|  |  |
| --- | --- |
| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 18 September 2018 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

|  |  |
| --- | --- |
| **Time** | **Item of business** |
| 1:00pm | Welcome |
| 1:05pm | Confirmation of minutes of meeting of 21 August 2018 |
|  | New applications (see over for details) |
|  | i 18/NTA/142  ii 18/NTA/144  iii 18/NTA/145  iv 18/NTA/146  v 18/NTA/147  vi 18/NTA/148  vii 18/NTA/149  viii 18/NTA/150  ix 18/NTA/151  x 18/NTA/152  xi 18/NTA/153  xii 18/NTA/154 |
| 6:30pm  6:45pm | General business:  Review of ongoing amendments   * Noting section of agenda |
| 7:00pm | Meeting ends |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Brian Fergus | Lay (consumer/community perspectives) | 11/11/2015 | 11/11/2018 | Present |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 13/05/2016 | 13/05/2019 | Present |
| Dr Christine Crooks | Non-lay (intervention studies) | 11/11/2015 | 11/11/2018 | Apologies |
| Dr Kate Parker | Non-lay (observational studies) | 11/11/2015 | 11/11/2018 | Present |
| Dr Nora Lynch | Non-lay (intervention studies) | NTB Co-opt | NTB Co-opt | Present |
| Dr Catherine Jackson | Non-lay (health/disability service provision) | 11/11/2016 | 11/11/2019 | Apologies |
| Ms Toni Millar | Lay (consumer/community perspectives) | 11/11/2016 | 11/11/2019 | Present |
| Ms Rochelle Style | Lay (ethical/moral reasoning) | 14/06/2017 | 14/06/2020 | Present |

**Also in attendance:**

|  |  |
| --- | --- |
| Name | Position |
| Mrs Sandy Gill | Lay member T/C Central HDEC Co-opt |

## Welcome

The Chair opened the meeting at 1:16pm and welcomed Committee members, noting that apologies had been received from Dr Christine Crooks and Dr Catherine Jackson.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Nora Lynch and Mrs Sandy Gill confirmed their eligibility, and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 21 August 2018 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **18/NTA/142** |
|  | Title: | World Bleeding Disorders Registry (WBDR) |
|  | Principal Investigator: | Dr Mark Smith |
|  | Sponsor: | World Federation of Hemophilia |
|  | Clock Start Date: | 06 September 2018 |

Dr Mark Smith 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 application to enrol haemophiliac patients onto a World Bleeding Disorders Register (WBDR), which was created in 2017.
2. The aim is to gather data on at least 10,000 people from at least 200 haemophilia Treatment Centres (HTC) in 50 countries over the next 5 years. The Researcher(s) confirmed that it is currently haemophilia A and B though other rarer and less serious bleeding disorders may be added in future.
3. The database is physically in Sweden; the administrators of the project come from the Karolinska Institute Sweden, Health AB Sweden (IT) and the World Federation of Haemophilia Canada. The purposes of the register are:

* Improvement of evidence based treatments / knowledge based on research projects with an adequate sized data set
* Identifying gaps in care in some jurisdictions compared to others.
* Advocacy.

1. Each contributing HTC will only be able to access its own data unless given permission by the WBDR Steering Committee to access other HTC data; mutual data sharing agreements between participants will be signed first.
2. The Researcher(s) explained that the application relates only to one Christchurch site participating in this international registry, explaining that the request to join the registry came from 40 patients who are treated the Christchurch site.
3. The Researcher(s) explained that this is a low frequency disease. There are various attempts to compare region to region, country to country, outcomes. A world registry that collects data in a uniform way would be beneficial.

Summary of ethical issues (resolved)

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

1. The Researcher(s) confirmed that all eligible patients at the site will be offered to participate, and if they agree will consent to their data being included in the WBDR
2. The Committee asked if other New Zealand sites were going to sign up. The Researcher(s) stated not at this stage. Other centres have been informed but are not yet signed up. They may come on board in future.
3. The Researcher(s) confirmed that details of the WBDR are provided in a PIS when patients are seen at clinic. The Researcher(s) agreed consent would be on-going, adding they see these participants on average 6-12 monthly, if they are well. The Researcher(s) confirmed that patients will be given time to read and consider the material.
4. The Committee queried the purpose of the patient ID card which links the registry ID with a patient’s name and all sorts of other personal information which presents a security and confidentiality risk. The Researcher(s) stated that they do not need this card and could not see a function for it. The Researcher(s) stated they would not use it.

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 governance documents for the WBDR Steering Committee so the HDEC can understand the selection of representatives, how often the representatives change and how decisions are taken on requests from researchers to use linked data, etc
2. The protocol says 'year of birth' is to be collected but the registration form collects date of birth (DOB). DOB is potentially identifiable information. The Committee prefer it is only the year of birth, please clarify.
3. The Committee asked how participants would be invited to participate in clinical trials if the data is not identifiable. The Researcher(s) stated this would occur when through the registry via an approach to HTCs to invite their patients for clinical trials. If more data than what is in the database is required (for research) they would contact the local HTCs. The Researcher(s) stated they will follow this up with the World Federation of Haemophilia for clarification of process as it is a key objective of the Registry.
4. The Researcher(s) explained that a HTC would have the key to link data from the registry back to the individual. The Committee noted this was outlined in the ethics application but is not aligned with the protocol which states that identifying information would be entered into the Registry in order to identify patients, but was then ‘hashed.’ Please address this inconsistency.
5. Please provide some information in the protocol on the type of data (variables) collected.
6. The Committee noted that it is stated that the WFH (sponsor) will have access to the data. Please confirm that this isn’t identifiable data.
7. The Committee asked about ethnicity collection. The Committee noted that in New Zealand locally held data should collect ethnicity information, using the New Zealand Census categories <https://www.health.govt.nz/publication/hiso-100012017-ethnicity-data-protocols>. Please clarify the process.

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

1. The Committee recommended using the HDEC template for revising the PIS as it contains the required information, not all of which is in the current PIS.
2. The Committee noted the composition of current Steering Committee. No governance document to tell the Committee about how Steering Committee will be elected/rotated in the future, how often they will meet, how decisions will be made in relation to research applications etc. The Researcher(s) explained that considers any requests to extract information, including for research and would need to be confident that the question was valid and useful to ask. Please make this clear in the participant information sheet, that the decision making body is not in New Zealand and does not have New Zealand representation.
3. Make it clear that data is sent to the WBDR database which is located outside New Zealand and expand upon the data being collected so that potential participants are aware that matters such as their HIV and HVC status are collected, hospitalisations and questionnaire data. They also need to be aware that the site may contact them to see whether they are interested in participating in clinical trials or other studies.
4. Page 1 – define HTC when that term is first used (it is used and defined on page 2). In the section headed “Privacy Protection” on page 2, please note that the protection offered may be different to the protection offered in NZ.
5. Page 2 – define WFH – it is defined in the title but not otherwise
6. Page 2 – provide a short explanation of Health Solutions (according to the separate document “Data Privacy & Security”, it is a Swedish healthcare IT provider.
7. Include data access rights and rights of correction in the “Legal Rights” section, localised to New Zealand legislation (the Health Information Privacy Code).
8. Consenting: The assent form needs to be simplified and there should be more than one for the different age brackets. Use the HDEC template (or see Starship website for examples) to construct the consent form Assent Form – the Committee noted it looks like it is pitched at a 12-15 year mark. Please prepare another form suitable for younger children so they can retain it and will know later on, that they were entered into the database. Guidance on assent can be found at <http://ethics.health.govt.nz/guidance-materials/assent-guidance>.
9. The assent form says that “Should anyone attempt to steal your data we will do all that we can to protect it, and we will notify you immediately if this happens”. This is not mentioned in the adult PIS and should be. Please confirm to the Committee that the governance and management procedures are such that this statement will be fulfilled and immediate notification of any data breach to every participant will occur–
10. Please add a parent PIS and consent form, if children are to assent. This means that the reference to “Name of legal guardian (if applicable)” should be removed from the main (adult) consent form. The Committee would like to see the two different kinds of consent kept separate please.
11. The Committee explained the need for re-consent of participants once they reach 16 – this needs to be in both the PIS and the protocols.

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, and ensure the parents have a consent form if assent is being provided (*Ethical Guidelines for Observation Studies 6.21)*
* Provide updated protocol details, taking into account governance of data (*Ethical Guidelines for Observation Studies* *para 5.5*).

After receipt of the information required by the Committee a final decision will be made on the application by Dr Brian Fergus and Dr Karen Bartholomew.

|  |  |  |
| --- | --- | --- |
| **2** | **Ethics ref:** | **18/NTA/144** |
|  | Title: | Liberal glucose control in critically ill patients with pre-existing type 2 diabetes |
|  | Principal Investigator: | Dr Colin McArthur |
|  | Sponsor: | Royal Adelaide Hospital |
|  | Clock Start Date: | 06 September 2018 |

Dr Colin McArthur was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is an Australasian ICU study which involves randomising Type 2 diabetics who are critically ill in ICU to either conventional glucose management with intravenous (IV) insulin (start when blood glucose exceeds 10mmol/l and manage glucose into the usual ICU target range of 6-10mmol/l) or experimental glucose management with IV insulin (start when blood glucose exceeds 14mmol/l and manage glucose into the target range of 10-14mmol/l).
2. The aim is to reduce the chance of hypoglycaemia (blood sugar that is too low).
3. The study intervention will terminate at 28 days or when the person leaves ICU.
4. A single phone call at 90 days from research nurse provides follow-up.
5. The background underpinning the study consists of observational evidence that suggests a high sugar level in Type 2 diabetics who are critically ill is less harmful than a high blood sugar level in normal people who are critically ill.
6. There have also been a couple of studies in Australian ICUs done as single arm trials with different glucose treatment thresholds.

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 increased risk of infection with short-term exposure to higher glucose levels (app r.1.1). The Researcher(s) confirmed it was a theoretical risk.
2. The Researcher(s) confirmed ethnicity is collected.
3. The Committee asked about the independence of peer review. The Researcher(s) stated that ANZICS is an expert group, reviewers are anonymous and are not involved in the study.
4. A lengthy discussion took place about whether this study will comply with the HDC Code of Patient’s Rights, Right 7(4) and, in particular, how it is in the best interests of an individual if he or she is not competent to make an informed choice or give informed consent to participating in the research.
5. The Researcher(s) explained the background and context of the study (scientific gap, patient population and background knowledge to support the intervention arm). The Researcher(s) described prior studies that generated findings to show very intensive glucose control was hazardous.
6. The Researcher(s) explained that a one size fits all approach is not suitable for treatment (glucose management) in this particular patient population.
7. The Researcher(s) explained that some observational data analyses (retrospective) have indicated there is a difference in effect between diabetics and non-diabetics. This data is not enough to demonstrate that changes in practice should occur, but does provide data that justifies the study design.
8. The Researcher(s) also referred to uncontrolled studies undertaken in Australia (small pilot study) that looked for benefit from a higher glucose target for diabetic patients. The Researcher(s) explained that these studies support the view that individual patients may benefit from the current research through the reduction of harm (e.g., risk of hypoglycaemia) but further research is required to prove the findings regarding benefit (though potential benefit is hypothesised).
9. The Researcher(s) explained that, on the balance of probabilities it is currently more likely, but unproven, to be beneficial to individual type 2 diabetic patients in ICU for glucose treatment to start when blood glucose exceeds 14mmol/l and manage glucose into the target range of 10-14mmol/l (the intervention arm) than the standard glucose management (start when blood glucose exceeds 10mmol/l and manage glucose into the usual ICU target range of 6-10mmol/l)) but more data was needed to implement a change of practice across the board.
10. The Researcher(s) also explained the general participant effect (benefit), increased monitoring, particularly for blood glucose levels in both arms in this study, as algorithms will be used, and attention to staying in target is expected to be equally rigorous in both arms. The Researcher(s) confirmed there will be no increase in the number of blood glucose samples taken.
11. A lengthy discussion took place about the need for this group of vulnerable patients to be researched rather than other patients who could provide consent. The Researcher(s) explained that type 2 diabetic patients in ICU comprise a group of patients with significant uncertainties and deviations. This population is the right population for the question, it cannot be answered in another group.
12. The Committee asked if this study be done in a less ill, consentable population of Type 2 diabetics first e.g. T2D on a general medical ward who are to be put on an insulin infusion for hyperglycaemia coincident with infection or with a myocardial infarction. The Researcher(s) stated they were not sure if the same glucose targets were used in that population. In ICU there is more testing, the ability to target is much higher than in the ward. In the ward there is different dosing, and it is also a different patient population
13. The Committee asked what data do New Zealand ICUs have on the incidence of hypoglycaemia (<4mmol/l) in their critically ill Type 2 diabetics using the conventional regimen. The Researcher(s) stated they would provide accurate data to the Committee on this point. The Researcher(s) explained the gap in knowledge, reiterating the risk to participants if the research did not occur. The Researcher(s) stated they would want to provide accurate data to inform a change in practice, but emphasized there is a good reason to do the study. This addresses the cause for increased mortality for the prior study. The Researcher(s) and Committee discussed the evidence from the protocol, and the pilot studies.
14. The Committee noted there is an independent data safety monitoring committee that will do an interim safety analysis at one half (225 patients), and queried if this is sufficient to mitigate risks of harm. The Committee asked is it possible to do earlier assessment. The Researcher(s) stated that the independent group are happy with the proposed threshold, there is a trade-off between accurate information and safety information. The Researcher(s) explained the SAE monitoring, SAE will be picked up earlier, and the analysis at 225 patients is an incremental analysis. The Committee was satisfied with current plan.

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

1. The Researcher(s) explained data is submitted in a de-identified form to Australia. Please add this to the participant information sheet and make it clear to participants that privacy protection in Australia may differ from that available in New Zealand.
2. Please remove the participant information sheet wording “Although individual participants may not directly benefit from study participation, information gained from this study will help clinicians decide how best to manage critically ill patients in the future” because it is possible that individuals may benefit, but it is not guaranteed. Please phrase the statement in the PIS in this way. The PIS should also be very clear about what the potential benefits and risks are for participating in the research, both from the perspectives of the control arm and the intervention arm.
3. The PIS currently states that liberal glucose control (i.e., the intervention arm) “may increase the risk of developing infections in ICU”. However, this is inconsistent with the advice to the Committee that the risk of infection is theoretical only. Please clarify.
4. The PISC submitted is meant to double for both relative of nonconsenting participants (as an information document) and for subsequent consent to proceed for participants who regain consenting ability. As an example, it is written in the future tense yet for any participant giving late consent to continue, the interventions have already happened. Please separate these out into two participant information sheets.
5. Similarly, the consent form clauses are written in the first person for a participant and don't adequately capture the role of a relative giving an opinion on whether their relative would have agreed to participate.
6. Please include in the PIS data access and correction rights. Please also address in the PIS what happens to a participant’s study data if he or she wishes to withdraw from the study.

Decision

This application was *provisionally approved* by majority, 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*).

After receipt of the information required by the Committee, a final decision will be made on the application by Dr Kate Parker and Mrs Toni Millar.

|  |  |  |
| --- | --- | --- |
| **3** | **Ethics ref:** | **18/NTA/145** |
|  | Title: | Starship Pain Review (SPaR) |
|  | Principal Investigator: | Ms Elaine McCall |
|  | Sponsor: |  |
|  | Clock Start Date: | 06 September 2018 |

Ms Elaine McCall was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a prospective cross sectional observational study to be conducted in the Starship Children’s Hospital on a single day next March. It aims to collect quantitative information from children or parents (if < 5 years) on the nature, severity and management of pain experienced during their admission.
2. The study is nurse-generated and led.
3. Participants: all children inpatients in Starship at 0700hrs on the designated day.
4. Exclusions: no parent available to consent / clinical ward staff consider not appropriate to include/clinical crises.
5. Data collected: verbal answers from child to questions on type of pain/severity/pain history/staff response to pain etc at any time during their admission.
6. Data will also be collected from children’s charts data to review staff assessments and responses to pain (focussing on the previous 24 hours).
7. Recruitment scripted approach. Participant information sheet can be perused for at least an hour (or straight away).

Summary of ethical issues (resolved)

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

1. The Committee queried the process for children who could provide their own consent. The Researcher(s) explained that they would recognise some children can provide consent, but planned to seek consent from parents too. The Committee acknowledged that many 13-16 year olds can provide consent however the proposal assumes all will have Gillick competence. This may not be the case.
2. The Researcher(s) explained that they will involve nurse researchers who can use clinical judgement to determine ability to consent.
3. The Researcher(s) and the Committee discussed assent and consent for this age group in the study context.
4. The Committee asked whether the Researcher(s) are working from 9am to 5pm and whether this would limit their ability to seek consent from parents. The Researcher(s) noted that this was a potential limitation for seeking consent from parents.

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 there is a need to make a clearer distinction between the role of researcher and clinician in the Introductory Script and the PIS. Currently, the Introductory Script commences with the following wording: "Hello my name is \_\_\_\_\_\_\_\_\_. I work here at Starship Hospital and today we are asking children and/or parents some questions about pain. We know pain can be a part of healing, but we want to reduce and treat children’s pain as much as possible". The Committee is concerned about the suggestion that the researcher is part of the child's pain management team which is not correct. The Committee would like the Introductory Script and aspects of the PIS which suggest this to be amended.
2. The Committee noted the following paragraph from the protocol: "There may be actual/implied criticism of clinical practice and ward staff which may cause some discomfort for children and/or parent/guardian. The researcher will acknowledge the concerns raised, seek approval to refer to the nurse in charge for immediate management, and offer information on the ADHB complaint process if the family want to take the matter further and talk to someone about making a complaint."
3. The Committee and The Researcher(s) discussed the complaints process and balancing between roles of researchers and clinical team. The Committee discussed the suggestion that researchers will be offering information on how to go down the formal DHB complaints pathway if parents are unhappy with how their child's pain has been managed. The Committee noted the importance of getting help for current pain which needs assessment but was concerned that the proposed plan has potential to damage relationships with treating clinicians by escalating the matter to a formal complaints pathway. The Committee discussed whether it was better to encourage parents/care givers to raise concerns initially with the child’s the clinical team. The Researcher(s) responded that they had thought very carefully about this matter and felt it was the right thing to do, to provide information if there is a potential complaint. The Researcher(s) noted the first suggested step is to refer issues/complaints back to the clinical team.
4. The Committee preferred such a tiered approach to complaints, focusing on clinical team first, but having a process for complaints as well.
5. The Committee prefers that the information is removed from protocol and participant information sheet.
6. Please collect ethnicity data Ethnicity Data Protocols (<https://www.health.govt.nz/publication/hiso-100012017-ethnicity-data-protocols>.).
7. The Committee noted participation involves collecting data from the clinical record. This must either be consented or a waiver of consent justified pursuant to guideline 6.43 of NEAC’s Observational Guidelines
8. Please provide the external peer review for the Committee to review because it was unable to access the version uploaded onto the portal.

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

1. All PISs should mention rights of access to data and correction.
2. Please review the statement in the PIS for parents/caregivers: “The information we keep will not have any names or hospital numbers.” In fact, there will be a unique study number and, initially, the NHI will be used to link from the survey responses to the clinical record.
3. PISC parent - use some headings to improve readability e.g. what are we doing /what does my participation involve? What are the risks and benefits? What are my rights? Guidance may be obtained from the templates on the HDEC website.
4. Make it clearer that this is a research study and you are not the clinician who is responsible for managing a child’s pain
5. Remove the word "well" from the following sentence so that the study seems less judgemental and therefore less likely to undermine confidence in their careers. "We will also look at your child’s clinical record to see how *well* nurses and doctors assess, document and respond to children’s reports of pain..."
6. Please include in the PIS for parents/caregivers information about the risks of re-traumatising a child who has had a bad in-hospital pain experience and is trying to forget it.
7. Provide a tick box option for the receipt of a lay summary of results. This can be sent by email.
8. A participant information sheet for 16 year olds needs to be provided
9. –The current Assent document for 8-12 year olds currently says: “Could the research help me? Yes. What you tell us will help lots of children who come to Starship”. In fact, the research may not help an individual child participant. Accordingly, please reword this statement.
10. Please include in all relevant PISs a clear statement that information given is kept in confidence and ward carers won't know what you've said.
11. Please simplify and convert the 13-15 year old document into an assent document not a consent document and remove parents’ signature panel.
12. Please include an assent form for under 5s – guidance on assent can be found at the HDEC’s website.

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*).

After receipt of the information required by the Committee, a final decision will be made on the application by Mrs Rochelle Style and Dr Nora Lynch.

|  |  |  |
| --- | --- | --- |
| **4** | **Ethics ref:** | **18/NTA/146** |
|  | Title: | (duplicate) Lithium and Fampridine EEG |
|  | Principal Investigator: | Professor Paul Glue |
|  | Sponsor: |  |
|  | Clock Start Date: | 06 September 2018 |

Professor Paul Glue 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 resubmission of a declined application.
2. This is a proof-of-concept study looking to see if fampridine (a drug used for MS) produces similar EEG changes to lithium in healthy volunteers. If it did, this would open the possibility of fampridine being used for bipolar disorder instead of lithium which has frequent significant side effects when used long-term.
3. Both are registered drugs, but Fampridine is not registered for this purpose. There is some theoretical evidence underpinning the hypothesis
4. There is a disconnect between the protocol which describes a single 8 day study and the HDEC form which describes 2 studies: an 8 day 2 -arm study then a longer 3-arm crossover study. The Researcher(s) confirmed it was an 8 day study.
5. Participants: healthy men and women, > 18 years (although 5.1 in the Protocol says 18-40years)
6. Intervention: Fampridine 10mg day 1 10mg bd day 2-6 20mg od day 7
7. Comparator: Lithium 750mg day 1-7
8. Outcomes : EEG changes ( EEGs done day 0, 1 and 7- ? 2 on day 7/) Bloods for haem and biochem days 2 and 7 VAS mood
9. The Committee noted that the study documents refer to a variety of number of participants – 12, 16 and 30 - the Researcher(s) confirmed this involves 16 participants.

Summary of ethical issues (resolved)

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

1. The Committee queried if study samples are going overseas because of a statement in the PIS (page 5). The Researcher(s) noted this was an oversight.
2. The Committee asked about safety of administering lithium in a fasted state (as raised by Southern HDEC). The Researcher(s) stated they had addressed this, referring to the response letter. Food effects EEG. The Researcher(s) explained the safety issues, noting they did not relate to this study.
3. The Committee asked whether ECG has been added as a screening test, as noted by Southern HDEC. The Researcher(s) responded that neither drug has an impact on QTC or arrhythmia, no cardiovascular risks. Risks are related to renal function, which are being screened for.
4. The Committee asked whether the peer review was independent. The Researcher(s) explained that the three peer reviewers are not working on this study, but has been a collaborator before. The Researcher(s) clarified the independence.

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 reconcile the proposed study as detailed in the Protocol with what is written in the HDEC form. Either amend the protocol or submit a covering letter to explain the discrepancy. The Researcher(s) explained that there has been old detail added accidentally, clarifying that the current research application is for an 8 day study.
2. Add minimum weight and specific level of renal dysfunction to the exclusion criteria in the study protocol.
3. The Committee noted that despite a negative answer to r.4.1, the study could turn up incidental health findings of significance e.g. anaemia. Please outline in the Protocol and participant information sheet how this will be handled.
4. The Committee asked about safety monitoring of participants The Researcher(s) explained that volunteers are under close scrutiny, if there are any concerns about safety the CI would stop the study. There is also a data monitoring committee, with 4 members. They make decisions about whether to proceed or not. The Committee asked that this is documented in the protocol (data and safety management).

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

1. In the PIS, please be specific with exclusions– and quantify risks where possible.
2. Please amend ‘excreted’ in breastmilk (page 4, PIS).
3. The Committee noted that the hourly reimbursement rate is below the New Zealand minimum wage, please reconsider appropriate compensation for the time of healthy volunteers required in the study. Please add more information on payment in general.
4. Given the possible side effects, please add a number to contact if participants have severe side effects, or provide assurance that the phone numbers available are able to be contacted around the clock.
5. The Committee asked about the Fampridine end dose. The Researcher(s) explained there is different evidence for safety and tolerability. Please make it clear in the PIS that doses are given higher than the currently approved dose. Please also make the range of doses clearer (page 3); consider a table or graphic for clarity.
6. Pease view the HDEC contraception template and include relevant information in the PIS.
7. Please move the risks described in the section “What is the purpose of the study” (page 1, PIS) to the risks section (“What are the possible benefits and risks of this study”, page 3, PIS)
8. Add stopping rules for the study in the participant information sheet.
9. Add details on implications for normal life in the PIS.
10. Add more information on blood tests in the PIS including what is being tested for and where and how long these will be stored.
11. The section in the PIS entitled “What happens after the study or if I change my mind?” needs improvement - e.g., describe what happens to data (this is only referred to in the consent form - items of significance should not appear for the first time in the consent form). Mention that the participants may be withdrawn by the researchers if it is not in their best interests to remain, despite their wishes to do so.
12. The ACC wording used in the PIS is incorrect. Please review and amend having regard to the HDEC template.
13. The Committee noted that the research may disclose incidental or abnormal findings. This should be explained in the PIS and optionally consented for (including whether the participant consents to the results going to his or her GP).
14. The Committee noted that healthy volunteers’ usual GP should be told about participation. Please include in the PIS and consent form.
15. Make it clear in the PIS there is no therapeutic benefit to individuals.
16. Please separate risks between study medication, EEG and bloods.
17. The Committee noted that the study procedures may be easier to follow if they are included in a table format.
18. Participants should not have remember their identification number to be able to get access to their data - please remove this from the PIS (page 5)
19. Samples are not being sent overseas - please remove the reference from the PIS (page 5)
20. The consent form should include tick boxes only where the matter is truly optional.
21. Add some detail into the PIS on what medical information is collected or accessed.
22. This is a pilot study, please add this to the participant information sheet.
23. Make it clear that the study will be included in a PhD.
24. Add, as a potential risk, the potential impact participation in the research may have on exams or assignments (as participants may be students).
25. Please add potential risk about driving. The Committee noted the researcher’s response about the absence of any driving risks, but referred to the Medsafe Data Sheet on lithium carbonate (Douglas Pharmaceuticals) that has driving as a risk.
26. Please improve data management procedures including how data and samples will be de-identified (note that use of patient initials and date of birth in addition to a unique study number must be justified).
27. Explain whether individual results may be returned to participants and include a section in the consent form.

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 in the protocol(*Ethical Guidelines for Intervention Studies para* 5.4)

After receipt of the information required by the Committee a final decision will be made on the application by Mrs Sandy Gill and Dr Kate Parker.

|  |  |  |
| --- | --- | --- |
| **5** | **Ethics ref:** | **18/NTA/147** |
|  | Title: | (duplicate) Atopy & Allergies following Paediatric Solid Organ Transplantation |
|  | Principal Investigator: | Dr Amin Sheikh |
|  | Sponsor: | Auckland District Health Board |
|  | Clock Start Date: | 06 September 2018 |

Dr Jonathon Bishop was present by teleconference for discussion of this application in the absence of the CI, Dr Amin Sheikh, who is overseas. Dr Bishop is a colleague but not an investigator on this study.

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 re-submission of a declined application.
2. It is a cross sectional observational study collecting information about allergies, treatment and some other relevant medical history from ~ 250 child and adult solid organ transplant patients (transplanted 2003-2017).
3. There is an unexplained rise in allergies after transplant, particularly in children. This study aims to establish a point prevalence, to compare adult and children's rates and reflect on possible causes.
4. Recruitment: names and contact details will be obtained from the National Transplant Registry and a PISC will be posted to potential participants asking them to answer questions about allergies over the phone for a period of about 5-10 minutes. The PIS asks potential participants to post the consent form back with a Y or N to being contacted by phone to do the 5-10 minute questionnaire. It also requests potential participants email the researcher if they do not wish to participate so they will not be disturbed by a phone call if there is a delay in the decline reply reaching the researchers. Answers to the questions will be linked to data obtained from a review of clinical records held at the relevant hospital, then all data will be de-identified.
5. The Committee noted the basis for study is good but the application and explanation of the study processes are not adequate. The Committee suggested the CI may benefit from an experienced researcher supporting his application.

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 the protocol is very light on detail and would like to see it bolstered by the provision of more information.
2. The Committee queried the rationale to compare prevalence data between children and adults. The Researcher stated he could not fully answer this, but noted the differences between populations. The Committee asked if adults are included in this study. The Researcher stated that adults are included, as well as children who have had liver transplants, who are now adults.
3. The Committee asked about adults who had a transplant in their adult life. Please provide clarity on the study design.
4. The Committee noted that case matching between children and adults would constitute a different study design, with different ethical issues as well as scientific considerations. The Committee noted currently the study appear to be descriptive, a re-design would be required if the intention was to draw comparisons. This design query will require addressing by the CI.
5. The Committee queried recruitment, asking how individuals will be identified to invite them to participate in the research. The Researcher explained that the renal team would be involved in carrying out the study – they would access their data to identify the appropriate patients. The Committee also asked about the National Transplant Register and whether patients consent to storage of their information on the Register and to being contacted for research purposes. The Committee also asked who is authorised to access data held on the Register, and to outline the access requirements in the Protocol. These matters require responses from the CI.
6. The Committee discussed the recruitment process, as noted above, and noted it may be possible to obtain verbal consent over the phone rather than asking participants to post written consent forms (although provision of written information as part of a pre-invitation process and allowance for opting out of contact is best practice). Verbal consent for phone interviews is acceptable, however this would involve provision of a script that is read out to support informed consent with clear notes made by the researchers of whether consent was verbally obtained or declined. ,. The Committee noted the protocol currently requires a consent form to be sent back. Please clarify the recruitment and consent process in the protocol.
7. Add statistics justification for sample size and analyses.
8. Please collect ethnicity data using the ethnicity categories from the New Zealand Census categories <https://www.health.govt.nz/publication/hiso-100012017-ethnicity-data-protocols>.).Please write an analysis section into your protocol to describe what researchers will do with the data.
9. Please add to the protocol a section describing what the summer student will do if confronted with medical information which concerns him/her (i.e. who to contact, how and how quickly).
10. The questionnaires collect patient initials - please remove because they constitute identifiable information.
11. The Committee is concerned that the study data is going to be kept on one person's lap top, please provide an improved data management plan - this should be included in the protocol.
12. The Committee noted consultation with Maori is required.
13. The Committee noted the cultural considerations in the application form were very poorly completed. See <https://ethics.health.govt.nz/guides-templates-forms-0> for guidance on answering these questions.
14. The Committee noted data must be retained for 10 years, after a child turns 16.
15. Will data be kept on non-responders in order to report response rate or comparison features with the study sample? If so this needs to be in the Protocols.
16. Management of any potential distress or complaints should be considered in the Protocol.

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

1. The 11-16 years assent form is too detailed for participants at the younger end of the range. Please review.
2. The participant information sheet needs to make it clear that consent is being sought for access to health data and this must be specifically consented for in the consent form (a tick box).
3. Please use the HDEC consent template <https://ethics.health.govt.nz/guides-templates-forms-0> and assess missing information, for example the offer of a lay summary to participants and add Maori, HDC and HDEC contacts to all PISs.
4. If the Researcher(s) are planning to offer referral to an allergy service if they detect unmet need through the phone call, please put this in the protocol and participant information sheet.
5. Please tell participants in the participant information sheets that researchers intend to link their answers with their hospital notes (with their consent).
6. Please explain for the adult participants why a paediatric researcher is conducting the study, as this may be confusing.

Decision

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

* 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 update the study protocol to include more detail on study procedures, including recruitment and study design and analyses (*Ethical Guidelines for Observation Studies* *para 5.5*).

|  |  |  |
| --- | --- | --- |
| **6** | **Ethics ref:** | **18/NTA/148** |
|  | Title: | The heat vs. HIIT study |
|  | Principal Investigator: | Dr Kate Thomas |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 06 September 2018 |

Dr Kate Thomas 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 intervention study which looks at a high intensity intermittent exercise regimen (HIIT) or a combination of hot water soaking followed by a resistance exercise programme (HEAT) as alternative pre-surgical conditioning options to "usual care" for people waiting on a hip or knee replacement for osteoarthritis (“OA”).
2. There is an initial crossover intervention study which aims to select the best type of exercise equipment for the HIIT programme. Both studies use Dunedin Public waiting list patients recruited by reviewing lists and placing notices in public areas of the hospital.
3. The researcher, who the Committee understands will supervise the exercise sessions, has Advanced Cardiac resuscitation training. The baseline and endpoint maximum-effort exercise testing is to be done by a registered clinical electrophysiologist with a cardiologist on call.

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 the compensation arrangements for 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 protocol, PISC and HDEC form give slightly different information on the different interventions, for example the water temperature. Please revise and ensure the information is consistent across study documentation.
2. The Committee queried whether 3 days is long enough between exercise arms in the initial study, noting the potential for a "carry over" effect in terms of increased joint pain. The Committee suggested a minimum of a week. The Researcher(s) stated while the minimum is 3 days, they would touch base with the participants and see if they needed longer, but a week minimum may be acceptable. The Committee noted wording could change, to indicate checking that they would wait as long as needed to start next phase.
3. Study 2: Provide an analysis plan for results. Be clear about primary and secondary outcomes and what analyses will occur with the data.
4. The Committee noted that people will have both hip and knee OA or OA in both hips or knees. This may affect ability to exercise and influence VO2 peak compared to solitary joint OA. Similarly, some may have OA secondary to an inflammatory polyarthritis which could limit VO2 peak more than in solitary joint OA. The Committee noted the researchers could consider how to make their participant population more homogeneous to avoid having to stratify. The Researcher(s) noted this and would talk with the surgeon involved to more clearly define the research population.
5. Please clarify what exercise modality you will use for the HIIT intervention in Study 2. The Researcher(s) stated for HIIT itself, they would decide on individual basis for that person. The Committee noted training and testing exercise modes could be different. This does not come through in the protocol and participant information sheet. Please revise documentation with this in mind, for study 2.
6. The Committee noted that, with regards to the safety of participants, elderly people who soak in 38 degrees for 30 min then exercise for another 30 minutes are at risk from dizziness/syncope if not actively hydrated after soaking. The Committee requested more information is provided in the PIS than just telling participants to bring a water bottle. The Researcher(s) confirmed the actual temperature was 39 degrees. The Researcher(s) stated that they based safety information and protocols on a prior study. The Committee noted it was important to advise participants to how much to drink during the sessions. The Researcher(s) agreed.
7. The absolute and relative indications for stopping the exercise measurement sessions (participants exercise until they can't go on) seem to have been taken from a clinical setting where people are being investigated for cardiac disease by a physician.(Protocol pp17-18) The Committee noted they don't seem fit for the purpose of elective research exercise with an elderly cohort. For example, the following are described as only relative indications for discontinuing the test: increasing chest pain, BP>250 systolic, SVT, heart block, ST depression>2mm. The Committee stated they should be absolute indications to stop. The Researcher(s) agreed. The Committee asked whether a cardiologist looked over the protocol and requested a review of indications to stop the exercise tests.
8. . The Committee was unclear whether the pre-admission screening by an anaesthetist occurs in person or is based on information provided to them after the Baseline Screening session 1. The Committee noted baseline screening may result in not being eligible.
9. The Committee noted the storage of blood samples for future unspecified research would require considerably more information and planning, if the use is unspecified. This information appears in the participant information sheet of Study 2. The Researcher(s) and the Committee discussed whether it was future unspecified research or whether it was study related. The Researcher(s) explained that it is not specific but is within the parameters of the study. Please make it clear in the participant information sheet that it is an extended consent, related to this study, and make it clear what testing might occur.
10. Answers for F.1.2 should be in P.1.4 (for future applications. <https://ethics.health.govt.nz/guides-templates-forms-0/cultural-questions-%E2%80%93-guidance> ).
11. The Committee asked about the researchers’ access to pre-admission records. The Researcher(s) stated a letter is sent from orthopaedic clinic and the Researcher(s) will not be looking at pre-admissions data. The Researcher(s) confirmed they will receive information and once coming into clinic will be face to face session.
12. The proposed advertisements are insufficiently detailed and could waste the time of people who are clearly ineligible. Please review.
13. The Committee asked about some of the secondary outcome measures of the study. The Researcher(s) explained two week spa bathing helps with blood glucose control. In group with high cardiovascular risk, the study aims to assess impact of this intervention. The Committee asked this is clearly explained, what risks are involved and why.

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

General participant information sheet comments:

1. Make clear in participant information sheet that part of this research will form a PhD study.
2. Add a full study title – look at HDEC template <https://ethics.health.govt.nz/guides-templates-forms-0>
3. Currently, the PIS states that data is frozen, this should be amended to state tissue.
4. Be clear about the benefits of the study in the PIS – particularly that it may not help the individual participants.
5. Please make randomisation clear up front in the PIS.
6. Please be clear about what samples will be taken and their storage.
7. Please explain what drinks contain caffeine apart from coffee and tea.
8. Describe where the data is stored and who the "authorised personnel" are who can access it.
9. Add a Maori cultural statement regarding blood testing in the PIS: *You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
10. Add HDEC contact details, add signature panel for researcher.

Participant Information Sheet Study 2

1. Please explain early in the PIS that this is a randomised controlled trial and what "random assignment" means.
2. Explain the "spa therapy" also involves active land exercise in the Brief Overview paragraph.
3. Explain that after Baseline Session 1, participants may be ruled ineligible to participate further by anaesthetic assessment.
4. Please note for participants that the exercise will be explained and that it will be supervised as this is not clear.
5. Please tabulate the interventions and assessments to improve understanding.
6. Please revise the future unspecified research of tissue request.
7. Include: - exclusions such as recent MI, angina, joint revisions, and any other obvious ones - provide an estimate of number of visits/ time commitment - make it clear both interventions involve exercise and that allocation to intervention or comparator usual care is by randomisation not by preference.
8. Explain APAC (and jargon generally).
9. Remove ‘unlikely’ in ACC wording.
10. Add details on management of incidental findings in participant information sheet.
11. Remove optional choice for GP to be informed of study participation.
12. The Committee noted the use of pill thermometers – please explain in the PIS why these devices are being used, what is involved and whether there are any risks associated with their use.

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 in the protocol(*Ethical Guidelines for Intervention Studies para* 5.4)

After receipt of the information required by the Committee a final decision will be made on the application by Mrs Toni Millar and Dr Nora Lynch.

|  |  |  |
| --- | --- | --- |
| **7** | **Ethics ref:** | **18/NTA/149** |
|  | Title: | Fatigue After STroke Educational Recovery trial (FASTER) |
|  | Principal Investigator: | Dr Kelly Jones |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 06 September 2018 |

Dr Kelly Jones 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 randomised controlled trial of a 6 session cognitive-therapy- based group intervention for post-stroke fatigue compared with a single session of General Stroke Education (Usual care).
2. It follows a pilot trial of 16 participants which gave a signal of success. Both intervention and comparator will be delivered by a clinical psychologist or delegate. The protocol is comprehensive.
3. There is an external Data Monitoring Committee with planned interim analysis.
4. Participants: stroke sufferers 3-18 months ago with a minimum level of fatigue score.
5. Intervention: 60-90 minutes session weekly, for six weeks, with 5-6 participants.
6. Comparator: single general stroke education session 60-90 minutes.
7. Outcome: Primary-change at 6 weeks in severity of fatigue as measured by the FSS scale and a change in the dimensions of fatigue as measured by the MFI-20 scale.
8. There are a number of secondary outcomes including for a subset of 40, in-lab assessment of strength and looking for certain features in EEGs.
9. The researcher has identified that both stroke sufferer and their carer (if available) will be participants and will provide data although having a carer is not a prerequisite for enrolling. The carer will be asked questions about the impact on their lives of caring for a stroke patient.
10. Only adults who can consent will be enrolled.
11. Recruitment involves a post-clinic or telephone approach to seek permission for a more in-depth explanation session about the research.
12. Access to medical records is planned to confirm history of stroke and the details of it.

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 cohort figures, noting the large sample size. The Researcher(s) acknowledged the large study size and noted that, to ensure feasibility, they would add another year to the study duration.
2. The Researcher(s) confirmed that if stroke patients are taking part in other trials, they will not be eligible for this study, and that they would confirm this as an eligibility screen.
3. The Researcher(s) confirmed ethnicity data is collected.
4. The Researcher(s) confirmed that all participants would be able to consent for themselves.

Summary of ethical issues (outstanding)

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

1. The Committee asked for more information about the economic analyses, in particular where this data is coming from and the consent for it.
2. The Researcher(s) explained the recruitment process. The Committee asked if the people introducing the study will be knowledgeable about it. The Researcher(s) stated they would have a basic knowledge of the study.
3. The participant information sheet says potential participants will be phoned (after consenting to contact when asked by a referrer) to ask questions about eligibility and if eligible, will get the PIS but the app (p.2.1) says the PIS will not go out until after eligibility has been determined. Eligibility included the application of several specific questionnaires tests (e.g. for fatigue) which are study procedures. The process needs to be changed – the potential participants must get the PIS first before being assessed for eligibility. The Committee noted that the Researcher(s) need to get informed consent before screening with MFI-20 to see if eligible.
4. The Committee asked if not being explicit about the cognitive behavioural therapy (CBT) aspect of the research was intentional. The Researcher(s) stated it was not, they just trying to keep information simple. The Committee requested that the CBT aspect is made clearer in the PIS, in lay language.
5. The Committee asked whether the carers are linked to participants or whether they are entirely separate. The Researcher is to confirm.
6. The Committee asked about reimbursement, who will receive vouchers? The Researcher(s) stated reimbursement will be per participating family. Please make this clear in the participant information sheet.
7. The Committee noted the protocol says taxi chits will be provided for all group sessions and assessment sessions. The PISC is less clear on whether this is provided. (p.4) Please reconcile.
8. The Committee noted that no one should be out of pocket for participating in research. The Committee noted that reimbursement was not sufficient and should not be unequally distributed among participants.
9. The Committee noted that providing a ‘per recruit’ reimbursement to referring agencies could be construed as an inducement. Please rethink and perhaps provide a fixed koha to all who contribute.
10. Stroke participants may be upset to hear carers relate how they have been affected by their relatives’ stroke. Please think how the Researcher(s) can mitigate this e.g. conduct the questions while the stroke participant is in their group session.
11. The Committee noted the Carers’ Questionnaire needs tweaking to remove references to "your stroke" in 2.4.3 and 2.4.4. The benefits section is also not relevant (for the caregivers’ participant information sheet). The PISs need to be carefully reviewed and tailored for the particular participant groups with a particular focus on ensuring that relevant risks and benefits are correctly and fully outlined for all participants. This is especially the case with the PIS for the caregivers which includes information which is not relevant to that group. Similarly, please carefully review the consent forms for each group of participants.
12. The PISC for stroke sufferers doesn't go into any detail about the 40 sized subgroup who will have more extensive physical testing and EEGs at the Auckland University of Technology. The Researcher(s) explained this will be sub-study and will be the subject of a separate ethics application. The Committee noted this was not clear and should be clearly separated.
13. The Researcher(s) explained their data management. The Committee noted some of the data in the de-identified set is potentially identifiable. The Committee requested the researchers do not store DOB on otherwise deidentified database - use age or year of birth instead. DOB is potentially identifiable data. The Committee explained data identifiably levels. Please also remove initials.
14. Please submit the patient diary for the Committee’s review as well as the booklets that participants will be given (app r.1.1).
15. The Committee noted that the researchers propose to use a registered clinical psychologist or another suitable health professional ‘or trainee nearing eligibility for psychology training” (app (b.1.2). The Committee requested assurance on appropriateness of a trainee conducting some of these study procedures. Please explain mitigation of risk with this approach.
16. The Committee noted that the Researcher(s) propose that if a participant is at immediate risk (or another parson is) they will then “ be informed about the respective authority that will be advised (i.e., police, crisis assessment team” ) – participants should be given an indication of these possible steps before they take part, not once something has gone wrong. Please add this information into to the participant information sheet.

The Committee requested the following changes to the Participant Information Sheets and Consent Forms:

1. Add detail about what happens in the 6 sessions, please consider a table or graphic to aid clarity.
2. Please review tick boxes and remove the yes/no option if it is not actually optional.
3. Revise the tick boxes generally, to ensure they are relevant for this study.
4. The participant information sheet is 6 pages not 3 (incorrectly stated on page 1 of the stroke participant’s PIS).
5. Risks – please improve this section in the PIS for the stroke participants – currently, it does not include some of the risks identified in the application or elsewhere – e.g., distress about their recovery (app r.5.6). Group sessions- privacy implications. The Committee noted other risks such as the risk of identification, potential for upset (impact on partners, for example).
6. Please include information about what post study access to interventions is available for the control group.
7. Please include more detailed information about all participants’ health information – what will happen to it, during and after the study etc. Withdrawal – what happens to the data? This is mentioned in the consent form but not the participant information sheets – please include in the participant information sheets.
8. Currently, the PIS for stroke participants states that the Researcher(s) cannot share the results of any assessment measure with participants unless the participant askes a registered psychologist to request the results on their behalf (page 5 of the PIS). Please note participants are able to request information held on them without needing a registered psychologist. At most, the participant information sheet could suggest that it might be helpful to have a psychologist assist in explaining individual results. The consent form should include the option for stroke participants to receive individual results if they wish.
9. Please add plans for managing the distress of participants into the PISs (they are included in the protocol as are other health conditions sections 5 and 6).

Decision

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

* Provide further information on the recruitment and screening processes (*Ethical Guidelines for Intervention Studies para 6.2)*
* This study, as presented in this application, involves accessing health information from patients, and speaking to their clinicians, without consent.
* The Committee noted that participants have a right to know that their health information is being used in research. Right 6(1)(d) of the HDC Code of Rights states:
  + *Every consumer has the right to information that a reasonable consumer, in that consumer’s circumstances, would expect to receive, including … notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval.*
* The Committee noted that they can approve access to identifiable health information without consent for research in certain circumstances. The Ethical Guidelines for Observational Studies states at Paragraph 6.43:
  + *Access to identified or potentially identifiable data for research without the consent of the people the data identifies or makes potentially identifiable may be justifiable when:*
    - *the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; and*
    - *there would be no disadvantage to the participants or their relatives or to any collectives involved; and*
    - *the public interest in the study outweighs the public interest in privacy.*
* To approve a study involving access to health information without consent the Committee must be satisfied that these requirements are met by the study concerned.

After receipt of the information required by the Committee a final decision will be made on the application by Mrs Rochelle Style and Dr Kate Parker.

|  |  |  |
| --- | --- | --- |
| **8** | **Ethics ref:** | **18/NTA/150** |
|  | Title: | BP40657. A Phase Ib/II dose-finding / confirmation study of Atezolizumab (Tecentriq) Subcutaneous. |
|  | Principal Investigator: | Dr Anthony Rahman |
|  | Sponsor: | Roche Products (New Zealand) Limited |
|  | Clock Start Date: | 06 September 2018 |

Dr Chris Wynn 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. Atezolizumab is approved in New Zealand for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. It is given to patients as an intravenous infusion ('IVI' - a solution given into a vein over 60 minutes).
2. Researchers have now developed a subcutaneous ('SC') form of atezolizumab, given as an injection under the skin. To enable SC dispersal the atezolizumab is mixed with rHuPH20, an approved enzyme that helps drugs and fluids move across body tissues.
3. This study aims to find and confirm the dose of SC atezolizumab that most closely matches the recommended IV dose. The safety and effectiveness of SC atezolizumab will also be assessed.
4. Part I (Dose Finding). 36 adults with stage IV NSCLC will be enrolled into 3 planned dosing groups. Participants will each receive between 1 and 3 cycles of SC atezolizumab, followed by IV atezolizumab for subsequent cycles. The dose level and number of cycles of SC atezolizumab will be dependent on the dosing group. Additional dose levels may be studied, if required, until a SC dose is found that closely matches the IV dose.
5. Part 2 (Dose Confirmation). Once the best SC dose is found, approximately 200 patients with Stage IV NSCLC will receive the selected SC dose in addition to bevacizumab, carboplatin and paclitaxel. The results will be compared to historical IV atezolizumab data.
6. In all Cohorts, blood tests to measure study drug levels and immune response will be collected at certain time points, safety assessments will be performed, and any changes in health will be recorded. The results will be used to further develop SC atezolizumab as a viable alternative to IV dosing.

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) agreed to submit a progress report between the end part 1 and initiation of part 2.

Summary of ethical issues (outstanding)

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

1. The Committee asked about whether it is advantageous to receive the treatment in this study, noting it is not a standard of care in New Zealand. The Researcher(s) explained that there are benefits of receiving the study drug combination. The Researcher(s) noted the study drug and combination is not available as treatment in New Zealand, but would consider continuing to offer it after the study. The Committee asked that it is made clear in the participant information sheet that it is not standard regime and why this is the case in New Zealand (cost etc).
2. Please submit an insurance certificate that mentions New Zealand, please check with the sponsor to ensure insurance is applicable for New Zealand.

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

1. Please make it clearer in both PISCs that treatment cycles continue until it appears not to be helping or toxicity.
2. Change to ‘will’ be reimbursed.
3. Second participant information sheet page 3 – until the cancer worsens, please reconsider language and, as a suggestion, perhaps use terminology such as disease progression.
4. The Committee suggested the use of a table which summarises the study procedures and stages may help participants understand the research.
5. The Committee noted that in order to collect data on a new born child a re-consent was required once the child was born. The current participant information sheet is a combination of collecting data on the pregnant mother and resultant child. A solution is to add to the existing participant information sheet –a tick box underneath the consent to indicate that re-consent may be sought after baby is born. The re-consent can be verbal, over the phone. The Committee noted that making this change may occur via an amendment in the unlikely event of pregnancy.
6. Please include information in the PISs about the availability of individual results and include an option in the consent form for participants to request them (if they are obtainable).
7. The Committee thanked the Researcher(s) for using the updated ACC wording.
8. The Committee suggested that it is made it very clear in the consent forms, by including a separate section, that participants consent to (1) the use of their data (including information in participants’ medical records) and samples, and linking of their data with other data, by Roche, Roche affiliates, Roche’s representatives, collaborators and licensees, for research related to lung cancer or other types of cancer, common pathways (links) among diseases, the use of the study drug in disease therapy and/or the development of tests that help with detection or understanding of NSCLC and for advancing science and public health and for commercialisation; and (2) study samples being analysed anywhere in the world. These matters are included in the PIS (for example, at pages 14-15 of the PIS for Part 1) but they should appear under a separate heading “Future Unspecified Research using tissue and samples”
9. Following on from the above-referred point, The PISs state how data and samples may be used in future research but the PISs require further information for participants about the form in which the data and samples will be made
10. Please condense/combine the information about biopsy samples into one section so that all relevant information about the tests which will be performed on them, where they will be performed, any risks associated with those tests, storage (where), destruction, return (if possible), future use (for what and by whom) can be clearly understood by participants without the need to search through the PIS to piece together the relevant information.
11. The Committee asked about the volumes of up to 20ml provided by subcutaneous- injections. The Researcher(s) explained that prior study reported no pain or discomfort, due to the injection method. The Committee requested that a bit more description of how the subcutaneous injection is given and how the accompanying enzyme works, to reassure participants who may anticipate pain or discomfort from this.
12. Remove the option (yes no tick box) for GP being informed of study participation.
13. Please include a section in the consent form which enables a participant to ask for his or her samples to be destroyed. This will align with the option which is stated to be available for participants in the PIS (eg, page 8, Part 1).

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 submit evidence of sponsor insurance. *(Ethical Guidelines for Intervention Studies para 8.4).*

After receipt of the information required by the Committee a final decision will be made on the application by Mrs Sandy Gill and Dr Karen Bartholomew.

|  |  |  |
| --- | --- | --- |
| **9** | **Ethics ref:** | **18/NTA/151** |
|  | Title: | E-SACS use in Schools |
|  | Principal Investigator: | Ms Michelle Fowler |
|  | Sponsor: | Werry Workforce Wharaurau |
|  | Clock Start Date: | 06 September 2018 |

Ms Michelle Fowler was present in person for discussion of this application. Dr Grant Christie joined the meeting by teleconference during the discussion.

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

To evaluate the implementation of the Substance and Choices Scale (SACS) ABC and E-SACS tool and resources within a primary care setting. The ABC approach is A: Ask - administer SACS screening, review and score. B: Brief Advice - deliver feedback and brief advice. C: Counselling - recommend and make a referral to Alcohol and Other Drug (AOD) counselling

1. The School Based Health Nurses have requested that Werry Workforce Whâraurau support them in evaluating their trial which involved putting the E-SACS on their Pupilweb (health information system) and using it to conduct brief AOD interventions.
2. The Researcher(s) aim to report on the project’s implementation and outcome formally by evaluating data from the project and obtaining feedback about the training and the acceptability and utility of the process in general. If the results of this evaluation are positive, this project will set the stage for a roll-out of the E-SACS across a wide range of national primary care services across a variety of settings across New Zealand.
3. The aim is that all school based health nurses (SBHNs) in New Zealand will be able to use the E-SACS tool for screening and be able to provide brief interventions for young people who have AOD difficulties in school settings.

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 positive aspects of this project, especially if it will result in the reduction of harm to young people from alcohol and drug use.
2. There are two parts: a) a quantitative data analysis using de-identified data generated from the project and provided by the SBHN team; and b) a qualitative study seeking feedback from nurses and students. Feedback from nurses will be regarding the acceptability and ease of using the E-SACS and SACS ABC process and will be conducted via both paper surveys and electronic survey. Feedback will also be sought (via a survey) from a selection of students who have used the ESACS tool with regard to their overall experience, at the three month follow up visit timepoint.
3. This project already involves the collection of data and provision of an intervention (app r.8.1). The researchers confirmed they are only seeking ethical approval for the evaluation of the intervention (app: p.1.1).
4. The Researcher(s) explained all year 9 children are assessed with E-SACS and are scored out of 20.
5. The Committee noted that whakama was a potential cultural consideration.

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 requested information on what consent the young person provides to the intervention itself (regardless of evaluation). The Researcher(s) stated that the nurse would have a discussion about undertaking the assessment and that data would be collected. It is not clear that students would understand that the data may be used for other purposes than their clinical care, for example research or overall monitoring. There is no written consent.
2. The Committee noted the researcher should justify to the Committee, the repurposing of health data for secondary research use, against the standards of 6.43 Observational Guidelines for the quantitative part of the study. The Committee notes that the data requested is sensitive clinical and risk related data, and that even if anonymised that some students may be identifiable from their answers. Please consider in assessment against 6.43.
3. The Committee noted that the protocol requires updates for the nurses’ survey section –which currently lists the Training survey as the intervention rather than the tool assessing nurses’ acceptability of use of the tool.
4. Implied consent from the completion of a survey for both students and nurses could be considered, however an information sheet for Nurses is still required.
5. Please collect using ethnicity using the New Zealand Census categories <https://ethics.health.govt.nz/guides-templates-forms-0/cultural-questions-%E2%80%93-guidance>.
6. The Committee queried Maori consultation. The Researcher(s) stated kaumatua have been involved in process so far and confirmed they will be involved in final evaluation.

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

1. The Committee noted young pupils >16 years can legally give their own consent and already are in therapeutic relationship with the school nurse who will be able to respond to any issues that concern the nurse. However, the participant information sheet needs revision to focus on getting informed consent about the survey. It should not be an information sheet to tell pupils about the introduction of a eSACS/SACS-ABC tool or pilot – this is the intervention which the students have already undertaken as a clinical assessment, and if positive were followed up and are now being approached for their feedback. The consent should be about providing their feedback on their experience.
2. If the nurses are to complete a specific research survey to assess their experience and acceptability following the use of eSACS-SACS BC, then they are participants please construct a PIS.

Decision

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

* This study, as presented in this application, involves accessing health information from children for use in research without consent.
* The Committee noted that participants have a right to know that their health information is being used in research. Right 6(1)(d) of the HDC Code of Rights states:
  + *Every consumer has the right to information that a reasonable consumer, in that consumer’s circumstances, would expect to receive, including … notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval.*
* The Committee noted that they can approve access to identifiable health information without consent for research in certain circumstances. The Ethical Guidelines for Observational Studies states at Paragraph 6.43:
  + *Access to identified or potentially identifiable data for research without the consent of the people the data identifies or makes potentially identifiable may be justifiable when:*
    - *the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; and*
    - *there would be no disadvantage to the participants or their relatives or to any collectives involved; and*
    - *the public interest in the study outweighs the public interest in privacy.*
* To approve a study involving access to health information without consent the Committee must be satisfied that these requirements are met by the study concerned.
* 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*).
* All observational studies should be conducted according to written protocols that state the aims of the study, the data needed and how the data will be collected, used and protected. (*Ethical Guidelines for Observation Studies* 5.11)

After receipt of the information required by the Committee a final decision will be made on the application by Dr Brian Fergus and Dr Nora Lynch.

|  |  |  |
| --- | --- | --- |
| **10** | **Ethics ref:** | **18/NTA/152** |
|  | Title: | PROTECT in IgAN |
|  | Principal Investigator: | Dr Kannaiyan Rabindranath |
|  | Sponsor: | Retrophin, Inc. |
|  | Clock Start Date: | 06 September 2018 |

Dr Kannaiyan Rabindranath 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 randomized, double-blind, parallel-group, active-control study in patients with IgAN who continue to have persistent overt proteinuria and remain at high risk of disease progression despite being on a stable dose of an ACEI and/or ARB.
2. Eligible patients will undergo baseline evaluations and will be randomly assigned 1:1 ratio to receive either sparsentan or active control (irbesartan).
3. Following randomisation, the patient will discontinue prior ACEI and/or ARB therapy and any other prohibited concomitant medications (see Section 15.2.1), the study medication (sparsentan or irbesartan) will be initiated and titrated according to protocol guidelines.
4. During the study, participants will be maintained on the maximum allowed dose of study medication they can tolerate, while secondarily maintaining blood pressure as close as possible to the target level of 125/75 mmHg.
5. Treatment with additional antihypertensive agents is encouraged during the study, with the exception of ACEIs, aldosterone blockers, aliskiren, or ARBs. Study visits will be conducted 2, 4, 6, and 12 weeks after randomsation and at 12-week intervals thereafter. Following the 110-week blinded treatment phase, treatment with study medication will be discontinued.
6. At this time, the Investigator should resume standard-of-care treatment, and adjustments will be made to antihypertensive medications to maintain the participant’s blood pressure at the same level as at cessation of study medication.
7. Participants will attend their final visit 4 weeks after study medication has been discontinued. The primary analysis of proteinuria will be performed after the last participant randomised has undergone the Week 36 visit.
8. Subsequently, all participants will continue to be followed on a intent-to-treat (ITT) basis to Week 114 for the longer-term.

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 whether there had been reported side-effects. The Researcher(s) stated there were no reported side-effects to date.

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 expressed caution about reporting potentially identifiable findings, noting the intention to recruit only 10 participants in New Zealand.
2. The researchers propose to use identifiers of initials and date of birth ‘where applicable”. The Committee noted that use of identifiers over and above a unique study number must be justified – why are these additional identifiers required?
3. The Committee noted that there would need to be Maori consultation.
4. The Committee noted the answers for addressing Maori responsiveness were poor (for future applications. <https://ethics.health.govt.nz/guides-templates-forms-0/cultural-questions-%E2%80%93-guidance> ).

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

1. The Committee asked about future unspecified research. Please provide an overview of use of tissue, and clarify if there is further testing in addition to the biorepository optional research. The Committee suggested that all information which is pertinent to the optional biobanking should be grouped together – for example, there is a section about the biorepository but some related information appears later. The participant information sheet makes it clear that the optional study is for biomarking only – there will be no genetic testing. However, it does not say whether the biomarking research will only be in relation to IgAN or potentially to other diseases (similar or otherwise). Please clarify.
2. Clarify what other laboratories mandatory samples will be sent to to in addition to the laboratory in Singapore.
3. Frequency of side effects needs to be included; data harms should be included as a risk – e.g., of re-identification. The Researcher(s) stated they would quantify the side effects.
4. The compensation section should use the new template wording from <https://ethics.health.govt.nz/guides-templates-forms-0> .
5. The pregnancy participant information sheet requires a lot of amendment – for example reconsent is necessary for collecting data about babies once born. The pregnancy participant information sheet should be amended to reflect a New Zealand Audience. Delete reference to “the Privacy Rule” and GDPR and USA law.
6. The Committee requested that post study access to trial drugs is made clear.
7. Paragraph 6 –medical files disclosed to sponsor – please remove from participant information sheet. The Researcher(s) confirmed they are not sending identifiable data to sponsor.
8. Add rights of access and correction (health information privacy code rules in New Zealand).
9. Please remove collection of race. Please collect using ethnicity using the New Zealand Census categories <https://ethics.health.govt.nz/guides-templates-forms-0/cultural-questions-%E2%80%93-guidance>Paragraphs which provide information about the GDPR and the USA should be deleted from the participant information sheet and consent as they are not relevant for New Zealand participants. Please also revise language.
10. The general participant information sheet needs amendment - incidental findings should be covered, as should the fact that a positive Hep B test is notifiable.
11. The reimbursement sections have not been completed. Please revise.
12. Add a Maori cultural statement regarding blood testing: *You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
13. The Committee noted there should be no requirement to sign each page of the participant information sheet.
14. Add samples going overseas on consent form

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*).
* Explain what happens to health information (with regards to publication and use during the study) (*Ethical Guidelines for Intervention Studies* *para 7.7)*
* Please address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed (*Ethical Guidelines for Intervention Studies* *para 4.7*).

After receipt of the information required by the Committee a final decision will be made on the application by Mrs Toni Millar and Dr Karen Bartholomew.

|  |  |  |
| --- | --- | --- |
| **11** | **Ethics ref:** | **18/NTA/153** |
|  | Title: | Phase 1b CONCOCT trial in head and neck cancer |
|  | Principal Investigator: | Dr Navin Wewala |
|  | Sponsor: |  |
|  | Clock Start Date: | 06 September 2018 |

Dr Navin Wewala was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The Researcher(s) were commended on a well written Protocol and PIS.
2. Patients with cancers of the head and neck are often cured with cisplatin chemotherapy and radiotherapy, however, this can lead to permanent, treatment-induced reduction in hearing and kidney function. This trial will study the activity of cimetidine, to assess if it can protect kidneys and hearing from damage due to cisplatin chemotherapy in patients having this treatment for head and neck cancer.
3. The study will enrol 30 patients and randomise each patient to receiving cimetidine or placebo before and during cisplatin chemotherapy. Baseline evaluations will be collected before treatment starts. Evaluations for hearing loss (ototoxicity), kidney damage (nephrotoxicity) and peripheral nerve damage will be assessed to gather information regarding whether cimetidine can help prevent these side effects.
4. If cimetidine is found to be protective against these side effects in this group of patients, further trials will be undertaken to see if it may also be effective therapy for adults and children receiving cisplatin chemotherapy for other types of cancer.

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 long term effects or benefits, noting that it was 3 month follow up. The Researcher(s) stated there are no estimated long term risks, hence the 3 month follow up. The Researcher(s) stated the study is not powered to look at long term survival.

Summary of ethical issues (outstanding)

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

1. Recruitment/consent: The Committee noted it would be preferable if the research nurse does the explaining and takes the informed consent, to reduce the chance patients may feel obliged to become participants to please their oncologist (refer to the app: p.3.1 and 2.1).
2. The Committee noted there is no plan for an internal DMC. The Committee accept cimetidine is an older drug with a well-known safety profile. The Committee suggested some planned blinded interim look at adverse events even if by an internal committee. Please address this suggestion.
3. The Committee noted using date of birth and initials is regarded as potentially identifiable information. This information must not be sent off site to the database. The Committee noted using year of birth is acceptable. (see app: r.2.3).
4. Please clarify for the Committee whether samples are destroyed and the different uses of tissue.
5. The Committee noted it was surprising that the app: p.4.3 was answered as: "No, Maori consultation not required" when head and neck SCC is overrepresented in Maori and this study has a genetic component. The Committee noted that, despite this answer, the consultation has occurred. The Researcher(s) agreed that consultation was required and the application answer was an error.
6. The Committee noted participants have the right to return of individual results.

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

1. The genomic blood testing of SNPs for a correlation with the primary outcome, is exploratory and therefore should be an optional extra, not part of the Main Study. People who object to this should be able to be in the Main Study. Please create an Optional Genetic participant information sheet, or include it as an option.
2. Add a Maori cultural statement regarding blood testing in Main and Optional Genetic PISCs: *You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
3. Please include rights of correction and discuss the possibility of incidental findings (if likely) in the PIS.
4. Please add more information about the hearing tests – eg, how long they will take – what to expect.
5. Please use ACC template wording from HDEC <https://ethics.health.govt.nz/guides-templates-forms-0>
6. Page 7 – 4th bullet point – information is not anonymised. Please do not use that term – coded or de-identified is acceptable.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Provide details of the Data Safety Monitoring Committee’s composition and monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*
* Explain how the conflict of interest resulting from care provider being the researcher is addressed *(Ethical Guidelines for Intervention Studies para 4.19)*

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

|  |  |  |
| --- | --- | --- |
| **12** | **Ethics ref:** | **18/NTA/154** |
|  | Title: | Maori experience of Anaesthesia in the perioperative setting: A qualitative assessment |
|  | Principal Investigator: | Doctor Courtney Thomas |
|  | Sponsor: |  |
|  | Clock Start Date: | 06 September 2018 |

Doctor Courtney Thomas was present by teleconference for discussion of this application.

Ms Rochelle Style was not present at the meeting for discussion on this application.

Potential conflicts of interest

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

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

Summary of Study

1. The latest report from the Postoperative Mortality Review Committee (POMRC) in 2017 (POMRC, 2017) suggested that there are inequities for Maori in perioperative outcomes and recommended further research to understand why this is.
2. This study is predicated on the assumption that Maori experience of Anaesthesia may be enhanced or hindered by their specific interactions with Anaesthetists. This may inform future practice through a shared understanding of what is important for Maori and enable development of cultural competence resources relevant to the perioperative setting and to assist Anaesthetists in New Zealand in delivering culturally responsive care to Maori.
3. This research may stimulate more widespread and ongoing review of engagement with Maori patients as part of quality assurance activities in promoting safe and high-quality anaesthetic care. A key motivation of this research project is in promoting equitable access to care and equitable outcomes for Maori.
4. The Researcher(s) noted there are no studies in this context in New Zealand or internationally on indigenous groups.

Summary of ethical issues (resolved)

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

1. The Committee queried if children can decline to have their whanau present. The Researcher(s) stated they could. The Committee asked how this would be determined. The Researcher(s) stated they would ask when whanau present, as part of the informed consent process. The Researcher(s) stated it might also depend on age, noting it was important to be transparent in terms of whanau as well. The Committee noted the difficulty in managing this tension, and noted the need to act in best interest of participant.
2. The Committee noted children should also be empowered to make their own decisions.
3. The Researcher(s) confirmed koha is 20 dollar voucher, provided for the interview.
4. Please note that health data derived from the study must be stored for a minimum of 10 years (following children turn 16) [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html).
5. The Committee asked about how discrimination reporting was to be managed, particularly for the broader health system discrimination questions. The Researcher(s) explained the process for questionnaires and then interviews. The Committee noted the research must take into account perception and individual experiences.
6. The Committee asked why questions are wider than interactions with anaesthetics. The Researcher(s) stated their other experiences can impact experience with anaesthetists. This could also identify other issues so we can drill down further on this.
7. The Researcher(s) explained that other considerations can be when participants may not follow preoperative procedures, so this is another aspect that relates to access to treatment and access issues.
8. The Researcher(s) explained it is about their experience (survey) and the answers that might signal an issue, are used in interview to drill down. This is where thematic analyses and context is brought into it. The Researcher(s) is aware of limitations and of whakama.
9. The Committee asked who will assist with literacy issues. The Researcher(s) stated that the interviews are audio recorded and transcribed. The Researcher(s) confirmed personal details are taken down during survey, so no need to write in the session by participants. The Researcher(s) can record all of these details.
10. The Committee noted that the POMRC report showed significant difference by elective compared to acute, with larger inequities in the acute setting. The Committee noted the researchers should be aware of this, as the study is looking at just the elective setting.
11. The Committee noted that in the analyses experiences or differences might be related to surgery, anaesthetic, pre op or nurses/clinicians on the ward – and that it can be very hard to untangle this.
12. The Committee queried whether there would be recall bias introduced with the interview being undertaken 4-6 weeks after surgery
13. The Committee noted their concern for bias in the results, and urged the researcher to be aware of this.

Summary of ethical issues (outstanding)

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

1. Add data management to the protocol, including: de-identification, physical and electronic security of documents and limiting and monitoring the number of people who have access to the data. Clarify who will be undertaking the survey and how it will be undertaken.
2. Remove all identifiers off survey tool, including demographics, and ensure ethnicity is collected using NZ census questions <https://ethics.health.govt.nz/guides-templates-forms-0/cultural-questions-%E2%80%93-guidance>. Use a study number to protect privacy.
3. The Committee asked how participants are identified. The Researcher(s) noted that they are proposing to approach patients in the pre-operative setting and then undertake the survey in the post-operative period. The Committee advised a reconsideration of this approach, in order to allow participants sufficient time to consider participation. For example, a letter invitation or consideration of the pre-admission or booking
4. The Committee asked whether the pilot could be completed with adults, asking for a justification for inclusion of children. The Researcher(s) explained the need to include children, as well as to learn assent procedures. Further information on this justification was requested, the Committee noted that researchers must conduct research with least vulnerable population that can answer the research questions.
5. The Committee queried whether the Researcher(s) thought that there may be behaviour change in the hospital staff (e.g. anaesthetists) when they know that patients will be asked about cultural competence or experience of the operative pathway.
6. Note the peer reviewer comment about not having a non-Maori comparison group in order to correlate differences in experience to potential perioperative outcomes of interest. The Researcher(s) noted that they are interested in describing Maori experience only in this study. The Committee discussed the important of being clear about what study is trying to achieve, for example creating protocols to follow by anaesthetists to follow to support Maori rather than attribution of mortality differences.
7. Sample size of 300 for full study was discussed, there are no end points of within-group comparators from which to assess sample size, and it is descriptive. The Researcher(s) noted that their reference for the sample size was for a process of factor analysis used in other similar kinds of research. The Committee requested more information on the sample size justification, as factor analysis is a specific methodology. Suggest statistical support.
8. The Committee discussed consenting process for people who are not competent in the sense of having a cognitive impairment (i.e., not because they are children). The application suggest that those with an intellectual disability may require involvement of their legal guardian along with whanau. If the researchers wish to pursue this group of patients, a justification and PIS and consent form will need to be created for persons interested in the welfare of the intended participant and consideration will also need to be given to right 7(3) and 7(4) of the Code of Patients’ rights. The Committee suggests that it may be better not to include this group at this time.

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

1. Please use the HDEC template and fill in some of the things which are missing and to ensure participants are fully informed (mana tangata) (e.g., compensation wording, statement of risks and benefits, contact numbers, rights of access and correction, contacting GP and for incidental findings, return of individual results and summary of study results). <https://ethics.health.govt.nz/guides-templates-forms-0>
2. Please add ‘you may wish to talk to whanau about participation in this research’.
3. Is this part of qualification? The Researcher(s) stated possibly. If it does, needs to be added to participant information sheet
4. The Researcher(s) clarified that there will be a pilot first. Please include.
5. PIS and consent documentation needs to be amended – for example, there should be a PIS for parent/guardians to consent for the under 16s.
6. forms
7. The Committee think the PISs for both the 7-12 year age group and for the 12-15 year olds are too complex and need to be simplified.
8. The Committee noted there are no consent for parents – for 7-15 years old and this needs to be uploaded.
9. Linking individual survey data, to individual interviews, including for purposeful selection for interviews – this is not usual practice and will need to be carefully explained to participants in the PIS. Suggest including a consent element in the survey for consent to re-contact for the interview.
10. The two week withdrawal period is not in all PIS. Please clarify.

Decision

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

* 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)*
* All observational studies should be conducted according to written protocols that state the aims of the study, the data needed and how the data will be collected, used and protected. (*Ethical Guidelines for Observation Studies* 5.11)

## 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:** | 16 October 2018, 01:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

1. **Problem with Last Minutes**

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

The meeting closed at 6.45pm