from FUR.
5. Please clarify if participants still get Creon.
6. Please explain where samples will be sent for FUR and include the information in the FUR PIS.
7. The Committee suggested that transportation costs be reimbursed as parents will have to deliver samples.
8. Please clarify if the probiotic is available in New Zealand.
9. Please provide evidence that SCOTT review is not required.

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

1. Please localise the language in the PIS by removing foreign slang.
2. Please remove any reference to withdrawal needing to be in writing.
3. Please add details for parental support and cystic fibrosis support to the PIS.
4. Please remove that cystic fibrosis shortens life expectancy from the control PIS and clarify whether controls are to be recruited in New Zealand.
5. Please make it clear that children will have measurements taken and there will be questionnaires when parents visit the clinic.
6. Please add contact details for Māori cultural support and contact details for the Health and Disability Commissioner.
7. Please remove the long list of participating Australian physicians from the first page of the PISC. Only the Australian PI and New Zealand investigators are necessary.
8. Please list Prof Day on the PIS as the first contact.
9. Please remove reference to Sydney Children’s Hospital ethics committee approval and replace with HDEC.
10. Please clarify that one arm of the study will receive no probiotics for 15 months. All periods of no probiotics need to be clearly communicated.

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 FUR PIS and CF.
* Please clarify if the probiotic is available in New Zealand.
* Please provide evidence that SCOTT review is not required.
* Please clarify if samples can be withdrawn from FUR.
* Please clarify if participants still get Creon.
* The Committee asked that it be clarified if children who are breast fed will be excluded from the study. If they are then please clarify in the PIS and if not then please clarify how they will be managed.

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

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| **7** | **Ethics ref:** | **17/NTB/76** |
|  | Title: | Tonsil Analysis of Amoxicillin and Clavulanic Acid Study (TAACS) |
|  | Principal Investigator: | Dr James Johnston |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 20 April 2017 |

**CLOSED**

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| **8** | **Ethics ref:** | **17/NTB/77** |
|  | Title: | Cognitive Impairment Pathway Study |
|  | Principal Investigator: | Dr Michal Boyd |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 20 April 2017 |

Dr Gary Cheung and Associate Professor Michal Boyd were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates the effectiveness of the Cognitive Impairment Pathway (CIP) that was rolled out by Counties Manukau DHB compared with traditional dementia care.

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 stated that they were unclear if the CIP is being rolled out as part of standard care or for the purposes of the study.
2. The Committee stated that it is not possible for HDECs to approve an application unless it is consistent with New Zealand law, including the right not to be subjected to medical or scientific experimentation without that person's consent (section 10 of the New Zealand Bill of Rights Act 1990). Research involving participants who are not competent to consent is inconsistent with the Bill of Rights unless it is undertaken in accordance with Right 7 (4) of the of the Code of Health and Disability Services Consumers’ Rights. In addition to requirements regarding ascertaining the views of the consumer and other suitable persons (forms consistent with this aspect are currently included in this application), Right 7(4) of the Code requires that any health services provided without the informed consent of the consumer must be in the best interests of the consumer. This means that there must be some benefit, or potential benefit, to the participant beyond what they would receive if they were not participating in the research. The Committee were not satisfied that, as an observational study the criteria for Right 7.4 were justified.
3. The Committee stated that, as presented, there did not seem to be clinical equipoise between the arms of the study.
4. The Committee stated that they had concerns for the studies’ scientific validity due to the lack of randomisation.

Decision

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

* The Committee felt that the study, as presented, did not have good scientific design or justification for its methods. (*Ethical Guidelines for Intervention Studies para 5.5*)
* The Committee felt that the study, as presented, did not meet the Equipoise Standard. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 5.18 – 5.21*).
* The Committee stated that it is not possible for HDECs to approve an application unless it is consistent with New Zealand law, including the right not to be subjected to medical or scientific experimentation without that person's consent (section 10 of the New Zealand Bill of Rights Act 1990). The Committee were not satisfied that the criteria for Right 7.4 were justified.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 06 June 2017, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

1. **Problem with Last Minutes**

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

The meeting closed at 4:00pm.