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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 01 May 2018 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:10pm | Confirmation of minutes of meeting of 03 April 2018 |
| 12:30pm | New applications (see over for details) |
|  | i 18/NTB/62  ii 18/NTB/63  iii 18/NTB/65  iv 18/NTB/67  v 18/NTB/68  vi 18/NTB/75 |
|  | General business:   * Noting section of agenda |
|  | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2015 | 01/07/2018 | Present |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 20/05/2017 | 20/05/2020 | Present |
| Mrs Kate O'Connor | Lay (ethical/moral reasoning) | 14/12/2015 | 14/12/2018 | Present |
| Dr Nora Lynch | Non-lay (health/disability service provision) | 24/07/2015 | 24/07/2018 | Present |
| Mrs Leesa Russell | Non-lay (intervention studies), Non-lay (observational studies) | 14/12/2015 | 14/12/2018 | Present |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Apologies |
| Mrs Jane Wylie | Non-lay (intervention studies) | 20/05/2017 | 20/05/2020 | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Mr John Hancock.

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 03 April 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/NTB/63** |
|  | Title: | Development of mSACSBI – a mobile SACS brief intervention |
|  | Principal Investigator: | Dr Grant Christie |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 April 2018 |

Dr Grant Christie 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 project will involve building and testing an mHealth brief intervention related to drug and alcohol use that can be completed independently by a young person alone or in association with their health worker.
2. The current paper and pencil screening test will be translated into an e-Health format and using co-design methodology, work with youth alcohol and drug clinicians and young people to develop an acceptable and effective brief intervention that maximises the potential of the e-Health format.
3. The study will pilot the new e-Health brief intervention (called the mSACSBI) in a sample of young people attending youth alcohol and drug services and gain initial data about its acceptability and utility in addition to qualitative feedback about its use in comparison to older paper based interventions.
4. This application covers the youth and community engagement processes for the co-design process and to check its acceptability and usability.

Summary of ethical issues (resolved)

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

1. The Committee noted that that study proposed to use the CADS group without parental consent for participants 14-15 years. The Committee were satisfied on the basis of the Gillick principles the Researcher knows the participants and their capability to give informed consent.
2. The Committee noted that there was potential commercial gain from the study and highlighted that participants appointment time was being used to generate data for the study. The researcher stated the discussion groups will take place before or after appointment time and noted that from experience the children gain real benefit from being involved and appreciate the opportunity to give feedback.
3. The Committee queried what would happen if participants in the CADS group did not want to take part in the focus group and whether they would receive treatment in that time. The Researcher noted that the focus groups are in addition to therapeutic time. Please ensure it is clear to participants that taking part in focus groups will not interfere with their ordinary appointment time.
4. The Committee noted that some participants in the CADS group would be under 16 years of age and queried whether this age group would be in the same focus group as older participants. The Researcher confirmed that they would look at referral notes and separate participants by ages. The Committee were satisfied that there is appropriate age separation in place on a clinical basis.
5. The Committee queried if there had been consideration for Not in Education, Employment, or Training (NEET) young persons as potential / possible users who are more likely to be lost to systems and institutions as these could potentially be a group requiring most access to this service. The Committee queried how the Researcher would ensure the intervention worked on the right type of people in most need, as they are excluded from testing. The Researcher noted using groups at Odyssey House would compensate for this.
6. The Committee queried the type of personal information to be collected from participants. The Researcher confirmed that no personal information would be collected. The Researcher confirmed that a tally of males, females, age ranges, etc. would be taken from the group but there would not be any linking of individual participant’s comments to their demographic details.
7. The Committee queried if participants would receive a gift to compensate for their time. The Researcher confirmed that refreshments would be provided at the sessions.

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 would like a copy of the paper questionnaire which is being used to develop the app, uploaded to the portal.
2. The Committee noted that the Researcher would like to approach schools to recruit potential school children participants. The Committee requested more information on this aspect of the study, for example, recruitment processes and gaining consent. The Researcher noted this is not a significant part of the research plan but was included in the ethics application in case this is required for future research. The Researcher is working with the HABITs project who already have groups working with schools. The Committee expressed concern over using school children aged under 14 years without parental consent. The Researcher agreed that if schools were approached then only those with older groups of children (16 years plus) would be included.
3. The Committee noted that this application is specific to Stage 1 of the study and asked the Researcher to clarify if the participant population includes over 16 years, Odyssey House and CADS. The Research confirmed that this stage of the study is targeted at older adolescents (16 year plus). Stage 2 of the study would include participants from youth services etc., however this would require a separate ethics application.
4. Please amend the study protocol to address the concerns of the Committee with respect to study including only participants 16 years and over, in the school setting and without parental consent.
5. The Committee would like to see screen shot examples of the app in order to know what the participants will be viewing.

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

1. Youth Participant Information Sheet -the committee suggested using a different word to “help” in the statement “If you want to help us you will need to sign a consent form”. The committee suggested using “participate”.
2. Please ensure audio-recording is included on the consent form.
3. Youth Participant Information Sheet – please rephrase / remove the statement “Most young people enjoy the experience a lot”. The Committee suggested using less coercive language.
4. Please proof read the document for typos / grammatical errors.
5. Both Participant Information Sheets - Please include contact details for a Maori support person who is independent of the study.
6. Please remove all tick boxes from statements in the consent form.
7. The Committee noted that the Participant Information Sheet says “We will spend 15 minutes of your usual treatment session”. Please modify this statement so it is clear to the participant that time is before / after usual treatment session.
8. Please ensure there is a separate Participant Information Sheet for school children aged 16 years and above.
9. The Committee noted there are discrepancies in the Participant Information Sheet and protocol for the length of treatment session. The Participant Information Sheet says 15 minutes and the protocol mentions 1 hour in the school setting. Please consider if 15 mins is a realistic timeframe and that times are consistent in the protocol and Participant Information Sheet.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies* paragraph *6.10)*.
* Please amend the study protocol to address the concerns of the Committee with respect to study including participants 16 years and over, in the school setting and without parental consent.
* Please respond to the outstanding ethical concerns detailed above.

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

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| 2 | **Ethics ref:** | **18/NTB/62** |
|  | Title: | Cognitive Stimulation Therapy and Chair Yoga in Dementia |
|  | Principal Investigator: | Dr Gary Cheung |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 19 April 2018 |

Dr Gary Cheung and Dr Kathy Peri were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This single-blinded pilot study will test a novel intervention combining cognitive stimulation and physical activities using chair yoga in the treatment of mild to moderate dementia.

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 how capacity will be determined. The Researcher confirmed that a member of the research team who is a qualified occupational therapist would assess participant capacity. The Researcher clarified that the Montreal Cognitive Assessment (MoCA) would be used to assess capacity using 10 as the cuff off, with some scope for flexibility. The Researcher confirmed the study would include participants with mild / moderate dementia only. Potential participants would be identified by the Selwyn Foundation retirement village’s staff and subsequently screened by a Researcher to determine eligibility.
2. The Committee noted that the Participant Information Sheet states the consenting process with take 20 minutes and queried whether someone with mild/moderate dementia would have the willingness and attention span to discuss the consent form for 20 minutes. The Researcher noted that this would include watching videos and that 20 minutes was an average figure and the time dedicated to the consenting process would be responsive to the participants needs.
3. The Committee queried whether participants have the ability to make their own decisions. The Researcher clarified that with mild dementia the participants would be able.
4. The Committee noted that that the video clips provided with the application were long and not focused. The Researcher confirmed that they would produce programme specific videos and include the faces of the research team as more reassuring for participants.
5. The Committee noted that there is not an assent document for people that Right 7(4) of the Health and Disability Commissioner’ Code of Rights best interest would apply to. The Committee were satisfied with the Researcher using short video clips as a method of conveying information required for assent.
6. The Committee queried whether Cognitive Stimulation Therapy is routinely offered at Selwyn Foundation retirement village. The Researcher noted that Cognitive Stimulation Therapy is provided on an ad hoc basis and therefore residents do not automatically receive it. The Researcher noted that Cognitive Stimulation Therapy is only delivered at Selwyn Village in Pt Chevalier but not Selwyn Heights in Hillsborough or Selwyn Oaks in Papakura. The Committee decided that participation in this research project would more reliably provide access to Cognitive Stimulation Therapy for residents with mild-moderate dementia.
7. The Committee queried what happens to participants at the end of the 10 week treatment programme. The Researcher confirmed that there would be a maintenance programme embedded in the Cognitive Stimulation Therapy if the study results are positive. The Researcher noted that Cognitive Stimulation Therapy ordinarily involves a 7 week programme (2 days a week for 1 hour) and a maintenance programme for 24 weeks (1 day per week).
8. The Committee queried how the relationship with Selwyn villages would be managed as some staff members are part of the Research team. The Researcher noted that that Lead Therapist would be employed one day a week to work with the Research team using a research grant and would be supported by Dr Kathy Peri, an experienced researcher, who would ensure participants are treated fairly.
9. The Committee queried who would take consent. The Researcher noted that an Occupational Therapist who works at the University would take consent.
10. The Committee noted that food and koha is accounted for in budget and asked whether this is being used for participants. The Researcher clarified that morning tea and biscuits would be provided at the group session.
11. The Committee asked for assurance that the neuroimaging component has been removed. The Researcher confirmed that this had.
12. The Committee queried how groups would be randomised. The Researcher confirmed that the statistician had advised using 3 sealed envelopes and selecting the groups using this method.

Summary of ethical issues (outstanding)

1. Data Safety Monitoring – please ensure there is an interim data analysis review in place to monitor incidence of refusal, for example. Please include this detail in the study protocol.
2. Please ensure the protocol includes the suggestions from Mrs Kahu Pou regarding Maori participation.
3. Please clarify how informed assent is being evidenced (by witness, or recording of oral consent).

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

1. Please proof read the document for typos / grammatical errors.
2. The Committee queried if the relatives of the Right 7(4) participants are allowed to be in the sessions. The Researcher confirmed that there is a policy in place to allow relatives to attend the first session to provide an assurance of what the session entails. Relatives are allowed to attend further session if they are particularly keen to, however they are required to sit at distance from the group and not participate. Please ensure this is clear in the Participant Information Sheet that this is the expectation of the Researcher and the reasons for this.
3. The Committee noted that 1.5 hour testing is a long time for participants with dementia and queried if all the tests are absolutely necessary. The Researcher noted testing usually takes 1 hour and that the tests are all necessary. Breaks would be included. Please ensure it is clear in the Participant Information Sheet that breaks will be included as part of the testing time.
4. Please avoid the term “pen and paper” in the Participant Information Sheet. Please ensure it is clear to participants that they are not required to write things down as if it is a pen and paper test.
5. Page 3 of the Participant Information Sheet – please remove the statement “As health professionals, we believe the potential benefits of the program would outweigh the potential risks”. The Committee felt that this statement is coercive.
6. Please ensure it is clear to participants that although the Researcher will attempt to maintain confidentiality, the intervention will be in a group setting with other participants watching.
7. Next of kin Participant Information Sheet and consent form – please call this an Information Sheet only as a next of kin cannot consent.
8. The Committee suggesting using “Family and Whanau” on the Participant Information Sheet title. This Participant Information Sheet should say that the family / whanau indication will be considered in the decision of whether or not to include that person in the study.
9. Next of kin Participant Information Sheet - Please review and amend the wording “Your involvement as a next of kin is important as some of the people with dementia, due to their memory and thinking problem, may not be able to decide whether to participate in the study.” The Researcher confirmed that they are not seeking consent from family members but their views on whether they think their loved one would wish to participate. Please ensure it is explicit in the next of kin Participant Information Sheet that their participation is secondary to the participation of the participant in the study.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please include Data Safety Monitoring in the study protocol *(Ethical Guidelines for Intervention Studies para 6.50).*

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

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| **3** | **Ethics ref:** | **18/NTB/65** |
|  | Title: | (duplicate) Improving detection and management of AF |
|  | Principal Investigator: | Dr Katrina Poppe |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 April 2018 |

Dr Katrina, Prof Rob Doughty and Dr Anna Rolleston were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The aims of this study are to enhance detection of Atrial fibrillation (AF) in primary care, to assess the management of stroke and cardiovascular diseases (CVD) risk in people with AF and compare to those without AF, and to evaluate the implications of adding systematic testing for AF to primary care practice.
2. The secondary aim is to contribute data from the Waikato region to a longer term project of developing new vascular risk scores for people with AF in NZ.
3. The study will use smartphone devices to test for AF among people aged 35 and over when they attend a GP appointment.
4. Patients who test positive for AF will be clinically assessed by their GP according to standard practice. At the end of recruitment, a pre-specified list of variables will be extracted from the electronic medical record on all study participants. These data will be de-identified and linked to national data on dispensing, hospitalisations and death.

Summary of ethical issues (resolved)

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

1. The Committee acknowledged the work the Researcher had put into the re-submission.
2. The Committee queried how health information is linked to a future health record and how is this done anonymously. The Researcher confirmed that when the patient is seen by the clinician their data goes in the electronic health record with a flag indicating research consent has been obtained. At the end of the recruitment phase (6 months) the primary health organisation clinician will extract the data of patients who agreed to be part of the study. The patients NHI will be replaced with a study specific encrypted NHI that is compatible with the encrypted NHI that will be applied to the national data set, which is then linked to the study data. Before the data leaves the primary health organisation it will have the encrypted NHI and no identifiable patient data in it. That data is sent to the research site. The Researcher obtains encrypted data from the Ministry of Health. This data and encrypted NHI and can be matched. The Research site never sees the patient’s name, NHI or other identifiable health information. The Researcher confirmed that in a research context it is not possible to unencrypt “patient x” encrypted number in order to identify them.
3. The Committee noted that the response from the Maori consultation referred to tissue samples and queried if the study involved human tissue. The Researcher confirmed that the does not involve human tissue.

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 queried the recruitment process for the opportunistic intercept group and whether their consent can be considered informed given that they may not have adequate time to digest the information or discuss with their families. The Researcher confirmed that the consent process would be similar to most research studies where a potential participant is provided with an information sheet at the time of their appointment and before consent is obtained. If the participant does not feel informed or if they have further questions then they do not give their consent for their data to be used in research. The Researcher noted that if the participant changed their mind after giving consent they could inform their GP and request to be ‘unticked” on their electronic health record. The Committee queried if potential participants could take the Participant Information Sheet away and provide consent at their next appointment, if they wish. The Researcher confirmed that there is a 6 month recruitment window which would allow ample time to digest the study information, discuss with family members and the research team.

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

1. The Committee queried if interpreters will be provided. The Researcher noted that participants are being seen as part of their standard clinical care. The Committee noted that as Maori and Pacific people would benefit from this study not having the Participant Information Sheet in their first language could exclude them from participating in the study. The Researcher agreed to the Participant Information Sheet could be translated to other languages.
2. The Participant Information Sheet should better inform participants that in addition to studying AF, the research is gathering cardiovascular risk information on all participants whether in AF or not. This is to be added to an existing database along with data from Ministry of Health and GP records at 2 years.
3. The Committee noted that minor differences are necessary between the Participant Information Sheets intended for patients with their appointment letter and those who are intercepted on the day of their appointment. Please customise the Participant Information Sheets to address the two different contexts. Please ensure it is clear to the intercept group that they do not have to make an immediate decision.
4. The Participant Information Sheet needs to be clearer on what 'pre-specified data variables' will be collected on participants such as whether or not prescription is filled, demographics, and chart data such as smoking etc.
5. Consent form – The Committee suggested using some of the standard statements provided in the HDEC consent form template, in particular those clauses around adequate time provided, opportunity to discuss the study, and awareness that their clinical data will be harvested. Please refer to: <https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates>
6. Please provide more detail in the Participant Information Sheet and consent form on how to withdraw within the 2 year study period and what will happen to data already collected.
7. Consent Form- please remove the reference to the waiting room poster.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies* paragraph *6.10)*.
* Please respond to the outstanding ethical concerns detailed above.

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Mrs Kate O'Connor.

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| **4** | **Ethics ref:** | **18/NTB/67** |
|  | Title: | Testing of a patient lifting and transfer device |
|  | Principal Investigator: | Dr Erin Mansell |
|  | Sponsor: | Hapai Transfer Systems Ltd. |
|  | Clock Start Date: | 19 April 2018 |

Dr Erin Mansell 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 study is to facilitate the design and development of a patient lifting and transfer device for home and institutional use. The device is designed to pivot the patient forward from a sitting position onto the device where they can be manoeuvred and transferred onto a different sitting surface. The use of mechanical advantage negates the need for the device to be powered but still allows a single carer, who may themselves be frail, to move the patient with little force or strength. This device would be considered a Class I medical device by the TGA.

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 studies connection with the University of Canterbury. The Researcher noted that a lecturer from the University had been working on the project for 20 years.
2. The Committee queried if there is an IP sharing agreement with the University. The Researcher confirmed that the project developed would be gifted to the sponsor company. The Committee noted that there is a potential commercial benefit.
3. The Committee asked for clarification if caregivers are participants, i.e. is the lift usability being researched from their perspective. The Researcher clarified that for purposes of study the person being lifted is the participant, and caregivers are not considered participants for this phase of the study.
4. The Committee queried if some participants will be intellectually disabled in addition to being wheelchair users. The Researcher noted that they want participants to give informed consent so would only include participants with enough intellectual ability to do this.
5. The Committee queried who would be responsible for determining capacity to consent. The Researcher stated that a welfare guardian could provide assent for a participant who does not have the capacity to consent. The Committee noted that it is not appropriate for welfare guardians to sign an assent of competency. The Committee noted that New Zealand law does not allow an adult to consent for another adult to participate in health research. The Committee noted this is an early phase study and requested that participants who are unable to consent for themselves be excluded from the study. The Researcher agreed that only persons with capacity to provide consent on their own behalf would be included.

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 queried whether the testing will occur in private residences. The Researcher confirmed that testing may take place in participant homes. The Committee requested that the Researcher consider cultural issues and developing a safety protocol for research staff.
2. The Committee queried what liability issues arise from this study, noting that early phase user-acceptability studies for the purposes of developing a product which may become available commercially does not meet the definition of intervention studies, but a later stage clinical trial of what effect the product or device had on health might. The researchers should seek the advice of the Research Office at Canterbury University regarding liability issues (including who will be responsible for compensating participants for personal injury or damage to property occurring as a result of the product being tested). Please ensure that the arrangements for compensation are clear in the Participant Information Sheet.
3. The Committee requested a peer review of the built prototype to provide assurance that the device is safe and robustly constructed.
4. The Committee suggested providing a video demonstration of someone using the device along with photographs, as an additional means of communicating how the device works to potential participants.
5. The Committee noted that storing data on Google Drive is not recommended as this is not a secure format. Please ensure that data is stored securely. The Committee requested a copy of the data management protocol.
6. Please consider consultation with other relevant groups, e.g. disability groups.
7. The Committee noted that the study requires Maori consultation, as per HRC Guidelines for Research Involving Maori.
8. The Committee suggested the Research collect ethnicity data. Please use the Health and Disability Ethnicity Data Protocols standard ethnicity collection question when collecting ethnicity data to ensure the options available are suitable for New Zealand participants. These options are: New Zealand European, Māori, Samoan, Cook Islands Maori, Tongan, Niuean, Chinese, Indian, Other (such as Dutch, Japanese, Tokelauan), please state.
9. Peer review – the Committee noted that the peer reviewer suggested the usefulness of testing over several days. The Researcher confirmed that this study is focused on single lift design as its still at the early phase.
10. Please provide copies of the study feedback interview/questionnaires.

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

1. The Committee requested a thorough review of all Participant Information Sheets.
2. The Committee suggested using the standard HDEC Participant information sheet and consent form template [https://ethics.health.govt.New Zealand/guides-templates-forms-0/participant-information-sheet-templates](https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates) . This will ensure essential information is included such as the rights of the participants, contact details (including a Maori contact) other than the Researcher, right to access information, etc.
3. Please remove the yes/no tick boxes from the consent form for all statements that aren’t truly optional, that is a participant could select ‘no’ and still participate in the study.
4. The Committee suggested using real photographs rather than stick figures in the Participant Information Sheets.
5. The Committee requested that any references to welfare guardians giving consent / assent should be removed. All participants > 16 years will consent for themselves. Study Information documents should be provided to relatives /carers purely as a courteous, information giving tool.
6. Please provide a clearer explanation in the Participant Information Sheets of how the devise works and provide some indication of how it will feel for the participant.
7. The Committee queried whether this is the first testing in humans of the device and suggested including some brief detail in the Participant Information Sheets to explain what stage of development the device is at.
8. Exclusion criteria - Please consider all exclusion criteria and ensure these are clearly listed in the Participant Information Sheets, such as height, weight, leg power, respiratory conditions, scars on chest, wounds, and any other exclusion criteria.
9. The Committee queried if audio recording would be used. The Researcher confirmed that recording would be by hand written notes only. Please ensure this is clear in the Participant Information Sheets.
10. The Committee queried if the participants for whom English is not their first language would be included in the study. The Researcher noted that there were no plans to include non-English speaking participants. The Committee recommend that in the interest of equity and representing the population in its entirety that using an interpreter servicers if available at rest home would be beneficial. The Committee requested that the Participant Information Sheet is very clear that participant may be excluded based on language.
11. The Committee queried where testing for children would take place. The Researcher did not have definite information at this stage. The Committee requested that this information is included in the Participant Information Sheet as well as any associated travel costs. The Committee noted that if travel costs are incurred by participants then these should be reimbursed.
12. Children PIS – Please ensure it is clear that even if the child’s parent agrees for them to participate in the study, it is acceptable for them to say no.
13. The Committee suggested providing a separate age-appropriate assent information sheet for participants 12-15 years.

Decision

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

* Please conduct Maori consultation – this may occur after HDEC approval but the process of consultation and detail regarding the consulted group must be outlined. (*Ethical Guidelines for Intervention Studies* *para 4.7*).
* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please provide a copy of the data management protocol (*Ethical Guidelines for Observational Studies* paragraph 8.3).
* Please provide peer review of the built prototype (*Ethical Guidelines for Intervention Studies appendix 1*).
* Please provide assurance to the Committee that appropriate safety protocols for home visits are in place.
* Please respond to the outstanding ethical concerns detailed above.

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| **5** | **Ethics ref:** | **18/NTB/68** |
|  | Title: | Upfront pembrolizumab for unfit patients with Hodgkin Lymphoma - PLIMATH STUDY |
|  | Principal Investigator: | Dr Leanne Berkahn |
|  | Sponsor: | Peter MacCallum Cancer Centre |
|  | Clock Start Date: | 19 April 2018 |

Dr. Leanne Berkahn, Joanne Lim and Marlynn Ali were present by teleconference for discussion of this application.

Potential conflicts of interest

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

Mrs Jane Wylie declared a potential conflict of interest, and the Committee decided that Mrs Jane Wylie could take part in the discussion and decision of the application.

Summary of Study

1. The aim of this study is to test how safe and effective the research study drug, pembrolizumab is as a treatment for patients with Hodgkin lymphoma who have not previously been treated for this disease and who are not deemed sufficiently physically robust to cope with standard first line curative chemotherapy.
2. Patients will go through a number of screening procedures to ensure they are eligible for the trial and if they pass screening they will all receive pembrolizumab 3 weekly for up to 2 years (35 cycles) of treatment.

Summary of ethical issues (resolved)

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

1. The Committee queried how the Researcher will assess co-morbidities and fitness of participants over 65 years. The Researcher confirmed that performance status would be an important indicator and participants must be fully functional and doing all their activities of daily living (ADL’s).
2. The Committee noted reference to CIRS assessment in the appendix of the protocol and queried whether participants would need a certain CIRS score to be eligible to participate. The Researcher noted that the CIRS score would be captured as part of screening and history taking however would not be used in the study’s particular algorithm. The Researcher clarified that participant eligibility would be determined by clinician judgement formed through a routine multidisciplinary meeting.
3. The Committee queried if Auckland Hospital would do all PET-CT's for all 6 assessments. The Researcher noted that they could substitute CT for PET-CT in the same patient if required.
4. The Committee queried the likelihood of a person receiving their diagnosis and being invited into the study on the same day. The Researcher confirmed that this would not happen.
5. The Committee queried whether there would be other staff members who could carry out the consenting process in order to introduce a degree of separation between the clinician / Researcher role. The Researcher confirmed that other members of staff would be available to assist the consenting process.

Summary of ethical issues (outstanding)

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

1. The Committee noted that Merck had been named as the funder but not as a sponsor. They queried if any other study information would be shared with Merck apart for the final study report. The Committee noted that statement on page 59 of the protocol - Overview of Correlative Studies: "*The chosen essay for assessment of expression of PDL1/PDL2 has been recommended by Merck and will be performed in a single lab either at Peter Mac or at a site with a study co-investigator. Expression will be scored in collaboration with Merck based on methodologies used in other lymphoma pembrolizumab trials. This enables comparison of tumour samples from this study with other clinical trials*." The Committee noted that this suggests Merck gets to be closely involved with the analysis of biomarkers and this information will be available to them for future research and they have access to important raw data. The Researcher would like to clarify this with Dr Michael Dickinson and report back to the Committee.
2. The Committee noted the implications for injury compensation and whether ACC cover apply. The Committee noted that in order for ACC to be activated in the case of treatment injury they need to be satisfied that the research is not carried out principally for the benefit of the manufacturer or distributor of the study drug. The Committee reserved judgment on whether the study is commercial / non-commercial until the Researcher provides a list of all the data that will be accessed by Merck. The Committee requested that the Researcher reflect on where the main benefit lies to determine if the study is to be conducted principally for the benefit of the manufacturer or distributor of the item being trialled.
3. The Committee queried if the Researcher had received a response from Auckland Maori Research committee. The Researcher confirmed this had not been received yet but would follow up.
4. The Committee queried how long tissue samples would be stored for and noted inconsistencies throughout the study documentation. Please review and update all study documentation to ensure consistency throughout.

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

1. Participant Information Sheet – please include more up to date safety data (currently March 2016 data is provided).
2. The Committee noted that participants do not have to complete a form to withdraw from the study. Please ensure it is clear to participants that they can withdraw verbally and completing the form is optional.
3. Please remove reference to hair and saliva samples on page 10 of the Participant Information Sheet.
4. Please remove the reference on page 11 of the Participant Information Sheet “Decisions made by the company that manufactures Pembrolizumab”.
5. Please ensure it is clear in the Participant Information Sheet that the study sponsor is based in Australia.
6. Page 9 of the main Participant Information Sheet – please review the section on genetic research and remove unnecessary information.
7. The Committee noted that the cultural statement for tissue samples is expressed in the future unspecified research form but not the main Participant Information Sheet. Please include in both where relevant.
8. Please use the correct New Zealand ethics committee name on page 13 of the Participant Information Sheet.
9. Page 12 of the Participant Information Sheet states “The assigned study ID and your initials will be the only identification used on all research records and study specimens”. The Committee noted that initials are considered identifiable information. Please ensure that only the study ID is used.

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 reflect on where the principal of benefit lies (*Ethical Guidelines for Intervention Studies* *Section 8*).
* Please provide a list of all the data that will be accessed by Merck.
* Please respond to the outstanding ethical concerns detailed above in a cover letter.

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

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| **6** | **Ethics ref:** | **18/NTB/75** |
|  | Title: | Is Activation Therapy Effective for Depressed Inpatients? |
|  | Principal Investigator: | Dr. Richard J. Porter |
|  | Sponsor: | Clinical Research Unit |
|  | Clock Start Date: | 19 April 2018 |

Professor Richard Porter 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 study looks at whether Activation Therapy (AT) added to standard inpatient treatment (TAU), compared with TAU alone is more effective at lowering the number of times people with depression are readmitted to hospital after they have been discharged home.
2. Patients who agree to take part will be randomly divided into the two groups to compare AT with TAU for two weeks. AT combines two therapies called Cognitive Activation (CA) and Behavioural Activation (BA). Patients receiving AT will have eight 35 minute sessions with a therapist and ten online computer exercise sessions to help with cognitive functions such as memory, planning and organisation. Physical activity will be recorded using special watches. Mood, and cognitive function will be assessed at the beginning of treatment and at intervals until twelve weeks after treatment.

Summary of ethical issues (resolved)

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

1. The Committee queried how capacity to give informed consent to participate in the research study is assessed. The Researcher clarified that individuals whose capacity to consent is significantly impaired would be excluded from the study.
2. The Committee queried whether there would be an opportunity for potential participants to consult with family members before consenting. The Researcher confirmed that there would be an opportunity to ensure a supported decision making process.
3. The Committee queried why individuals over 65 years were excluded from the study. The Researcher confirmed that there are future plans to conduct research in that group but for practical reasons (over 65 year-old patients are based at a different hospital) and cognitive deficient reason this group are excluded.
4. The Committee queried the scientific validity aspect of the study as the AT arm will be getting much more therapist time. The Committee queried how the study could show that it is the specific intervention rather than just the company/attention that helps if there is a significant outcome difference between the arms. The Researcher acknowledged this but advised that if they do not study this intervention against treatment as usual then they would not get uptake if it’s effective.
5. The Committee queried whether the FAST assessment involves gathering information from other people about the participant. The Researcher confirmed that usually the FAST assessment is completed with the participant and the Research Nurse however, where it was not possible to obtain the information from the participant information would be sought from family members. Please ensure this is clear in the Participant Information Sheet.
6. The Committee queried if the Sponsor has access to the data while it is stored in the online repository. The Researcher confirmed that the Sponsor will not have access.
7. The Committee queried how the Researcher would ensure the study included a representative sample with regards to Maori population. The Researcher confirmed that there are plans to recruit a Māori Researcher to be part of the study team if adequate funding can be secured.

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 queried where the data gathered via the cognitive testing tool is stored. The Researcher noted that the data is stored in an online repository. Please provide assurance to the Committee around the safety protocols in place to protect the data.
2. Please review the COBRA document for grammatical errors.
3. The Committee requested to a copy of the study safety protocol.
4. Please consider a different word to “blue” in the depression Inventory.
5. The Committee noted reference to the Mobility Watch and analysis of voice recording in the Participant Information Sheet only applying to the Hillmorton patients (i.e100/170). The protocol and consent form suggest these measures apply to all. The Researcher confirmed that this would only apply to the Hillmorton participants. Please amend the protocol. Please provide an adjusted consent form as participants at other institutions will not be consenting to this.

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

1. Please include a statement in the Participant Information Sheet how participants can withdraw, i.e. speak to the Researcher / clinical team.
2. Please remove the list of Researchers names on the consent form.
3. Please add the contact details (name and number) of the researchers, HDEC and Maori to the Participant Information Sheet.
4. The Committee requested the compensation wording is included in the Participant Information Sheet , they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
5. The Committee noted that page 1 of the Participant Information Sheet refers to 100minutes and queried if this is correct. The Researcher confirmed that this is correct.
6. The Committee suggested using another term for “flip of a coin” e.g. “chance”.
7. Please use the term “study” rather than “project” in the Participant Information Sheet.
8. The Committee queried whether the FAST assessment is part of standard treatment. The Researcher confirmed that it is not. Please ensure it is clear in the Participant Information Sheet that the Researcher may collect information from another person about the participant.
9. Please increase the Participant Information Sheet font size to 12 as a minimum.
10. Please provide an adjusted consent form as participants at institutions other than Hillmorton will not be consenting the Mobility Watch and analysis of voice.
11. Please ensure this is clear in the Participant Information Sheet that information may be sought from family members where a participant cannot provide information via FAST assessment.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide assurance to the Committee around the safety protocols in place to protect the online data gathered via the cognitive testing tool
* Please respond to the outstanding ethical concerns detailed above in a cover letter.

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

## General business

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

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| --- | --- |
| **Meeting date:** | 05 June 2018 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

**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 3:30pm