 ***Minutes***

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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 08 February 2018 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 19 December 2017 |
|  | New applications (see over for details) |
| 12.30pm | i 17/NTB/266  ii 18/NTB/3  iii 18/NTB/4  iv 18/NTB/5  v 18/NTB/6  vi 18/NTB/7  vii 18/NTB/8  viii 18/NTB/9  ix 18/NTB/10  x 18/NTB/11  xi 18/NTB/12  xii 18/NTB/17 |
| 5.30pm | Substantial amendments (see over for details) |
|  | i 15/NTB/123/AM01 |
| 6.00pm | General business:   * Noting section of agenda |
| 6.15pm | 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) | 20/05/2017 | 20/05/2020 | Present |
| 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 |
| Mrs Jane Wylie | Non-lay (intervention studies) | 20/05/2017 | 20/05/2020 | 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 19 December 2017 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **17/NTB/266** |
|  | Title: | DecubICUs |
|  | Principal Investigator: | Dr Rachael Parke |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 January 2018 |

Dr Rachael Parke 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. This is a 1-day point prevalence collection of data on ICU patients who have a pressure ulcer on 18 May 2018.
2. This is a multinational study coordinated out of Ghent University and aims to collect around 10,000 cases internationally. Data is collected on the day, at discharge from hospital (or day 84) and also from the day of admission.
3. The Researcher(s) explained that this study would describe current incidence of pressure ulcers in the ICU and current practice, and benchmark outcomes internationally.

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 status of international ethics processes. The Researcher(s) explained that the study has received approval in the Netherlands, other countries are in the application submission stage and Australia is nearing approval.
2. The study involves the enrolment of patients who may be unconscious and on a breathing machine that are therefore defined as vulnerable. The Committee asked whether consent would be sought from those who are conscious. The Researcher(s) stated if participants were awake they would explain that the study is underway, as part of clinical discussions. The Committee discussed selective consenting, and noted that this is only health information accessed through clinical records, and there are no procedures or additional data collected from the patients. The access would be retrospective.
3. The Researcher(s) acknowledged the patient population is acutely unwell, and explained the options for outcomes for these patients (death or transference out of the ward).
4. The Researcher(s) explained that this study only involves clinical care data. There will not be any additional data collected. The Researcher(s) explained that it is important to include unconscious patients, as it would bias the results and hence the scientific value of the study, if they were excluded.
5. The Committee noted the application makes a case for non-consent on grounds of 1) potential stress (if post-hoc discussion were to take place) and 2) selection bias (if conscious).
6. The Researcher(s) explained being awake in ICU does not necessarily mean that they have capacity and are still very sick.
7. The Committee asked whether the data sent abroad only "partially de-identified"? (p.1.6) The Researcher(s) confirmed it will be sent with the age, and explained what data is sent from clinical records to the study. The Committee noted that the data was standard care data and was sent in a sufficiently de-identified form.
8. The Committee asked whether clinical photos are to be sent to researchers. The Researcher(s) stated they would not be sent.
9. The Researcher(s) explained the local process if any injuries are identified though the study, but explained that the researchers were not looking for anything in particular or taking any further measurements, rather it was only accessing collected patient records for a snapshot of ICUs around the world.
10. Please provide update regarding Maori consultation. The Researcher(s) explained the locality assessments are underway at the lead site.

Decision

This application was *approved* by consensus.

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| **2** | **Ethics ref:** | **18/NTB/3** |
|  | Title: | MK3475-679 |
|  | Principal Investigator: | Dr Carmel Jacobs |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 January 2018 |

Dr Carmel Jacobs and Ms Panami (primary contact) were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study is a Phase 3 randomised controlled trial of a combination of investigational drugs (pembrolizumab for unregistered indication and novel epacadostat, both immunotherapy agents) compared against one of two standard of care tyrosine kinase inhibitors (sunitinib or pazoparib) for patients with virgin metastatic or locally advanced renal cell carcinoma.
2. The justification for providing these treatments in this group is that for this population existing therapies are relatively ineffective and have significant toxicities.
3. 8 participants in New Zealand
4. The Researcher(s) clarified that the treatment time with interventional agents is up to 2 years, and if no progression of cancer, there is a possible further year of treatment. For the active control, there will be continuous treatment until disease progression

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 which tyrosine kinase inhibitor drug is standard of care. The Researcher(s) explained both are available, based on clinician preference and patient context. The Committee noted the clinical uncertainty, and clinician driven treatment decisions.
2. The Committee asked whether SCOTT is being sought. The Researcher(s) explained that they have submitted to SCOTT.
3. The Committee asked about the fairness for patients in the control arm, and how their treatment was to be managed, noting they were unlikely to respond well. The Researcher(s) explained if the standard of care arm show benefit they will stay on the arm, however this is rare and not expected. If patients are randomised to the experimental arm there is a 2-year treatment period, while patients are monitored for progression. The Researcher(s) explained that after 6 months if the control group are well enough to receive the combination (experimental treatment), they could go on the combination for another 12 months. The scientific rationale is that if they respond to immunotherapy then the benefit is likely to be long lasting, but it will be unusual for this type of cancer.
4. The Researcher(s) explained that some aspects of the study that were not known, for example there remain questions around how much treatment, and duration of treatment, is required for best results for immunotherapy. The Researcher(s) explained that two years is the current standard for international studies of a similar nature.
5. The Committee asked whether re-starting treatment after the 6-month break has a scientific rationale. The Researcher(s) explained that while there is not a 100% response rate there can be a therapeutic benefit to re-start treatment.
6. The Committee noted that the application outlined participants that may not be able to consent for themselves. The Researcher(s) explained the patient group may involve participants with cognitive impairment, due to brain metastasise, or radiation therapy which could cause confusion. Due to the exclusion criteria it is unlikely such patients would be eligible, however it is possible that some may still be eligible. Therefore we have prepared for including participants who are particularly vulnerable.
7. The Committee noted that the protocol states participants who cannot provide their own consent, would be excluded. The Committee noted this review and approval is limited to consenting adults. The Researcher(s) explained they would not use a cognitive tool rather they would use clinical judgement, including specialists, to determine competency.
8. The Committee thanked the researcher for outlining their processes to determine capacity.
9. The Committee noted that for adults, the Protection of Personal and Property Rights Act 1988 governs people who hold enduring powers of attorney (EPOAs) on behalf of adults who assigned those powers while competent, but who are no longer competent to provide informed consent; and welfare guardians, who are appointed by the court on behalf of adults who are not competent to provide informed consent.
10. The Protection of Personal and Property Rights Act 1988 (PPPR act) substantially limits the powers of welfare guardians and EPOAs to consent on behalf of another adult for enrolment into medical research. There is no power to consent to that person’s taking part in any medical experiment other than one to be conducted for the purpose of saving that person’s life or of preventing serious damage to that person’s health.
11. The Researcher(s) and The Committee noted the protocol excludes those who cannot consent.
12. The Committee asked about reimbursement for travel, noting it was for petrol vouchers only. The Researcher(s) explained that car parks are free at Auckland hospital.
13. (p.4.3.1) The Committee asked for an update regarding Maori consultation. The Researcher(s) confirmed it is being sought through the locality process.
14. The Committee noted participation in clinical trials does not necessarily result in better outcomes (application form).
15. The Committee asked about prevalence of disease in Maori. The Researcher(s) explained prevalence in Maori, noting outcomes (mortality) was not informed by good data. The Committee noted that there might not be specific benefit for Maori in this study, and if this is the case it should be stated in the application. The Researcher(s) acknowledged this point.

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 explain how the survey and diary data would be translated, noting these were validated questionnaires. The Researcher(s) explained they would use the interpreter to assist for each assessment. The Committee asked for confirmation from sponsor, as some of these validated questionnaires are not designed to be used through an interpreter.
2. The Committee asked for more information on the publication restrictions (by the sponsor). The Researcher(s) explained they would need to provide this information after liaising with the sponsor.
3. Survey / Questionnaire: the Committee suggests replacing the word Australia with New Zealand for New Zealand participants.
4. The Committee noted that according to the protocol, the genetic component on blood and urine, which appears in the main Participant Information Sheet as though it is compulsory, however it is not compulsory (from p.22 of protocol: Blood for Genetic Analysis X Collect pre-dose. Do not collect if a documented law or regulation prohibits (or local IRB/IEC does not approve). The Committee asked that the researchers create an optional genetic research participant information sheet and move details from the main participant information sheet. Please also clarify the different tissue uses, and corresponding consents, and justify these decisions in a cover letter.
5. The Researcher(s) confirmed the optional tumour form is about release of leftover tissue.
6. P.18 of Main participant information sheet says initials and date of birth will be sent with health data (including genetic data) to the sponsor: "It is the intent of the study doctor, study staff, Incyte, and MSD that the health data (as described above) that is sent to Incyte and MSD will not identify you. Instead, it may include your initials, date of birth, and study visit dates. ". The Committee noted that the HDEC form b.4.4.1 reaffirms that data sent will be 'partially deidentified'. The Committee noted this is not acceptable. Data sent to sponsor must be adequately deidentified. The Researcher(s) explained DOB and initials would be sent. The Committee stated that this is considered identifiable, please send study ID and age, but not the DOB and initials.
7. The Committee noted that the insurance certificate does not name this protocol/study and does not list New Zealand as a specific covered site. The general and product liability levels of 3 and 5 million for an international programme of 630 participants. Please provide an updated certificate, and provide confirmation that ACC equivalent compensation will be available in the event of injury.
8. Please individualise the alert cards, putting treatment that participant is randomised to, as they can then know what treatment they are on immediately.
9. Health data for 50 years from consent – please clarify which dataset this is, in particular whether this is de-identified dataset or whether it involves 50 years of linking and access to people’s identifiable information. This must be clearly communicated to participants. The Committee expects it relates to deidentified data.

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

1. The Researcher(s) explained that the amount of tissue taken for the study depends on how much tissue is leftover. The Committee asked whether any tissue is left for clinical purposes. The Researcher(s) explained that tissue is used for diagnosis but is not used after, so there is little clinical risk for using all samples that are leftover. The Committee noted it should be clear in the Participant Information Sheet that all tissue is potentially used, therefore if new future treatment required tumour analyses it would not be possible.
2. The Researcher(s) confirmed the optional participant information sheet is about access to the standard of care biopsy. The Researcher(s) explained the second biopsy could be standard of care but it would be uncommon, and that the protocol only allows a second biopsy if the clinician thinks there is a clinical reason for one. The Committee noted it was unclear what samples are referred to in the optional tumour participant information sheet – please make it clear which one it is about.
3. Page 1 – ‘your health data’ please make it clear what data this is, identifiable or not. The Committee noted it should not be identifiable health information.
4. Page 18 please remove the statement that the study can be stopped for commercial reasons.
5. Please standardise the way adverse events are expressed so that all drugs have the same language as per pembrolizumab ie ' Very Common = more than 20 people in 100 Common = more than 10 but less than 20 in 100 etc' Remove all percentage expressions in sections on epacadostat, combination treatment and standard of care Group 2 drugs
6. Add some headings before sections on s- Immune Effects from Epacodostat Serotonin Syndrome from Epacodostat on pg. 10-11 to make them more readable
7. Replace mRCC with full title on participant information sheet and consent form.

Optional Sub-Study PISCF

1. Page 2, clarify if optionality refers to the follow-up biopsy by itself, or release of samples. Please tell patients what will be done with samples.

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 clarify use of samples, and if required provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
* Please submit evidence of sponsor insurance. *(Ethical Guidelines for Intervention Studies* para 8.4).
* Investigators should not normally enter into contracts that limit, or apply unreasonable time restrictions to, the publication of study results. Please check restrictions (*Ethical Guidelines for Intervention Studies para 7.18*).
* Provide further information on the study design, *in particular the use of interpreters with validated questionnaires* (*Ethical Guidelines for Intervention Studies para* 5.4)

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

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| **3** | **Ethics ref:** | **18/NTB/4** |
|  | Title: | Paediatic ctDNA (revised) |
|  | Principal Investigator: | Prof Parry Guilford |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 January 2018 |

Prof Parry Guilford 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. This is an observational study of paediatric patients with solid tumours in which a personalised test to detect tumour DNA will be created using their tumour sample.
2. The aim is to test the scientific and process feasibility of using this test to detect residual tumour/tumour relapse ahead of clinically detection.
3. This process is better established in adult cancer therapy but hitherto, has only been used in paediatric leukaemia. This application was declined last year by NTA.
4. It appears better presented on this occasion and in particular the return of incidental findings has been clearly addressed.
5. The Researcher(s) explained the lag that occurs with current practice, noting the new methods provide near-real time response, which prevents futile treatment.

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 how much of an archived tumour block will be consumed and what are the implications for the future management of these children who may have future treatment opportunities that are contingent on testing of available tissue from the original tumour? The Researcher(s) stated very little tissue is required.
2. The Researcher(s) explained they are in no rush for recruitment. Participants have as long as they need.

Summary of ethical issues (outstanding)

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

1. Do not use date of birth and an identifier on samples please. Use a unique number to ensure compete confidentiality.
2. The Committee noted that the Participant Information Sheet requires clarification about study withdrawal and sample use. Remove the option to re-identify the samples and destroy them, unless you are truly going to offer that option, in which case, that needs to be offered at withdrawal or the option of either given on the consent, not just the option to use in event of withdrawal. The Researcher(s) explained if someone wanted to withdraw they have the option to fully withdraw or partially withdraw. The Committee stated this should be clearly explained in the participant information sheet.
3. Application r.4.1.1 suggest that you will contact next of kin, The Committee suggested that researchers contact the participant and their guardian instead. The Researcher(s) confirmed the correct data for contact details would be on the medical records. The Researcher(s) agreed they would contact custodians and participants and not next of kin.
4. Death of participants – - please explain how you will deal with contact and participation in instances of a deceased participant. The Researcher(s) acknowledged this, noting clinical geneticists would be doing this, and they follow best practice, which involves checking mortality.
5. The Committee encourage letting older children to talk to doctors about more technical aspects of the study.

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

1. Please amend PICF. Finding of incidental genetic information - - all cases will be dealt with by sending to oncologist. The Committee noted there is quite a responsibility for that person to then risk assess etc. Please amend p2 under (2) which states the oncologist 'may' act, to something like 'will discuss any information relevant to clinical care with you'. The Researcher(s) explained the possibilities of incidental findings, small risk that they would identify a mutation in a gene that doesn’t cause cancer. However most likely a finding would be a germ line mutation, resulting in cancer risk for the wider family. The oncologist will need to make determination around clinical relevance. The Committee noted this process could be clearer for participants, please explain further in the Participant Information Sheet.
2. Please clarify answers to b.4.4 and b.4.4.1 (of the application form). If data is to be given to other researchers outside the current project, then this should be in the Participant Information Sheet as genetic data even when "deidentified" can be potentially reidentifiable and participants should know that this information is being shared. Currently the Participant Information Sheet statements only address the lack of sharing of the tissue itself.
3. The Committee would like to see the university of Otago logo on the front pages of the PISs along with the Canterbury DHB to visually acknowledge the significant involvement of research alongside clinical care, in the request being made.
4. The participant information sheet should give a reason for non-return of the results to parents- i.e. the test results and their interpretation are insufficiently reliable to use in clinical decision making at this time.
5. All the participant information sheets including those for children refer to pain and bruising from blood sampling. However as blood will only be taken from a central line, this should be painless. Review all documents for this.
6. Remove collection of ethnicity from the consent form, collect it elsewhere according to 2013 Census categories and add a tick box for a study summary to all consent forms.
7. Regarding the family genetic information, please reword, as these findings may not lead to better health or outcomes and this must be stated.
8. The Committee suggested a copy of the resulting publication be sent automatically, not by request. There is no mechanism or requesting this on the PICF. Please add a tick box to the consent form for receiving lay summary of results.
9. Remove the signature panel for a child older than 16 from the parents consent as these children have a separate version of the PISC written in the 2nd person and do not need a parents signature.
10. In the Assent document for 7-10 year olds, make it clearer that the benefits of "making cancer treatments better and easier" may apply in the future but will not benefit them. The Researcher(s) stated they felt there were benefits for the individuals in the study. The Committee stated they could add participation may result in new information to inform your treatment.
11. Regarding the participant sheet for 16 years, the application notes that parental consent may be sought for over 16, in what circumstance would this be appropriate? (p.3.2.1). The Researcher(s) explained when they felt a participant over 16 could not provide their own answers. The Committee noted that for adults (participants over 16), the Protection of Personal and Property Rights Act 1988 governs people who hold enduring powers of attorney (EPOAs) on behalf of adults who assigned those powers while competent, but who are no longer competent to provide informed consent; and welfare guardians, who are appointed by the court on behalf of adults who are not competent to provide informed consent.
12. The Protection of Personal and Property Rights Act 1988 (PPPR act) substantially limits the powers of welfare guardians and EPOAs to consent on behalf of another adult for enrolment into medical research. There is no power to consent to that person’s taking part in any medical experiment other than one to be conducted for the purpose of saving that person’s life or of preventing serious damage to that person’s health.
13. The Committee stated 16 year olds, who can’t consent, should be excluded from the study, noting the law. The Researcher(s) agreed.
14. PCIF - re-consenting at 16 years - p1 background, should mention 'and you were informed about the study and provided assent' - 'now you have turned 16..' suggest 'now you have turned 16 you are able to provide consent yourself and must be given the opportunity to make decisions about your participation in this study as an adult'.
15. Assent 7-10 years - this is a fairly underwhelming format for a 7 to 10 year old, can you provide something more age appropriate i.e. pictures. Name and signature not required suggest and yes or no option instead.
16. Assent 11-15 years - this is appropriate.
17. Future Use - - The future use of DNA and blood is appropriately specific in the PICF. Application b.4.5 should be a yes (future research can be for the same study question). Separate consent not required as use not unspecified. Note that this is inconsistent in PICF and application, it should be 10 years from age of majority (16), not just ' ten years'.
18. Cultural issues - Karakia offered at disposal in application, not offered or noted in PICF Please clarify process for withdrawal from study, this differs in protocol, PICF and application, and requires a clear statement of process please. i.e. inform study doctor, conversation about options 1) destroy 2) destroy with karakia 3) retain in study to point of withdrawal. Outline how this will be noted etc.
19. The Committee suggest child friendly font, pictures etc with assent forms. Content is appropriate.
20. The Committee noted the ability to withdraw assent and consent, bullet point second page 6.

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 provide age appropriate assent form for non-consenting (children) participants to sign (*Ethical Guidelines for Observation Studies 6.21)*
* The study design must minimise risk of harm, please make changes to the protocol in line with the HDEC suggestions and comments (*Ethical Guidelines for Observation Studies* *para 5.5*).

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

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| **4** | **Ethics ref:** | **18/NTB/5** |
|  | Title: | The CHAMPIONZ Study |
|  | Principal Investigator: | Professor Richard Troughton |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 January 2018 |

Chris Pemberton and co-investigators were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a long-term (2-3 years recruiting and up to 20 years of continued data checking) observational study of the cardiovascular health of elderly residents of Ryman Villages. It aims to gauge the prevalence of cardiovascular diseases and medications of ~10,000 residents through completion of a health questionnaire and accessing MOH/hospital admission data about them.
2. A sub study of ~1000 residents will also undertake a much closer look at their cardiovascular and lung function through examination and a series of non-invasive scans, tests and some blood testing. This group will also be asked to donate 10ml blood for future unspecified research that could include samples being given to other researchers overseas.
3. As noted by the reviewer the external validity (generalizability) of the results will be limited and the research is unlikely to be contributing to inequity-reduction.

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 generalisability of study findings, noting research needed public benefit. The Researcher(s) explained that no one has good handle on level of cardiovascular disease or risk, so it is important to conduct the study to generate this knowledge. The Researcher(s) explained that most participants are independent and can consent to participate, which to some extent adds to the generalisability. The Researcher(s) stated that it would be generalisable to demographic within Ryman healthcare facilities, and relate to certain number of alternative providers, such as Somerset or MetLife care. With regards to general public, and those living in independent circumstances, the generalizability is unknown.
2. The Researcher(s) confirmed it was not an ethnically diverse population.
3. The Researcher(s) noted consultation raised this issue, and the researchers have acknowledged that. The Researcher(s) explained that a significant number of Maori do not make it into rest home situation. The Researcher(s) explained that Ryman had some ethnicity data that indicated of 1082 residents 8 were Maori.
4. The Committee asked whether there are conflicts of interest that could impact recruitment, for example elderly participants wanting to please their career, or management of the residential centre.
5. The Researcher(s) explained that researchers are not involved in any of the resident’s care; they will remain under their GPs care. The initial questionnaire goes out to take a snapshot of as many participants as we can, and we request their agreement for us to ask their health from the GP.
6. The Committee asked about the capacity for consent, noting the research population. The Researcher(s) stated there were no people in a higher grade of care and no dementia patients, only independent people within the facilities. The Committee explained capacity should not be assumed just because people live in an independent apartment.
7. The Researcher(s) asked whether or not it is appropriate if someone can attest to the person being able to consent. The Committee stated a witness to consent is usually about ensuring informed consent occurred, not that the person is competent.
8. The Researcher(s) confirmed that no participants who cannot provide their own informed consent would be recruited.
9. The Researcher(s) explained the work they had done with Rymans, noting that they are not turning up cold calling, due to endorsement from a charity at Rymans, where the residents selected this study, and involvement from cardiologists.
10. The Committee asked who would receive follow up (of data), asking if it was the whole 10,000 first cohort. The Researcher(s) confirmed that this was correct.
11. The Researcher(s) explained the small sub study, where randomly selected participants in the first cohort would be asked to give samples. This will happen once, and the samples will be prepared and stored.
12. Personalise ‘senior nurse’.

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 ask if the validated questionnaire had been used in this population. The Researcher(s) stated 3500 healthy volunteers have used this before. The Researcher(s) noted they could change alcohol units to drinks, and would address any other technical language.
2. The Committee noted the power imbalance between people who run the facility and the residents. The Researcher(s) stated managers do not encourage them one way or another; it will be the resident’s choice. The Committee suggested a drop box in reception to ensure confidentiality.
3. The Committee noted that future unspecified research must be optional and separate. The Researcher(s) confirmed it would be.
4. Study data currently is coded with initials and code number, please do not use initials. The Committee suggested age, but not date of birth.
5. Please explain how updated consensus statement for cardiac risk assessment from GP will be incorporated into the study design.

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

1. The Committee noted that the benefit section is over stated, as only 10% will go into the sub study. The Committee noted the Participant Information Sheet should cover risk of a data leak – add details on that risk section.
2. The Committee noted that the blood tests have a moderately high chance of incidental findings. The Researcher(s) acknowledged this and explained that they are prepared for this. The Committee asked for information to be added to the Participant Information Sheet that explains what would happen, in terms of process, if something is identified from study testing.
3. Reword for neutral language, less overstating benefit and excitement.
4. Please make it clear that the study is not establishing a new tissue bank, rather it will be adding tissue into an established tissue bank.
5. The Committee suggested clarification for participants of what the tissue will be used for. I.e. what research areas it might be in.
6. Please make it clear that participation involves having health records scrutinised for up to 20 years.

Decision

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

* Please amend the information sheet and consent form taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Please address all potential conflicts of interest and explain how these conflicts will be managed or mitigated, particularly with regard to recruitment, and make changes to the protocol *(Ethical Guidelines for Observation Studies 4.18)*
* The study design must minimise risk of harm (*Ethical Guidelines for Observation Studies* *para 5.5*).

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

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| **5** | **Ethics ref:** | **18/NTB/6** |
|  | Title: | Microvascular Protection in Major Abdominal Surgery |
|  | Principal Investigator: | Dr Chang Joon Kim |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 January 2018 |

Dr Chang Joon Kim and Dr Marilynn Ali, and Davina McAlister and a co-investigator 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. This is an Australasian investigator-initiated pilot study of the use of combined dexamethasone 16mg and albumin infusion during major abdominal resection, to see if it reduces the level of syndecan-1 (measure of endothelial damage) at 24 hours postop.
2. Design: RCT, stratified by surgical site.
3. Control: 'Standard of care' which is said to be saline and no dexamethasone.
4. Follow-up calls at 6 and 12 months Recruitment procedure set up to minimise pressure and give time to read Participant Information Sheet.

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 what the current standard of care is. The Researcher(s) explained it depends on the anaesthetist’s preference, some give dexamethasone some would not. Patient context is also relevant, for example if a patient has risk for post op nausea vomiting, would likely be given dexamethasone. If immune compromised, would likely not get dexamethasone. With regards crystalloid solutions – most get this first. Depending on their hemodynamic status, they would be swapped to albumin.
2. The Researcher(s) stated that 98% get dexamethasone and 20-30% get some form of albumin in this treatment context.

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 noted that withdrawers/protocol violators will be replaced by inviting another participant into the same group from which the defector has left. There does not seem to be any control over how this person is chosen. The Committee asked how this does not invalidate the entire randomisation process particularly as the intervention is not blinded. A researcher could carefully chose the characteristics of the replacement to conform to personal bias about which arm is likely to be better. The Researcher(s) stated they would check with the study designers.
2. The Committee asked why there is no data safety monitoring committee described in the protocol. (HDEC r.1.4 says there is, see pp. 27-29 protocol but all this says is the PI will keep track of adverse event. No systematic timed reviews or other people involved). The Researcher(s) responded that they would raise this too.
3. Please upload questionnaires.
4. Peer Review: What response to queries e.g. re how the dosing described has been chosen; what safety monitoring will be in place; why restrict to age >65. Please respond with a cover letter.
5. The Committee asked about recruitment. The Researcher(s) explained that most patients who have a big operation are admitted the day before the operation, and are almost always seen day prior by anaesthetic team. The research team and CI will look for patients and assess their eligibility.
6. The Committee asked whether participant information sheets could go out with earlier clinical meetings. The Researcher(s) noted some surgeons would know quite late. The Researcher(s) agree they will give information as early as possible.
7. The Committee noted that there were cultural considerations with tissue – taking tissue, disposal etc. These should be addressed in the application, the Researcher(s) noted this was an oversight and apologised.
8. The Committee ask if there are better questionnaires (quality of life) that are better equipped for this context, citing potential concerns for this population, particularly with outcomes assessment.
9. Commended support of young investigator, particularly in the application.

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

1. Pg. 1 Para 1, line 2: Review spelling i.e. effect should be affect.
2. The documentation needs to be clearer about how treatment within the randomised controlled trial differs from standard of care.
3. Please remove any testing or procedures that is not occurring in the New Zealand trial.
4. p.2 typo . 8ml blood is 2 teaspoons not 2 tablespoons
5. p.1 line 2. Delete 'you'
6. Make it clear where tissue is going to be stored.
7. Add completion of questionnaire as a study procedure in participant information sheet.

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*).
* Scientific soundness is ethically important. Projects without scientific merit needlessly expose participants to risk and misuse their time, and waste resources. Please address the Committees concerns with regards to study design. (*Ethical Guidelines for Intervention Studies* *para* 5.5)

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Mrs Tangihaere MacFarlane.

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| **6** | **Ethics ref:** | **18/NTB/7** |
|  | Title: | (duplicate) (duplicate) Microbiology of posterior spine surgical wounds in a paediatric population |
|  | Principal Investigator: | Dr Haemish Crawford |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 January 2018 |

Dr Tyler Rudolf 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. This is an observational study in which 20 children undergoing elective surgery for scoliosis, will have aerobic and anaerobic swabs taken from 3 levels up the back and at 3 time points - from intact skin before incision/ from dermis of initial incision/ from surface of the open wound immediately before closure during their surgery.
2. The rationale is to see what microorganisms grow and whether the sensitivities match the current prophylactic antibiotics given.
3. There is no background literature summary to show the "gap" in knowledge which has led to this project being developed. There are a series of statements about infection being a problem and that Sally Roberts (microbiologist) agrees it is a good idea to do this.
4. The selection of N=20 seems arbitrary and quite small.
5. The analysis plan is vague ("Data will then be collated on the twenty participants and relevant statistical analysis performed by a qualified statistician").
6. The Committee noted they have not been told what the routine prophylaxis is in the protocol or the rate of infection.

Summary of ethical issues (resolved)

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

1. The Researcher(s) explained there are pre-op, inter-op and post-op antibiotics administered.
2. The Committee noted data must be stored for 10 years, opposed to 2.
3. The Committee queried how the samples would be processed and managed. The Researcher(s) explained they had been in contact with a lab in Auckland – once ethics sought, they will provide researchers with collection tubes that are specifically for research.
4. The Committee noted this means results are reported as research results. Will there be study coding? The Researcher(s) explained that they do not have specific details from the lab yet. The Committee noted these details need to be finalised prior to ethics approval.
5. Please check with the lab to determine how reporting and feedback will occur.

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 Researcher(s) stated there was no information to suggest bacteria was resistant to treatment in this treatment context.
2. Number of different prophylactic treatment regimens and modes of delivery-topical,systemic. These varied methods result in the need for this study.
3. The Committee asked for any literature or background to this study. The Researcher(s) stated there was no similar patient population that had been studied, as there are a small number of these surgeries worldwide. The Researcher(s) added that Starship has done most of these types of operations. The Researcher(s) explained that this study is based on a similar study that looked at microbiology in wounds (in general, not a paediatric population). This research looked at different levels (layers) of skin, and studied microbes at different layers resulting in different growths. The Committee suggested referencing the referred study in the protocol.
4. The Researcher(s) want to sample different stages of the children’s spine wound.
5. The Committee asked whether the researchers think this population have different microbes, or whether it is the metal that provides cause for investigation. The Researcher(s) stated it is primarily the nature of the surgery, which has a large and long wound, top shoulder down to upper buttocks. Length of incisions can be problematic and a lot of the anecdotal comments from clinical staff are that different levels present different bacteria, for example closer to buttocks has different bacteria. Adults do not typically have this incision.
6. The Committee asked if any medical data would be matched with swab microbiology outcomes. The Committee asked about the biostatistician involvement. The Researcher(s) stated they are taking tissue samples, will check treatment for bacteria and surgery details. The Researcher(s) explained that the study power will be clarified as it develops, starting with 20.
7. Explain what you have found on a literature search of research in the area of paediatric spinal surgery antibiotic prophylaxis and how this project fits in to existing research. What is the rate of infection in these surgical patients in your institution and/or in the literature?
8. Provide detail the outcome measures you will give to the statistician for analysis.
9. Provide further peer review with an updated protocol, including a specialist in this area and further discussion on study detail and design with the biostatistician.

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

1. Parent PIS under "Why are we doing this research" there is an implication that study participants will have their treatment adjusted around the swab results from the study (therapeutic misconception). See below. "Why we are doing the study, this study aims to identify which bacteria and fungi are typically present in the wounds of participants undergoing spine surgery. The objective is to identify the microbes (such as bacteria or fungi) so that the appropriate antibiotics can be selected to protect and reduce the risk a participant has of developing an infection post operatively.” Make it clear that the study is to generate benefits for future people.
2. If the researchers are planning to extract data from the children's notes e.g. length of time in hospital pre-op, number of siblings/housing information, whether any recent antibiotic use, this must be in the Participant Information Sheet.
3. Please go through the document any erase typos, template instructions to writer which are not intended for participant, update version number /date embedded in consent form p.3
4. Assent document 7-11 years. The opening statement implies a causal connection between scoliosis and bugs on the back. This needs rewriting. See below: "Why am I being asked to be in the study? You have Scoliosis or a bent spine - in this study, we will find out what bacteria are present on your back and which antibiotics we need to treat these with.” Reword to state no connection between scoliosis and having bugs.
5. Remove language ‘sickness’ change to condition.
6. Insert Maori health support details
7. Make it clear what each support number is relevant for, on the contact details.
8. The Committee noted that the 11-15 assent form has not been submitted.
9. Document for parents is suggesting they are the participants – must change to ‘your child’. Revise for this. Revise headings.
10. Please make a 16-17 year old Participant Information Sheet for participants to consent for themselves.
11. Consent form – remove notes to researcher from the template.

Decision

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

* Please provide evidence of favourable independent peer review of the study protocol, and provide further evidence of literature review (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Scientific soundness is ethically important. Projects without scientific merit needlessly expose participants to risk and misuse their time, and waste resources. (*Ethical Guidelines for Intervention Studies* *para* 5.5)
* 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*).
* The study design must minimise risk of harm, please address the outstanding ethical issues in a cover letter as well as amending the protocol where required (Ethical Guidelines for Observation Studies para 5.5).
* Please provide age appropriate assent form for non-consenting (children) participants to sign (*Ethical Guidelines for Observation Studies 6.21)*

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

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| **8** | **Ethics ref:** | **18/NTB/9** |
|  | Title: | Blood product usage and cost pre and post introduction of TEG in cardiac intensive care. |
|  | Principal Investigator: | Dr Scott Robinson |
|  | Sponsor: | Haemonectics |
|  | Clock Start Date: | 25 January 2018 |

Dr Scott Robinson and Dr Kelly Burn 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. Thromboelastography is a procedure performed on 3ml blood to determine, with the help of an algorithm, whether post cardiac surgical bleeding is primarily due to a surgical problem e.g. leaky join in a vessel, or whether it is due to a dysfunctional coagulation system after bypass.
2. Currently in Waikato it is used in theatre but not postop in ICU. This is because the ICU doesn't have the necessary trained staff to do the test. However a new generation machine is on offer that requires minimal training. It has been validated against the existing machine. The use of thromboelastography in ICU is standard of care in many other ICUs.
3. This is a project aimed at

* measuring existing rates of blood product use/ return to theatre for bleeding/ duration ventilation/ amount of bleeding in 400 post cardiac surgery ICU patients (without TEG)
* Implementing thromboelastography (TEG) with a new machine and after competence is attained, using it in the next 400 similar patients where the cause of post-op bleeding is uncertain then making the same measures on those patients.

1. The Committee discussed how this study is a combination effectively implementation researcheffectively implementation research, where the researchers propose to measure-implement change-remeasure.

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 machine in ICU has been proven, and is best practice. The utility in their particular unit is the focus of the study.

Summary of ethical issues (outstanding)

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

1. The Committee discussed if this is a genuine departmental audit of a modified service delivery, noting it is being offered to all patients.
2. The Researcher(s) explained there is no funding for the intensive care machine. Evidence that it is effective is clear, but not evidence for it being cost effective. Internationally a number of guidelines are supportive for its use in post cardiac surgery.
3. The Researcher(s) explained that taking blood for testing is routine when coming into intensive care, part of surgical management.
4. The Committee asked why the researchers couldn’t consent at least the prospective cohort prior to cardiac surgery. The Researcher(s) explained that they do not consent for those blood tests in clinical care and to seek consent would be prohibitive. Seeking individual consent would be a burden, as not all patients will qualify, and it would result in consenting a massive number who would not end up being in the study.
5. The Committee discussed the type of study and noted that this was effectively an implementation and audit for cost effective data that would be used for resource planning, and that the intervention itself was a gold standard test that was clinically validated. The Committee determined that it would both be in participant’s best interests, but also was not necessarily research, as the object of the study was not validating the device.
6. The Committee asked about the data collection. The Researcher(s) stated data will be collected in an excel spread sheet, NHI on it initially, but stripped for analyses.
7. The Committee asked if there was any involvement of external researchers. The Researcher(s) confirmed the entire study only involved hospital staff.
8. The Committee asked whether this data, albeit de-identified, goes to the sponsor/machine maker. The Researcher(s) stated no, purely for own use internally, although they plan to publish the results.
9. The Committee discussed photos or a poster to inform potential participants but determined in this context it was not effective.
10. The Committee noted taking, storing and disposing of tissue raise significant cultural issues. Please note this on future applications.
11. Please explain why not collecting ethnicity data. The Researcher(s) stated they would not think it would make a difference to results, as coagulation does not vary by ethnicity.

Decision

This application was *approved* by consensus.

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| **9** | **Ethics ref:** | **18/NTB/10** |
|  | Title: | Effect of retinopathy of prematurity screening on regional oxygenation and cardiorespiratory stability of neonates |
|  | Principal Investigator: | Dr Angus Goodson |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 January 2018 |

Dr Angus Goodson 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. This is a study of the effects of pupil dilatation and examination in premature neonates at risk from retinopathy of prematurity.
2. Researchers explained that there is anecdotal evidence that this process stresses babies and there is suspicion that reduced brain and gut blood flow may underlie this, causing negative outcomes.
3. The incidence of necrotising colitis is suspected to go up after the retinopathy screening procedures. This study aims to measure brain and gut blood flow as well as blood pressure and pulse at various stages during the procedure.
4. The project involves full consent from parents.

Summary of ethical issues (resolved)

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

1. The Researcher(s) explained rationale for the study.
2. The Committee asked whether parents are agreeable to the screening generally. The Researcher(s) stated that any premature baby that meets the criteria for the screening will undergo the test.
3. The Researcher(s) acknowledged talk of possible risks in the research is likely to be more salient than from standard care, as knowledge of risks is anecdotal or based on relatively small studies.
4. The Committee asked whether there is a risk of people saying no due to risks outlined, which could cause harm due to the lack of screening. The Researcher(s) acknowledged this is a risk but explained many iterations of the participant information sheet has led to the current version, to best balance the risks and explain the importance of the screening.
5. The Researcher(s) explained that the usual pamphlets would be given to potential participants, which stresses importance for prevention of blindness.
6. The Researcher(s) explained that potential participants have 3-4 weeks to consider participation, with lots of time to talk through the study.

Summary of ethical issues (outstanding)

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

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

1. The Committee asked whether any of the measures result in burdens or risks for the babies. The Researcher(s) explained that they have two similar studies running, in terms of the monitoring. Theoretically no issue except for blood pressure monitoring, there are special tools for this. The Researcher(s) experience is that it is fiddly but well tolerated, adding that if there is too much monitoring they can reduce monitoring for the two secondary measures. The Researcher(s) will submit to HDEC if turns out only going for primary outcome.
2. The Committee request this is detailed, i.e. if felt (by clinicians or the parents) that the baby is not tolerating the monitoring they can stop it, and that the research should not cause any stress.
3. r.2.5 – 10 years after 16.
4. Review for technical language – turn into lay language.
5. Add length of time – 3 hours, and how much the research adds to the screening.
6. Visuals are helpful, please consider time lines that are understandable, or a visual time line. P.1.1
7. Moving para 1 to para 3 would result in a more user-friendly approach (less abrupt, confronting).
8. Maori cultural support contact details: Provide name and extension number.

Decision

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

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| **10** | **Ethics ref:** | **18/NTB/11** |
|  | Title: | Periosteal Block vs. Biers Block a randomized clinical trial |
|  | Principal Investigator: | Dr Sierra Beck |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 January 2018 |

Dr Sierra Beck 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. This is an open RCT comparing 2 forms of regional anaesthesia before reducing a wrist fracture in ED.
2. The investigator explained that the IV anaesthesia in a cuffed arm is the 'standard of care' but some in the department quite commonly uses the periosteal anaesthetic method.
3. This technique was described for wrist fractures in a 42 patient case series published in 2015. There are potential advantages of speed and economy if this technique works as well as standard of care.

Summary of ethical issues (resolved)

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

1. The Researcher(s) explained that all patients receive standard pain medication prior to the procedure, so they can then consent, adding it is not so painful that it threatens consent.
2. The Committee noted the study states data will be used for future research. The Researcher(s) stated this is not identifiable information.

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 Researcher(s) confirmed that only qualified specialist ED physicians to be involved. The Researcher(s) confirmed will train all staff on both methods. The Committee asked for details of the pre-training programme.
2. The Committee asked about monitoring of data, particularly what will researchers do if one method is clearly superior halfway through the study. Patients in the non-superior arm will then be receiving non-superior treatment. The Researcher(s) explain no interim analyses planned, as number of study small. The Committee recommended interim analyses. The Researcher(s) stated they would conduct interim analyses.
3. Conflict of interest - r.5.4.1 this at least needs to be addressed in the Participant Information Sheet. The Researcher(s) stated it would be treating clinician who seeks consent. The Committee asked how much time would elapse between asking and enrolment. The Researcher(s) explained that triage nurse will give information, then later the treating clinician will consent prior to implement study procedures.
4. The Committee questioned the lack of collecting ethnicity data. The Researcher(s) confirmed they would collect ethnicity with 2013 categories.
5. The Committee request details of the peer review. The Researcher(s) confirmed they would submit the commentary.
6. The Committee asked that a screening form is used, if eligible then consent process can occur, then data collection once consented, otherwise may result in consenting patients who are not be eligible. Please provide more detail on the screening and recruitment.
7. Please send Maori consultation when completed.
8. Retain health information for 10 years in line with health retention regulations
9. The Researcher(s) confirmed they would exclude any potential participants that can’t provide consent.
10. The Researcher(s) confirmed they are asking researchers to be participants, in terms of seeking feedback from them about the use acceptability of method of anaesthesia they used in the study. The Committee noted if they were asked some research questions they would also be participants. The Researcher(s) agreed to make a very basic participant information sheet.

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

1. The plan for this needs to be outlined in Participant Information Sheet as well as elsewhere, i.e. if one treatment is proven to be effective, the study will be stopped as all patients will begin to receive this treatment.
2. The Committee noted that the Participant Information Sheet lacks clarity. Make it clear that the patients will be getting either 1) what they would standardly get or 2) a treatment they may standardly get elsewhere, but which is being introduced to ED staff, taught, and then implemented as comparator for this study.
3. Cultural consultation statement and contact details required, ethics statement required. Suggest the researchers look at the HDEC template.
4. Clarify bone reduction is the same as pushing your bones back in the first time you mention this i.e. in brackets.
5. Please remove y/n boxes unless there is a decision required from the participant. ACC/compensation statement required.
6. Suggest you provide more information about the 2 different treatments and some information about effectiveness or specific side effects similar to a.1.5. Risks need to be clearer as per r.1.1.
7. Add ‘if you are in too much pain please ask your doctor for more pain relief.' The Researcher(s) agreed.

Decision

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

* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
* 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 on what processes are in place to accommodate the vulnerable context of recruitment *(Ethical Guidelines for Intervention Studies para 6.2).*
* Provide further information on the study design, *in particular training of researchers and adding clinicians as participants* (*Ethical Guidelines for Intervention Studies para* 5.4)

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

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| **11** | **Ethics ref:** | **18/NTB/12** |
|  | Title: | Optimising PCIT |
|  | Principal Investigator: | Dr Melanie Woodfield |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 January 2018 |

Dr Melanie Woodfield in person Mrs Mary-Anne Woodnorth 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. This is a 2 part evaluation of a relatively new therapy for children 2-7 who are referred to ADHB psychologic services because of difficult behaviour.
2. The programme, PCIT, involves training a parent/caregiver in strategies and then having the person actively 'parent" under the covert observation of the therapist who can instruct through a parent earpiece.
3. The programme was introduced in 2013, lasts about 12 weeks and 30 families have been through it. Part 1 of the project is a retrospective audit of all 30 cases looking at the progress data collected during and immediately after.
4. A standardised evaluation of 36 questions was undertaken many times. This part is unconsented and meets the definition of audit
5. Part 2 involves requesting the parent to partake in a 1/2 hour recorded interview outlining their experiences of the programme, how it rated compared to other treatments they partook of and how the child is doing now. The child will be at school and excluded from the interview.
6. The interview will be done by a research assistant who had no part in the PCIT programme delivery although there is a plan to share the audio transcripts with these clinicians as part of the feedback loop of audit.(R.2.3)
7. The Committee don't think this is sufficiently clear in the participant information sheet and raised if it is wise as it is confounding the research aspect of the programme with clinical care feedback.

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 the research assistant role and asked about home safety protocols. The Researcher(s) explained that they work in front line mental health, and have good home safety protocols. The Researcher(s) noted unlikely physical danger but always good to prepare, in particular for emotional distress. The Researcher(s) added they have a bodyguard app that alerts people if individuals feel in danger.
2. The Researcher(s) explained the training for the research assistant.
3. The Committee asked if there were potential issues if people choose not to consent for phase 2 then represent later as clinical patients. The Researcher(s) stated no, this is common.
4. The Committee confirmed the record access met the definition of an audit – though as it was submitted with the application, it should be justified against reasons for not seeking consent.

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 provide an outline of the proposed interview questions/topics. The Researcher(s) explained the qualitative research process. The Committee noted signposting or guidelines for structure is still required.
2. The Committee noted that while you distance the PI from interviewing to enable free flow of information, all the interview contents are going back to her and to other clinicians involved in the PCIT delivery, in identified form. This is partially justified on the basis of providing clinician feedback. However, The Committee asked if it is possible for the transcripts of the interviews to go to the PI in deidentified form and to omit feedback to other clinicians. The Committee noted this would help protect participant’s privacy if they disclose critical opinions and will increase the scientific validity of the results. It would also remove the confounding of research and clinical feedback which is inherent in the current plan.
3. The Committee noted that if the Researcher(s) are not willing to forgo this, then information in the participant information sheet will need expanding to explain that the treating clinician will be given the information from the interview in identified form.
4. The Researcher(s) stated basic information will go back to clinicians – like last 3 families said this this and this, but not the cases that they look after. The Committee noted that direct feedback would be problematic.
5. The Committee urge caution around sharing that information and requested information be clearer as to what level of data sharing will occur between parties.
6. The Committee need participants to know in participant information sheet that you as a PI may know who things came from.
7. Please ensure participants get summary at the end of the study.
8. Add confidentiality statement, for example what happens with data.
9. Please explain p.4.5.1- see below: This is not well explained in the protocol. "The project will include anonymously electronically surveying clinical staff from District Health Board CAMH services throughout New Zealand, in relation to their perception of the effectiveness, and advantages and disadvantages of PCIT. PCIT is an intervention that could benefit many children and families by offering an effective, time limited treatment. This would also benefit clinicians, who could be supported to offer an intervention that would allow for more defined treatment, with potentially briefer treatment duration. It is hypothesised that there are a collection of inaccurate perceptions held by clinicians in relation to the intervention (for example, that the equipment required is prohibitively expensive, that the discipline strategies involved are harmful to the parent/child relationship) and it would be useful to confirm if this is indeed the case. If so, targeted information could be provided in the future to address these concerns. The Committee stated this required further embedding into the protocol.
10. Confirmed consultation occurring for Maori.

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

1. Remove unnecessary consent tick boxes.
2. Offer a Pacifica contact given the overrepresentation of Pacifica in the cohort.
3. Use the HDEC ACC statement.

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 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)*
* The study design must minimise risk of harm, please consider data sharing and amend the procotol taking into account the Committee’s comments (*Ethical Guidelines for Observation Studies* *para 5.5*).
* Submit questionnaires.

This following information will be reviewed, and a final decision made on the application, by Mrs Mali Erick and Mrs Jane Wylie.

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| **12** | **Ethics ref:** | **18/NTB/17** |
|  | Title: | Improving detection and management of AF |
|  | Principal Investigator: | Dr Katrina Poppe |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 January 2018 |

Dr Katrina Poppe 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.

Mrs Mali Erick and Mrs Leesa Russell declared a potential conflict of interest, and the Committee decided Mrs Russell will abstain from the discussion and decision, but stay in the room.

Summary of Study

1. This study is about the feasibility of a simple screening test for atrial fibrillation in general practice. It involves collecting data on how well this is managed and measuring the CVD risks in these patients.

Summary of ethical issues (resolved)

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

1. The Researcher(s) confirmed manufacturer of device has no access to data, and is not aware of the study. The Researcher(s) added they are buying through a New Zealand provider.

Summary of ethical issues (outstanding)

1. The Committee sought further justification for the screening age cut offs (men>35, women>45) other than general statements about Maori developing AF earlier than European. The Researcher(s) explained the similarities to the Predict database, which contains 400k people aged 35-74. The Committee noted the current recommended screening age is 65. When proposing to introduce a new screening programme, it is usual to provide data on the risk: benefit equation of the test in the proposed group. This should include some incidence data on AF at various ages and information on how the complication rate (i.e. stroke) of AF is lower in the younger people compared to the older. The Committee requested scientific evidence to support this age range and the information being recorded.
2. The Committee noted sustained AF may give an indication and justification for age cut off.
3. The Researcher(s) noted theoretical risk for Maori getting it younger having risk longer, which meant current age for screening may increase inequity. The Committee noted this.
4. The Committee asked why a simple consent cannot be sought, noting that the patients will be available to consent. The Researcher(s) explained that these are 10 minute GP visits, to consent would take twice as long. It is impractical to seek consent.
5. The Researcher(s) and The Committee discussed opt out consent, noting need for either a justification without consent, as opt out is effectively not consent, or a prospective consent method.
6. The Committee noted that the study could not be considered under right 7(4) of the Code of Rights because these participants are competent, and there is no impairment that results in the inability to seek consent, other than practical reasons.
7. The Committee noted that currently the opt-out consent poster is flawed in that it doesn't offer opt-out as a possibility, doesn't explain how to opt-out, and doesn’t adequately inform that all who are screened will become database subjects even if not in AF (the majority) or that their health data will be repeatedly sampled.
8. The Committee noted that requiring the receptionist to provide the PIS will mean that many will miss out if receptionist is busy/on phone/ patient is called in before able to get a copy or read it
9. The PIS is quite detailed but again lacks a heading "How to Opt out".
10. Researchers need to explain why there can't be a consent form attached to the PIS for the patient to sign with the GP
11. The Researcher(s) should probably have a script for the doctors or nurse for them to check whether patient saw the poster and understands that the use of the device and the linking to the health data is for a research study, possibly obtain verbal consent.
12. The Committee stated that a more robust process if people could choose to have the ECG, but not have health info used in this way.
13. The Researcher(s) confirmed they will only access de-identified data. The Researcher(s) explained there would be 6 months of recruitment, then another extract from PMS. Please explain how the data will be coded/'anonymised' when extracted as well as when stored on database.
14. The Committee noted there seems to be a significant interest in getting access to participants to add to the existing CVD risk database. Not just the AF cases but anyone who has the AF screening test will become a participant on the database. Data will be extracted from their clinical record and form their MOH script data, hospitalisation, death data and there will be repeated looks and records of such data. The Committee do not understand the process of linking through "anonymous" encrypted NHI. Please explain this.
15. The Committee noted Maori consultation is required.

Decision

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

* Justification of recruitment, with relation to informed consent and how the study is legal with the use of opt out consent, or an update protocol that seeks consent to participate (*Ethical Guidelines for Observation Studies* *para* 6.42)
* Justification around the scientific design of the study. (*Ethical Guidelines for Observation Studies* *para* 5.7)

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

## Substantial amendments

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **15/NTB/123/AM01** |
|  | Title: | Otago Women's Health Survey, Child Sexual Abuse St |
|  | Principal Investigator: | Dr Charlene Rapsey |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 December 2017 |

Dr Charlene Rapsey was present by teleconference for discussion of this amendment.

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 amendment will:
2. Undertake extensive data linkage through the IDI, on women who completed a postal survey of childhood sexual abuse
3. Increase the number of women on whom mortality and extensive health data is collected from the MOH, from ~ 400 to the entire 2000 cohort.
4. There was an Otago Women’s Health postal survey conducted in 1989, the nature of which is not entirely clear. There was a cohort of 497 women who disclosed sexual abuse in the survey. An analysis was done comparing them with 497 matched controls looking at the risk of poor physical/metal health. In 1995, a further study was done on them and on a matched group without childhood abuse history. This involved interviewing them- 354/497 were reinterviewed. At a later date (not given) a third set of interviews were done. This time, only 196/497 were reinterviewed. The Committee are not told how many could not be traced and how many refused further interviews
5. Then there was this study, which was given HDEC approval to access the medical records of the 497 childhood abuse women (and their matched controls) without consent and draw out information of disease, death and factors such as employment, social support, engagement with psychological services which may have contributed to resiliency.
6. Now the researcher seeks to extend this approval to access without consent, the NHI and clinical records/MOH mortality data of all 2013 women in the original Otago Health Survey of 1989 to boost power of study to show associations which they have failed to do in the 497 sample.
7. Additionally The Researcher(s) wants more information on the whole cohort from the IDI including income data, use of social services, births etc

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 Researcher(s) and The Committee clarified the numbers of participants in the various sections of the study and who were controls.
2. The Committee asked about the number who participated in the earlier re-interviews. The Researcher(s) explained that of those who responded, 83% participated and less than 6 declined, with 2 or 3 being unable to participate. Many were unable to be contacted.
3. The Committee asked about existing consent and identifiability of old records. The Researcher(s) explained there was no consent procedures for the initial cohort, other than the postal questionnaire that was from 1989, adding there may be names, address and year of birth on floppy disks.
4. The Committee noted the generalisability of the study data was questionable due to the age of the research population, which diminishes the value and social benefit of the analyses, which is taken into account when considering access to records without consent.
5. The Committee noted that these people would never have thought that if they fill in a questionnaire in 1989 it would be linked with every government agency in the future. This is related to the ethical principle of respect for persons and diminishes the social licence of the activity. The Researcher(s) need to make a much stronger case to the ethics committee.
6. The Committee suggested the researchers consider a privacy impact statement.
7. The Committee suggested the researchers look at the data future partnership work to inform their resubmission.
8. The Committee asked the means of ID for the purposes of linking into the IDI, and the potential for relinking of personal information to individual’s datasets.
9. The Committee asked whether informed consent be sought from the individuals concerned, or does this risk breach of privacy to family etc. by re-contacting the respondents.

Decision

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

* A case was not made for respecting people, or a social licence to use data without consent (*Ethical Guidelines for Observation Studies* *para* 4.2)

## 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:

|  |  |
| --- | --- |
| **Meeting date:** | 06 March 2018, 08:00 AM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

The following members tendered apologies for this meeting.

* + Leesa Russell
  + John Hancock

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 6.00pm