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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 01 July 2014 |
| **Meeting venue:** | Rydges Auckland, 59 Federal Street Cnr Kingston St, Auckland |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 03 June 2014 |
|  | New applications (see over for details) |
| 12.00pm  5.00pm | i 14/NTB/75  ii 14/NTB/74  iii 14/NTB/77  iv 14/NTB/78  v 14/NTB/80  vi 14/NTB/81  vii 14/NTB/86  viii 14/NTB/87  ix 14/NTB/88 |
| 5.05pm | General business:   * Noting section of agenda |
| 5.20pm | 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 | 01/07/2014 | 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 | 01/07/2014 | 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 12.12pm and welcomed Committee members. The Committee welcomed Ms Sarah Coates, an observer.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 3 June 2014 were confirmed subject to the following amendments:

The Secretariat informed the Committee that [14/NTB/64](https://nz.ethicsdatabase.org/applications/applicationmeeting.aspx?id=99481) had been amended to remove the provisional approval requirement to “include on both PIS that the CGM device has not been registered for use in New Zealand.” This is because there is no regulatory body to register with in New Zealand.

## New applications

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| **1** | **Ethics ref:** | **14/NTB/75** |
|  | Title: | Tolerability comparison of small caliber oesophagogastroduodenoscopy vs. conventional oesophagogastroduodenosocpy |
|  | Principal Investigator: | Dr Alexander Huelsen |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 June 2014 |

Dr Alexander Huelsen 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.

* The Committee asked the researcher to explain the study design, and whether there was a comparative arm with standard practice.
* Dr Huelsen stated that it is designed as a tolerability study. Dr Huelsen explained that there seems to be a cultural variant as to whether the study procedure is tolerated without sedation. We would like to see if it is tolerable in New Zealand. The study aims to clearly show that the intervention does not require sedation. This would inform a larger study which would compare the costs associated with sedated versus not sedated in an effort to change standard practice.
* Dr Huelsen stated no study has compared the three different procedures and their tolerability without sedation, adding that the procedures are well known to be safe and feasible.
* Dr Huelsen explained that the study is important as if it shows that sedation is not necessary it reduces costs. By not sedating patients there is no requirement to have someone accompany patients to the procedure, reduces the clinical support required and would enable participants to drive after the procedure.
* The Committee queried what standard treatment was. Dr Huelsen stated it was standard practice to sedate. The Committee noted this was problematic as it was a comparative study, comparing sedated verses not, that did not have participants compare with standard treatment.
* Dr Huelsen explained it is difficult to ask patients how it felt while sedated as they don’t remember.
* The Committee suggested participants who are undergoing standard treatment could provide a comparative arm, without having any additional procedures. The participants could consent to a similar patient information sheet, yet undergo standard treatment, while filling out the questionnaires.
* Dr Huelsen responded that this study was only concerned with tolerability, but acknowledged a later study would look into differences in terms of cost and experience between sedation and not sedated.
* The Committee clarified that this study is a feasibility study as it aims to show that participants can tolerate this intervention to assess whether a larger study can be run to compare sedated verses not and the resulting costs and gains associated with this.
* The Committee queried if the sample size of 30 was sufficient for a feasibility study. Dr Huelsen explained that there had been consultation with statisticians to determine that the study had enough power and was able to be completed. The Committee requested the further peer review and evidence of consultation with the statistician.
* The Committee queried if the study had been through the Awhina Research Office at Waitemata DHB. The Committee suggested that Dr Huelsen consults with the research office.
* R.1.5 is the data safety monitoring independent? Dr Huelsen explained there was no independent oversight. The review body is to look at any adverse events. Dr Huelsen added that the sample size is small and the treatment is a global standard of care, as well as having a good safety profile.
* The Committee queried if there was any specific training to use the small calibre procedure, and if it was used at the site. Dr Huelsen explained that the small calibre is used in special cases where it is appropriate. It is not typically used for outpatient examination, and there is no official training.
* The Committee would like to see stopping rules with respect to terminating the study.
* The Committee suggested an independent monitor could be appropriate.
* Dr Huelsen explained that this is a normal standard procedure and did not think that such measures were required. Please confirm what standard practice is.
* The Committee noted that the participants are healthy individuals. The Committee queried if there were concerning safety trends, or a consistent reporting of the procedure being intolerable, would it constitute a stopping rule?
* Dr Huelsen responded that this was not likely with 30 participants.
* R.5.6 The application states they will recruit medical students, health care staff within the DHB. Please explain how the potential conflict of interest will be managed. Please explain why it is appropriate to ask medical students to take part. Dr Huelsen explained that medical students are keen to take part to know what we expose patients to on a daily basis. Dr Huelsen stated that there is no requirement to take part.
* Dr Huelsen stated that they plan to raise the study at the morning meetings as well as informing staff. The Committee queried whether there would be a potential power imbalance, for instance if the person recruiting was a supervisor. Dr Huelsen stated that some may have a direct relationship with the medical students. The Committee requested a justification of recruiting medical students and a plan to mitigate any conflict of interest or coercion.
* Please explain the risk benefit ratio for the actual participants. Dr Huelsen explained that this procedure was one of the safest procedures that we have in this department. The risks are very low. The benefit is to inform future practice.
* The Committee queried if there was any ‘carry over effect’ between the procedures – for instance they might experience discomfort after the first intervention and that may impact the evaluation of the second intervention. Researcher stated they could postpone the interventions if the participant reported they were uncomfortable or was experiencing anxiety.
* Dr Huelsen stated they would not start a new procedure if the participant had already reported soreness or pain.
* The Committee asked whether the Maori consultation had been received. Dr Huelsen stated it had not been received.
* Please explain why you are not collecting ethnicity data. The researcher stated the study was too small.
* The Committee queried what will happen if the procedure was reported to not be tolerable during a study procedure. Dr Huelsen stated they would stop.
* The Committee queried whether nursing staff would be on site to ensure patient safety. Dr Huelsen confirmed the procedure would be conducted in an appropriate environment.
* The Committee queried if there would be any referral in place for unexpected findings. Dr Huelsen stated they will inform the GP and make sure arrangements are in place. If they wanted to do a further procedure they would use the sedated measure. Please include this information in the PIS.
* The Committee queried how researchers will manage the potentially high dropout rate, as participants must come back to hospital for the second uncomfortable intervention yet receive no compensation. Dr Huelsen stated they had no funding for the project.
* Dr Huelsen indicated they may apply for a small grant.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please review for grammar and spelling.
* Technical language ‘upper GI tract’ etc. Please explain terms in lay language or think of a simpler term.
* Include information on potential to take a biopsy if unexpected results are found and informing GP.
* In general needs more information on what may happen during the study for participants.
* Please complete your email address.
* Include information on what will happen if the participant does find procedure to be uncomfortable.
* Pg.17– Please reword compensation information. ACC ‘may’ be available, not would.
* Please use a simple, lay language study title.
* Add statement about ethics committee approval, include ethics committee contact information.
* Please add a hospital number that is not a cell phone as it may be prohibitive due to cost for participants.
* The Committee noted that many parts of the HDEC template had been left in the PIS and needed to be deleted, including the Future Unspecified Research component which is not relevant.

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 consultation with statistician (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Provide details on what processes are in place to accommodate the vulnerable context of recruitment *(Ethical Guidelines for Intervention Studies para 6.2).*
* Please assess protocol and make the intended result of the study clear. Investigators should develop clear study questions that identify the participant population, the intervention and the main outcome of interest *(Ethical Guidelines for Intervention Studies para 5.2).*
* Please justify sample size. The intended number of participants in an intervention study should be sufficient to generate reliable study findings, and the consequent recruitment targets should be realistic. Statistical issues relating to trial design, sample size and analysis can be complex, and usually require expert advice. *(Ethical Guidelines for Intervention Studies para 5.6).*

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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| **2** | **Ethics ref:** | **14/NTB/74** |
|  | Title: | Quantification of Cerebral Hemodynamics |
|  | Principal Investigator: | Dr Shieak YC Tzeng |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 01 July 2014 |

Dr Shieak YC Tzeng was not present for discussion of this application.

Potential conflicts of interest

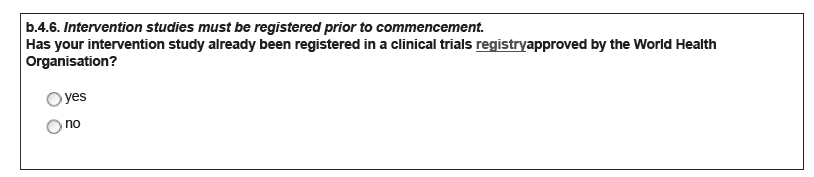
The Chair asked members to declare any potential conflicts of interest related to this application.

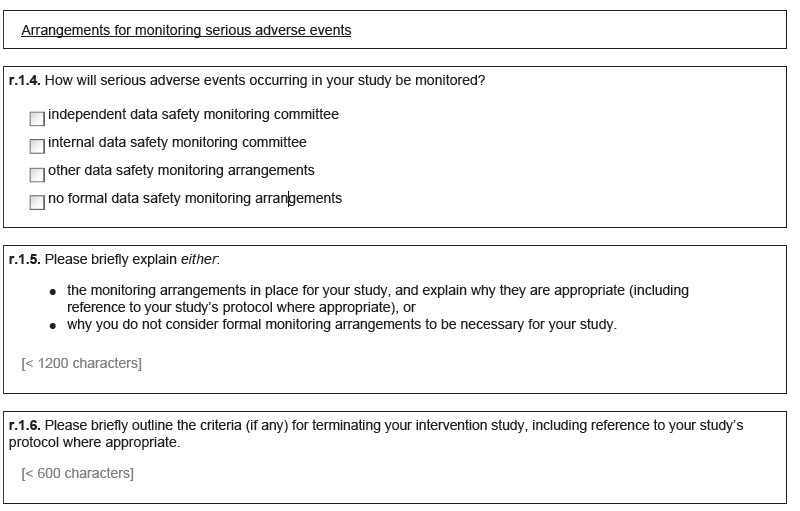
No potential conflicts of interest related to this application were declared by any member.

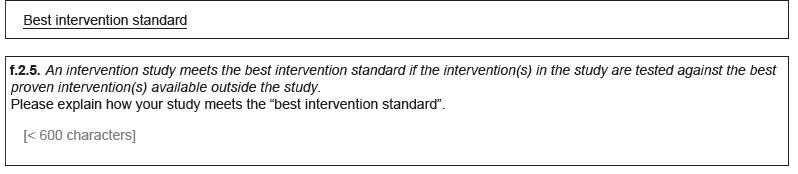
Summary of ethical issues

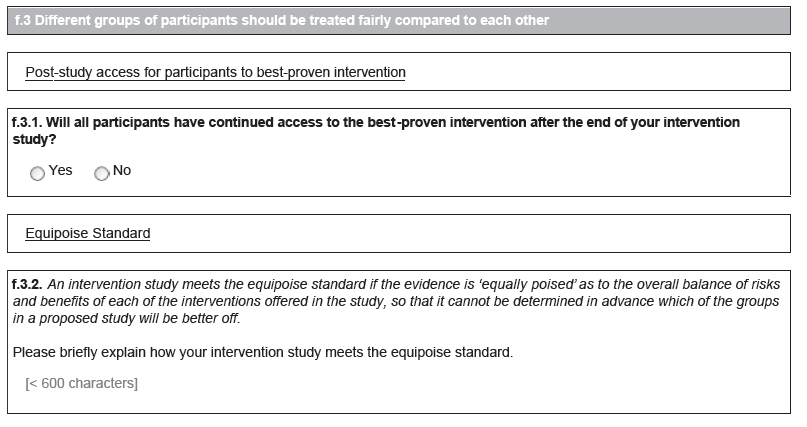
The main ethical issues considered by the Committee were as follows.

* The Committee noted potential participants will be identified through existing registries.
* P.2.7 please provide a variety of options for receiving the lay summary of results. For instance participants may not have access to a computer, a letter may be more appropriate.
* The Committee commended the compensation statement in the patient information sheet.
* The Committee commended the study goal.
* The Committee noted that the procedures may be uncomfortable.
* The Committee would like to see a full side effect risk profile of the study drugs.
* Please explain why you are not testing all women of childbearing age if pregnancy is an exclusion criteria, not just those who think identify that they ‘may’ be pregnant.
* The Committee felt the PIS did not adequately explain what was involved for participants, including a lack of information on the risk profile of the drugs, the equipment, and a lot of technical information with no explanation.
* The Committee noted that this study is an intervention study, not an observation study, as the participants are being randomised and are taking study drugs. Please address questions that were not covered in a cover letter response to the Committee, due to the application being listed as ‘observational’.









* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* The Committee noted there was a lot of technical language. Please assess and remove or explain in lay language.
* Please review sentence structure and Americanisation spelling.
* Add page numbers.
* Please explain what the devices are and provide pictures of the devices.
* Please amend the Central Health and Disability Ethics Committee to Northern B Health and Disability Ethics Committee.
* Be clear about the study being non-diagnostic, non-therapeutic.
* Be explicit that the payment is in petrol vouchers.

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 responses for the questions that have not been populated in the HDEC application form, in the form of a cover letter.

This following information will be reviewed, and a final decision made on the application, by Dr Paul Tanser and Miss Tangihaere Macfarlane.

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| **3** | **Ethics ref:** | **14/NTB/77** |
|  | Title: | RELY |
|  | Principal Investigator: | A/Prof Jonathan Koea |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 June 2014 |

Jonathan Koea 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.

* The Committee clarified that the outcome for these patients was not good. A/Prof Koea explained that historically the 5 year survival rate was 30% but with new chemotherapy treatments it has increased to 60%. A/Prof Koea added it is not as good as it could be but it is improving.
* The procedure does not require any additional surgery, occurring during the standard surgery operation.
* The Committee queried the starting date, noting it stated 2010. A/Prof Koea explained that this study has had started overseas but recruitment had been slow. A/Prof Koea explained that he felt this study was worthwhile and could be conducted in New Zealand.
* The Committee queried if the universal trial number is still pending, given the study started in 2010. A/Prof Koea stated he would look into this.
* The Committee queried why there is no mention of tissue banking or tissue samples in the patient information sheet? A/Prof Koea stated the tissue will go through normal lab process and will not be used for any other study. A/Prof Koea confirmed there will be no tissue banking.
* R.5.4 is the Co-ordinating investigator the usual health provider? A/Prof Koea stated that they will be in some cases. Please explain how this conflict will be managed. A/Prof Koea explained they will introduce the study and then leave the patient information sheet with the potential participant. At a later stage they will then have a nurse talk to them about the study. This occurs in an outpatient context. A/Prof Koea will then approach the participant with their family to discuss further if interested. The Committee was satisfied with this process.
* Please explain the decision to state that the study involved a Kaupapa Maori research methodology? A/Prof Koea explained that a high proportion of the participants will be Maori and there is substantial Maori support in place. The Committee noted that this is not a research methodology.
* Committee queried if the study was blinded. If this is the case it must be made explicit in the patient information sheet particularly that they will not be told which treatment arm they are in unless there is a good clinical reason to disclose the arm of the study.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please reword ACC statement to say ‘may’ not ‘will’ receive compensation, as compensation is a process not a guarantee.
* The Committee noted participants have a right to their information. Please include information on participant rights.
* The Committee noted that they participants can withdraw their data but can’t withdraw their surgery; although it may seem obvious please make this clear.
* Please include HDEC contact information.
* Pg.7 last bullet point – please make it a statement ‘GP will be informed’ rather than having it as an option.
* Please make it clear to participants what is standard treatment and what the experimental treatment procedure component of the study is.
* Please do not explain randomisation as ‘flip of the coin’.
* Please make it clear that telephone follow up will continue for 2 years.
* The Committee noted the incorrect HDEC has been referenced (Northern Y rather than Northern B). Please review and amend.
* Please explain what the quality of life changes are? A/Prof Koea explained that from his personal experience there is no difference in length of hospital stay or quality of life resulting from different interventions. Committee suggested rewording to make it clear that it is not known if there will be any differences between treatments.
* Please provide an alternative to mobile number as some participants may be unable to pay to call a cell phone prohibiting them from contacting.
* Please add an additional space for an interpreter to sign if you do plan to use one.

Decision

This application was *approved with nonstandard conditions* by consensus

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| **4** | **Ethics ref:** | **14/NTB/78** |
|  | Title: | Baby Spice - Pilot Study |
|  | Principal Investigator: | Dr John Beca |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 June 2014 |

Dr John Beca 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.

* A.5.1 is the ANZIC-RC the sponsor? Please describe relationship between this institution and the study team.
* B.2.2.1 please provide further documentation on the review process. Provide some form of evidence of peer review with the study groups listed.
* Please justify the use of delayed consent – is this in order to increase recruitment? Present reasons why you must enrol children before seeking consent from the parents, noting this is a vulnerable context of recruitment.
* Please explain what occurs if a parent declined consent to participate but the child had already been randomised to a drug? Would the drug be changed over if the doctor who is treating the child would not have selected that drug in that instance?
* P.4.3 please justify lack of formal consultation with Maori. The study may involve Maori children and as a result it is appropriate to have some form of consultation.
* If you are recruiting children up to 16 could you provide an assent form for older children? Participants should provide assent if they are enrolled into a study and are competent.
* Please explain what is different between being enrolled and not being enrolled in the study? Particularly the lighter sedation element.
* Is there a risk of discomfort that is not able to be communicated by the children, due to lighter sedation?
* When will the lighter sedation occur? From the onset? Once consent is sought?
* The Committee acknowledged the need to research lighter sedation.
* The Committee noted the PIS must include a section on ‘what will happen to my data’.
* Please provide more information on standard practice.
* R.2.5 please store health information for 10 years after the last participant turns 16.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please address the inconsistency in the patient information sheet, noting that the children are the participants not the parents. ‘I.e. I understand what it means for my child’ rather than ‘for you’.

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 information sheets and assent forms for younger participants and amend the existing information sheets and assent/consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide evidence of peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Please justify lack of any Maori consultation (*Ethical Guidelines for Intervention Studies* *para 4.9*).
* Provide further information on the recruitment process, in particular justify delayed consent (*Ethical Guidelines for Intervention Studies para 6.2)*
* Provide further information on the study design, in particular when the lighter sedation occurs (*Ethical Guidelines for Intervention Studies para* 5.4)

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

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| **5** | **Ethics ref:** | **14/NTB/80** |
|  | Title: | Surveillance of nasopharyngeal Streptococcus pneumoniae |
|  | Principal Investigator: | Dr Emma Best |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 June 2014 |

Dr Emma Best 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.

* The Committee noted the application was clear and well put together.
* Study is public health surveillance.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **14/NTB/81** |
|  | Title: | A Study of RG1662 in Adults and Adolescents with Down syndrome (CLEMATIS) |
|  | Principal Investigator: | Prof Ed Mitchell |
|  | Sponsor: | Roche Products New Zealand Limited |
|  | Clock Start Date: | 19 June 2014 |

Prof Ed Mitchell 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.

Dr Paul Tanser declared a potential conflict of interest, and the Committee decided to have Dr Tanser to abstain from the discussion and the decision, but stay in the room.

Summary of ethical issues

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

 The Committee commended Prof Mitchell for the great deal of work that had gone into addressing the concerns raised by NTA as well as the number of assent / consent forms, the video processes in place and the pictorial assent forms to aid participant understanding.

* Prof Mitchell explained that the study has three groups. The first are adolescents (under 16) with Downs Syndrome (DS) where parents can consent on their behalf, and the adolescents provide assent. The second are adults with DS who clinicians consider have sufficient capacity, with appropriate support and information materials, to provide consent. The third group is adults with DS who lack capacity to consent and for whom there is no other person who, in law, can consent.

 Prof Mitchell requested that the NTB committee formally rule on the third group being able to participate in the study. The NTB Committee decided that the third group should be excluded from the study as they lacked the capacity to consent for themselves, short of a court order, there is no other person who can, in law, give consent on their behalf.

 The Committee confirmed that the study would only recruit minors under 16 and adults who had the capacity to give informed consent. The remainder of the discussion about the application focused on the study with respect to adolescent participants and adults able to give fully informed consent.

 Prof Mitchell explained that his personal view was that he did not think that any adults screened so far would have adequate capacity to give informed consent. Prof Mitchell explained that the preliminary screening study did not find any DS adults able to provide informed consent. In relation to the screening study, another co-investigator stated that, in his opinion, whilst the participants might be able to understand what was involved in participating in the screening study, he thought it unlikely that they would have the capacity to understand what was involved in participating in the current clinical drug trial.

 Prof Mitchell said that he plans to approach the Office of the Health and Disability Commissioner to ask for a law change to enable recruitment of people into research without their consent (where they lack the ability to consent).

 The Committee asked the researcher to explain why this research is specifically being conducted in people with DS, noting this was a vulnerable population and questioning why it could not be conducted in less vulnerable participants to establish whether the medicine improves cognitive function. Prof Mitchell explained that there are no other drugs that are available to increase memory and cognitive function for people with DS. This drug shows promise and is the only potential treatment to help people with DS improve their lives.

 The Committee asked whether there any other population groups that the researcher could do this study in? Could researchers get the answers from any other patient group? Prof Mitchell explained that it might be possible to test the medication in people with Alzheimers. Prof Mitchell stated that this group could pose similar problems with respect to capacity to consent, however there was no indication the results would be transferable to a patient population with DS.

 The Committee queried what the researcher thought the Maori review comments that suggested excluding Māori from the RCR sub-study. Prof Mitchell stated that at an individual level participants should be able to choose whether they should participate. Prof Mitchell did not think Maori should be excluded. The Committee accepted that this is an optional sub study and it is up to the participant if they want to join or not.

* The Committee queried the confidentiality statement in the header of the PISCF. Mitchell agreed it should be removed and was not sure why it was on the letterhead.

 The Committee queried whether the patient information sheets are appropriate for the target population. Prof Mitchell said that in his view they were not simple enough for the adults to make an informed decision. Prof Mitchell stated that, in his personal opinion, none of the participants would be able to give informed consent.

 The Committee asked for information on the risk-benefit ratio for the study drug. Prof Mitchell explained that for the active treatment group, the study drug would provide 6 months of treatment with the chance of cognitive improvement. The limited information provided by phase I studies indicates the likelihood of health risks are low. Prof Mitchell explained that enrolment in clinical trials provided some additional benefit to participants as they would have better access to regular doctor appointments and increased monitoring.

 The Committee asked Prof Mitchell to explain the referral process for any participants who express suicidal ideation. Prof Mitchell explained the FDA requires questions about suicidal ideation to be included when any drug operates on the central nervous system. Prof Mitchell explained they have a duty of care, so if suicidal ideation was identified the participant would be referred to their GP.

* The Committee queried whether rebound phenomena should be mentioned in the PIS/CF? Prof Mitchell said that this is not expected to occur. The Committee sought clarification that rebound effects would not be a likely outcome from discontinuation of the study drug. The Committee was satisfied with the response.

 The application currently states that Roche may cancel the study for any reason. The Committee asked the sponsor to note that the study should not be terminated for purely commercial reasons.

 The Committee asked Professor Mitchell to ensure that participants' GPs are informed about their patients' involvement in the study.

 The Committee sought confirmation that the contact numbers listed in the patient alert card were contactable 24/7.

 Professor Mitchell confirmed that reimbursement of travel costs will be covered.

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

* Please amend ‘your doctor’ to your ‘study doctor’.
* Pg 9 of 20 – please include the relevant and appropriate follow up details here.
* The Committee requested that the sponsor state where the tissue samples would be going iin the PIS, in line with *Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes.*

Decision

The Committee agrees with NTA's reasons for declining the component of the study that aimed to recruit adults who lack the capacity to consent, and for whom there was no one else who, in law, could provide consent.

The Committee approves the study for consenting adults. The Committee notes that Prof Mitchell considers this unlikely but can see no reason not to approve the principle in theory. The Committee reminded Prof Mitchell that he and the research team are responsible for assessing competency and documenting consent, and must include information on consent requirements and evidence of this in respect of any participants over the age of 16.

The Committee approves the study for adolescents under the age of 16 whose parents have consented on their behalf and who have themselves assented to participate.

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

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| **7** | **Ethics ref:** | **14/NTB/86** |
|  | Title: | Clozapine Safety Study |
|  | Principal Investigator: | Ms Brandi Bellissima |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 19 June 2014 |

Ms Brandi Bellissima 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.

* The researchers explained that the study drug is standard treatment for these patients.
* The Committee asked about the vulnerability of the participants. The researchers explained that Clozapine is the last resort for this patient population. This drug has a lot of side effects associated with it. If participants develop significant side effects they will be withdrawn from Clozapine, as per standard practice.
* The researchers explained that the study does not involve any interventions or changes in treatment, apart from seeking consent to analyse tissue.
* The study does not require any interaction with participants beyond consent.
* Please explain the consent mechanisms in place. The researchers explained that when the clinician feels that the participant is ready they will introduce the study and the CI will seek consent following interest being expressed in the study*.*
* The researchers have consulted with ADHB with respect to the consenting process. The possibility of not seeking consent was discussed, due to the trial being observational, however it was decided that it was appropriate to seek consent.
* The recruitment process is to wait until the participant is able to be consented appropriately, in consultation with the potential participants treating doctors and psychiatrists. The Committee confirmed that if there was never an appropriate time to approach for consent within 18 weeks then they will not recruit the potential participant.
* The Committee noted the study will only recruit participants who are able to provide informed consent. Assessment of their capacity for informed consent will be assisted by the carers who are familiar with the potential participants.
* The Committee asked if there was any other way to study the adverse events of Clozapine. The researchers explained that this is the only population that takes this drug, and there was no way of studying the adverse effects on another patient population.
* The design of this trial ‘sits on top’ of normal clinical care. No extra samples, no extra visits. The adverse events from this drug can be fatal so existing monitoring is already adequate.
* The Committee confirmed ethnicity data is being collected.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please review ‘disrupting the heart…’ – most lay people will not understand this. The ‘electrical system’ of the heart may be easier to understand.
* Please call blood and urine, rather than tissues. This is more understandable for lay participants.
* Health and disability rather than ‘human disability’ pg. 2/8.
* Please review for Americanisation, including version date.

Decision

This application was *approved* by consensus.

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| **8** | **Ethics ref:** | **14/NTB/87** |
|  | Title: | Stool bacterial patterns in very low birth weight pre-term infants |
|  | Principal Investigator: | Dr. Arun Nair |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 June 2014 |

Varun Thirayan was 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.

* Please explain how recruitment is managed. Mr Thirayan explained that Dr Nair has experience in consenting or requesting consent. Please provide clarification from Dr Nair on the procedures that will be followed.
* B.1.2 please provide evidence as to whether probiotics is standard treatment in the localities that you are conducting the study in.
* Please explain the relationship with pre-term and low birth weight babies in relation to the peer review provided. Please provide further information.
* Mr Thirayan stated they will collect ethnicity information.
* Committee queried if it was possible to have unexpected lab findings. The Committee requested a statement either stating there will be no adverse findings, or if there are then they will contact GP or participant etc.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please review the template PIS/CF and incorporate into the existing PIS.
* Include letter head of DHB
* Amend start date.
* Requires clarification on whether study assumes babies are already taking probiotics or not.
* Refer to Northern B Health and Disability Ethics Committee, not ‘national ethics committee’.
* Include cultural contact information on PIS.
* The Committee noted the PIS needs to refer to the baby, not the parents, as the participants are the babies not the parents.
* Include information on the potential for unexpected findings, if this is a possible outcome from the study related testing.

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 further information on the study design, in particular whether probiotics is standard treatment for this study(*Ethical Guidelines for Intervention Studies para* 5.4)
* Clarify the peer review of the study protocol as it refers to pre term babies rather than underweight babies (*Ethical Guidelines for Intervention Studies* Appendix 1).

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

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| **9** | **Ethics ref:** | **14/NTB/88** |
|  | Title: | Beta-blockers for COPD: Feasibility study |
|  | Principal Investigator: | Associate Professor Robert Hancox |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 June 2014 |

Associate Professor Robert Hancox 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.

* The Committee congratulated the researcher on his Health Research Council funding.
* The application is of high quality.
* A.5.2 clarified no sponsor and confirmed the study is investigator led.
* B.2.2.1 have you assessed the review committee’s questions and made any changes? Associate Professor Hancox explained that the comments only required a justification and he explained the decision the research team had made. The Committee was satisfied with the response.
* Please ensure study summary is in a lay language.
* Committee confirmed ethnicity data collection would use NZ census structure.
* Committee queried the reason for waiting up to 96 hours before treating. Associate Professor Hancox explained that they would not recruit people who were using a face mask or may be particularly vulnerable, as it was too difficult and not appropriate to seek informed consent at this time. It is a matter of recruiting when it is appropriate. Safety mechanisms would usually be satisfied by 48 hours but 96 gives the research team some leeway.
* Committee confirmed if childhood asthma was identified participants would be excluded from study.
* Explain why there is no placebo arm. Associate Professor Hancox stated that this is a feasibility study – in a large RCT it will have a placebo arm. This is to see how many people in this context we could practically start on beta blockers. The study is not powered to prove the study treatment is effective.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please review wording ‘all out of pocket expenses’ and reword ‘reasonable reimbursement’.
* Pg.5 please include information on how often and how much blood is taken, suggest wording ‘as part of study we will take x ml for trial specific tests’
* Associate Professor Hancox explained there is sometimes enough left over from routine samples but it would have to be done once during screening to determine whether they are a high risk patient or not.
* Remove italics in interpreter box.
* The Committee suggested reviewing the yes/no options and only leaving yes/no for options that are truly optional. Make the other ones statements.
* Please remove the GP being informed as optional and make mandatory for study involvement.
* Committee suggests separating the optional PIS/CF from the main PIS.
* ACC change ‘would be eligible’ to ‘may’ under heading ‘what if something goes wrong’.
* Optional PIS – 4th bullet point from bottom up– review the option to include types of research a participant wants to specify, considering whether a participant would be able to actually answer this.

Decision

This application was *approved* by consensus.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee discussed the possibility of having GCP training as part of new member training.
3. The Committee discussed future venues.
4. The Chair discussed the need to have some meetings in Hamilton.
5. The Secretariat will send out NTB committee member details to the committee.
6. The Committee noted that tracked changes is a fundamental requirement to review provisional responses. The Committee queried if it was possible to have a provisional approval response template (cover letter style) to show how best to present answers.
7. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| --- | --- |
| **Meeting date:** | 05 August 2014, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, 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 4.25pm