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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 05 June 2018 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:15pm | Confirmation of minutes of meeting of 01 May 2018 |
| 12:30pm | New applications (see over for details) |
|  | i 18/NTB/87  ii 18/NTB/100  iii 18/NTB/89  iv 18/NTB/81  v 18/NTB/88  vi 18/NTB/90  vii 18/NTB/93  viii 18/NTB/94  ix 18/NTB/83  x 18/NTB/101  xi 18/NTB/96  xii 18/NTB/97 |
| 6:25pm | General business:   * Noting section of agenda |
| 6:30pm | 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 | Apologies |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Present |
| Mrs Jane Wylie | Non-lay (intervention studies) | 20/05/2017 | 20/05/2020 | Present |

## Welcome

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

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 01 May 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/NTB/87** |
|  | Title: | Evaluating the Safety, Tolerability, Pharmacokinetics and Efficacy of EDP-305 in Subjects with NASH |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Enanta Pharmaceuticals Inc. |
|  | Clock Start Date: | 24 May 2018 |

Prof Edward Gane and Olivia Thame were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a phase 2 study of a potential treatment for NASH, the study will involve patients with NASH and will investigate the safety of the study drug and the best dose.
2. There are no current clinical treatment, other than lifestyle changes, for NASH.

Summary of resolved ethical issues

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

1. The Committee queried the identifiability of study data and samples, as the application states Date-of-Birth will be included. The Researcher clarified that the information in the Participant Information Sheet is correct and states that data and samples sent to the sponsor only include the unique study code.
2. The Committee queried whether potentially identifiable data may be available for future researchers. The Researcher clarified that this will be de-identified and was intended to refer to the optional research.
3. The Committee noted that the period covered by the insurance certificates provided differs from the proposed study period, adequate insurance coverage must be in place for the entire duration of the study.
4. The Committee noted that studies should not be terminated simply for reasons of commercial interest or public relations (*Ethical Guidelines for Intervention Studies* paragraph 6.65). The Committee stated their preference that this option is removed from study documentation, and noted that if the study is terminated early for any reason consideration must be given to reducing the disadvantages from this for participants, such as by offering post trial access for participants on compassionate grounds.
5. The Committee queried the status of Māori consultation for the study, noting that this consultation is a standard requirement for studies involving Māori participants. The Committee noted that consultation with Pacific communities may also be appropriate as NASH is common in this group.
6. The Committee queried how participants will be recruited. The Researcher explained the referral and recruitment process, noting that they have used this method for other related studies and it is working.
7. The Committee queried the level of reimbursement for participants. The Researcher confirmed it has been determined and is $1000, calculated with the usual method.
8. The Committee queried how targeted recruitment of Pacific participants will be done. The Researcher explained that this is an indirect recruitment strategy.
9. The Committee requested that the application form is carefully completed or checked for each application, rather than using template answers for all studies.

Summary of outstanding ethical issues

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

1. Please ensure that suitable headers are added to the Participant Information Sheet.
2. Please add study contact numbers to the Participant Information Sheet, including details of a suitable person to provide Māori cultural support, as per the HDEC template.
3. The Committee noted that if it is intended to collect information about participant’s partners, should they become pregnant, then a suitable Participant Information Sheet and Consent Form must be provided.
4. Please review the Participant Information Sheet to remove all typographical errors, including run-on words.
5. Please add further information on the study sponsor to the Participant Information Sheet.
6. Please ensure that consistent terminology is used in participant facing documents in relation to the identifiability of study data and samples being sent to the sponsor.
7. Please state up front in the Participant Information Sheet how many people have received the study drug.
8. Please don’t refer to ‘n=’ in the Participant Information Sheet, just state the number.
9. Please ensure that numbers in the Participant Information Sheet are provided in real numbers.
10. Please clarify what is meant in the Participant Information Sheet when it states participants must ‘keep their food consistent’.
11. Please ensure that the framing of information in the Participant Information Sheet and Consent Form are consistent.
12. The Committee suggests updating the data information in the Participant Information Sheet to state that data collected will be relevant to the purpose it is collected, not just relevant.
13. The Committee suggested that the reference to flipping a coin is removed from the Participant Information Sheet.
14. Please clarify the statement about participants paying for their standard care, to ensure participants understand that their usual care will continue to be covered by the public health system.
15. Please add the study sponsor address to the Participant Information Sheet.
16. Under the additional blood sample collection information in the Participant Information Sheet, the last sentence may confuse participants, please revise this sentence.
17. If genetic analysis is planned for the study please add a statement to the Participant Information Sheet about the significance of genetic research.
18. Study records should be retained for 10 years, not 1 or 2 years as stated in in information sheets, please clarify this in the Participant Information Sheets.
19. Please clarify the reimbursement levels for the study in the Participant Information Sheet, and clarify whether reimbursement for the PD/PK study is additional to the main study payment.

Decision

This application was *approved* by consensus, subject to the following non-standard conditions:

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* paragraph *6.22*).

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| **2** | **Ethics ref:** | **18/NTB/100** |
|  | Title: | Testing of a patient lifting and transfer device |
|  | Principal Investigator: | Dr Erin Mansell |
|  | Sponsor: | Hapai Transfer Systems Ltd. |
|  | Clock Start Date: | 24 May 2018 |

Dr Erin Mansell and Mr Richard Shepherd 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 resolved ethical issues

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

1. The Committee thanked the researchers for taking on board the comments made in the earlier decline decision.
2. The Committee queried how participants will be identified and approached. The Researcher explained that they have partnered with rest homes and the staff from the rest home will conduct the initial approach, this will be followed up by researchers providing further information and obtaining informed consent. A physio or occupational therapist will also ensure that participants are suitable to be in the study. Referrals from physiotherapists or occupational therapists will also be used.
3. The Committee queried whether data available to employees will be potentially identifiable. The Researcher explained that raw, identifiable, data will be available to the employees of the company who will de-identify it before it is provided to researchers from the University.
4. The Committee queried how participants will be protected from potential sharp edges, especially those who are in rest homes and may have fragile skin. The Researcher explained that the prototypes used in the study will be very safe.
5. The Committee queried if there is a minimum age, or a minimum height and weight requirement for the study. The Researcher explained it was primarily related to the size of participants, but agreed to put the age range of under 10 as an exclusion criteria in the study protocol.
6. The Committee noted that the period covered by the insurance certificates provided differs from the proposed study period, adequate insurance coverage must be in place for the entire duration of the study.
7. The Committee noted that a suitable researcher safety protocol is included in the study protocol.
8. The Committee noted that although this applications has been submitted as an observational study they view it as an intervention study.
9. The Committee considered whether participants would be covered by ACC for injuries obtained in the study. The *Ethical Guidelines for Intervention Studies* paragraph 8.2 states that participants in clinical trials are excluded from cover under the general provisions of the Accident Compensation Act 2001 if they agreed in writing to participate in the trial and an approved ethics committee did not approve the clinical trial. Participants are also excluded if all of the following conditions are met:
   * the participant’s personal injury results from medical treatment
   * this injury occurs during or after his or her participation in a clinical trial
   * the medical treatment is provided as part of the study
   * the medical treatment is provided by a registered health practitioner
   * the participant agreed, in writing, to participate in the study
   * an approved ethics committee approved the trial, and was satisfied that the trial was to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled.
10. The Committee noted that these conditions are not met by the study, as the study does not involve the provision of medical treatment by a registered health practitioner, The Committee agreed that the participants will be covered by ACC if they are injured during the study. The Committee noted that it is still necessary to have product liability insurance, as provided, in case study participation results in a non-injury cost for participants, for example if the participant’s glasses are broken on accident during their participation.
11. Please ensure that any health information is stored for the appropriate length of time. The Committee noted that the Health (Retention of Health Information) Regulations 1996 impose an obligation on providers of services to retain identifiable health information for a minimum period of 10 years. The Committee noted that these requirements may not apply to this study, however, it is primarily the responsibility of the CI to ensure all legal requirements are met.

Summary of outstanding ethical issues

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

1. The Committee queried the status of Māori consultation for the study, noting that this consultation is a standard requirement for studies involving Māori participants. The Researcher explained that they are in the process of obtaining this. The Committee suggested that the University Research Office or DHB Research Office should be able to assist with referring to an appropriate person for cultural consultation (contact details for these offices are available at ethics.health.govt.nz). Please provide confirmation of cultural consultation for this study, and clarify how cultural issues will be addressed in the study protocol (Ethical Guidelines for Intervention Studies paragraph 4.9).

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

1. Please clarify in the Participant Information Sheet what is involved in the study, including the duration and time involved.
2. Please clarify the screening process with the physiotherapist, occupational therapist, and doctor mentioned in the Participant Information Sheet.
3. Please revise the Participant Information Sheet to remove the statement ‘people like you…’
4. Please provide suitable information sheets and assent forms. This includes an information sheet and consent form for parents of participants unable to provide informed consent, an information sheet and consent form for participants able to provide their own informed consent (this includes all participants aged 16 years or older and may include some younger participants if they are deemed competent), an information sheet and assent form for children, and a very simple information sheet and assent form for young children that should very simply explain their participation in the study. Please ensure these forms have suitable labels. Guidance on assent can be found at <http://ethics.health.govt.nz/guidance-materials/assent-guidance>.
5. In the carer Participant Information Sheet please remove the reference to collecting their medical information.
6. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
7. Please offer in the Consent Form the option for participants to indicate whether they are interested in the longer study participation.
8. Please remove the 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.

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* paragraph 6.22).
* Please provide confirmation of cultural consultation for this study, and clarify how cultural issues will be addressed in the study protocol. Any potential cultural and ethical issues pertaining to Māori must be addressed through appropriate engagement with Māori, which may include discussions with appropriate representatives of specific whānau, hapū and iwi as determined by the scope and method of the study (Ethical Guidelines for Intervention Studies paragraph 4.9).

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

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| **3** | **Ethics ref:** | **18/NTB/89** |
|  | Title: | Infant muscle growth at risk |
|  | Principal Investigator: | Professor Susan Stott |
|  | Sponsor: |  |
|  | Clock Start Date: | 24 May 2018 |

Sîan Williams 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 study involves measuring muscle growth (with MRI and ultrasound) in infants with suspected brain injury, to investigate whether the muscles of babies with suspected brain injury develop in the same way as healthy babies.

Summary of resolved ethical issues

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

1. The Committee questioned what a baby "at risk of brain injury" is, and how they will be identified. The Committee queried whether the injury is something that occurs at birth or if the injury could be related to criminal or negligent behaviour. The Researcher clarified that the most common reason is from premature birth, as part of standard care they have a cranial ultrasound. Participants will be at risk of cerebral palsy and this is one area of particular interest.
2. The Committee noted that as the first tests are 2 weeks after birth this is likely to be a very stressful time for the parents. The Committee queried how this would be mitigated during recruitment. The Researcher explained that usually babies with cerebral palsy are not diagnosed until after 2 years of age, and this means that an early opportunity to provide additional care is missed. Feedback from parents is that they would welcome additional testing and information to be provided. The Researcher explained that as part of standard care risks and options are identified, one of the options that will be available is study participation (although it will be clear that this is not for diagnosis or treatment). The NICU clinicians will identify potential participants who will then be approached by the research team and offered study participation.
3. The Committee discussed the study sponsor, noting that this is the organisation responsible for the conduct of the study. Please clarify who the study sponsor is, the Committee noted that the study sponsor may be the university research office.

Summary of outstanding ethical issues

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

1. The Committee queried the status of Māori consultation for the study, noting that this consultation is a standard requirement for studies involving Māori participants (Ethical Guidelines for Intervention Studies paragraph 4.9).
2. The Committee queried whether $30 per visit is sufficient given the time and effort involved in study participation.
3. The Committee queried why the control group has been presented as a separate application. The Researcher explained that they will be using the results of the separate PhD study with healthy infants, but that the control group is being done for this study. The Committee raised concerns with this approach, noting that as the control group is for this study all the relevant documentation for this must be included with the HDEC application, this should be one protocol rather than a separate protocol. Please provide an updated study protocol that fully includes the control aspect of the study.
4. The Committee queried how control participants will be recruited. The Researcher explained that they intend to recruit early through antenatal groups. The Committee stated that this information must be provided in the study protocol. The investigator should choose a method of approaching participants that meets applicable ethical and scientific standards (*Ethical Guidelines for Intervention Studies* paragraph 6.2).
5. The Committee queried the expected rates of babies failing to be able to have the MRI scans. The Committee queried whether infants who fail the MRI scan, e.g. because they are moving too much, will be excluded from the study or if they will have to come back for another scan. The Researcher explained that they hope it will work out, but they also have an option to make the comparison using the ultrasound instead of the MRI scan if it isn’t practicable to continue the proposed methodology. The Committee requested that it is clarified in the protocol what will happen if participants fail the MRI scan, i.e. will they be removed from the study and another participant recruited.
6. The Committee queried the funding application process for the study. The Researcher explained that the funding should pay for the MRI scans and they intend to begin with the pilot aspect of the study, funding is intended to support the ongoing study.

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

1. 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.
2. Please review the Participant Information Sheet to remove all typographical errors.
3. Please clarify in the Participant Information Sheet the reasons for the study, specifically to compare the muscle development from infants with suspected brain injury to infants who do not have suspected brain injury.
4. In the Participant Information Sheet and Consent Form please ensure that it does not refer to ‘my information’ as it should be ‘your child’.
5. Please clarify in the Participant Information Sheet what happens if the infant is unable to be successfully MRI scanned, for example whether they will be withdrawn from the study.
6. Please provide a suitable Participant Information Sheet and Consent Form for control participants.

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 Mrs Jane Wylie and Mrs Kate O’Connor.

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| **4** | **Ethics ref:** | **18/NTB/81** |
|  | Title: | Qualitative Research into the Lived Experience of Dementia in New Zealand |
|  | Principal Investigator: | Mrs Elizabeth Smith |
|  | Sponsor: | Alzheimers New Zealand |
|  | Clock Start Date: | 24 May 2018 |

Mrs Liz Smith and some co-investigators including a representative of Alzheimer’s New Zealand were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study is being conducted by Alzheimer’s New Zealand and is investigating what it is like for people to live with dementia. The study involves interviewing people with dementia and their family.
2. The Researcher explained the way they developed the research in conjunction with members of the community of interest, human rights experts, and others.

Summary of resolved ethical issues

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

1. The Committee noted that the answer to question p.4.1 in the application form should include the incidence of the condition being studied in Māori. The Researcher explained that they are not certain of the rates by ethnicity, but they are aware that a recent study found that Māori present with dementia at a younger age than New Zealand Europeans.
2. The Committee noted that whakama (embarrassment) is a stand out cultural issue pertinent to this study, but has not been identified in response to question p.4.2 in the application form.
3. The Committee queried the Māori approach to this study, and whether any participants may be Māori. The Committee raised concerns about the comments made in the scientific review document about not following a kaupapa Māori research methodology and the comments made about the potential inclusion of Māori participants. The Researcher explained the reasons for this, noting that other studies have recently been conducted targeting minorities and they do not want their study to duplicate other already done research.
4. The Committee noted that the provided commencement and end date for the study is incorrect.
5. The Committee raised concerns about the proposed timeline. The proposal allows ~ 20 working days (about a month) to do all the interviews and most of the recruitment of 40 people over the North Island, with an interviewer team of 3 and a total working team of ~6. All 40 interviews have to be transcribed, the transcripts offered back to the participants for review and then analysed using phenomology methods. The whole research project will be all but wrapped up and reported to Alzheimer NZ by September in time for them to use the data to feature NZ on World Alzheimer’s Day in September 2018. The Committee queried the need to rush the project. The Researchers explained that it is a best case scenario, and they recognise this may not be met.
6. The Committee queried if there is a risk of over burdening participants who are already being interviewed for another study. The Researcher explained their plans to mitigate this, and to share de-identified data between studies, including that part of exclusion criteria is people who have participated in another study.

Summary of outstanding ethical issues

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

1. The Committee queried the status of Māori consultation for the study, noting that this consultation is a standard requirement for studies involving Māori participants (Ethical Guidelines for Intervention Studies paragraph 4.9).
2. The Committee queried how capacity to consent will be determined, noting that a staged consent process is proposed that involves differing levels of consent. The Researcher explained their proposed consent ladder to involve participants and their carers to varying degrees, depending on their capacity to consent. The Researcher confirmed that no formal capacity assessment will be undertaken. The Researcher explained that they intend to check with the participant’s carers before obtaining consent or assent from participants to the degree they are able, additionally participants will be monitored for ongoing signs of dissent and if they no longer seem keen to participate the researcher will gently end the interview.
3. The Researcher explained that they are proposing a broad consent process that will involve consenting participants at multiple stages to the various optional aspects of study participation, including the use of videos of them by Alzheimer’s New Zealand (which participants will be able to review before it is used).
4. The Committee raised concerns to the use of the term ‘assent’ in this study, noting that this is usually used with children whose parents provide consent on their behalf. The Researcher explained that internationally the term ‘assent’ is used, but understand that this term may not be suitable in New Zealand. The Researcher and Committee agreed that it was better referred to as supported decision making.
5. The Committee noted that supported decision making (as per Right 7(3) of the HDC Code of Rights) is still consent, and if the participant is unable to provide consent then Right 7(4) of the HDC Code of Rights applies.
6. The Committee noted that the researchers seemed to have a good understanding of Right 7(4) of the HDC Code of Rights and have presented an argument based on research which shows being in research made dementia sufferers feel valued, socially included, improved wellbeing. However, the Committee stated that in their view Right 7(4) does not seem to be met by this study, as study participation does not seem to be in the best interest of the participant, then only participants able to provide some degree of consent can be included in the study.
7. The Committee questioned whether the Researcher’s agree to the exclusion of participant’s unable to provide their own informed consent. The Researcher stated that they are happy to obtain informed consent from those with early dementia, and to obtain consent from those able to provide consent in a supported decision making framework, participants unable provide consent, even with support, will be excluded from the study.
8. The Committee queried how this would work without a method for determining capacity to provide informed consent. Please add a formal method for determining capacity to consent and for determining which participants are able to provide their own consent, who will need supported decision making, and who will be excluded as they lack the capacity to provide informed consent.
9. The Committee raised concerns about the plan to not assess capacity and the fact that an advocate will not necessarily accompany the dementia sufferer during the 'supported consent' and no clarity has been provided around how anyone would know what the participant understood about the process. The Committee noted that this becomes of greater concern when examining the proposal to ask the person to agree to the following at the end of the interview:
   * 'broad consent' to share the transcript with two other Auckland dementia researchers who want to use it in their research, and
   * consent to allow identified information with a photo be used in their report for a sample of the interviewees, and
   * consent to allow Alzheimer’s NZ to use some of the videos in their advocacy programme
10. The Committee requested that videos are not obtained as part of the study. The Researcher agreed to make this change to the study protocol.
11. The Committee requested that details are provided of the supported decision making process, including whether the support person would be present at the beginning and throughout the interview and during review of the transcripts and videos.
12. The Committee suggested that alternative methods of sharing the stories are considered, such as by having their story presented by an actor to protect the participant’s privacy.
13. The Committee raised concerns about whether all participants will be able to understand the implications of some of the options, such as having their videos being made public. The Committee noted that participants required a supported decision making process are unlikely to understand the full implications of this.

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

1. The Committee noted that an information sheet for the support person, for supported decision making, is required for this study.
2. Please include more information in the next-of-kin information sheet about the options for privacy and how study data may be used.
3. Please ensure the Participant Information Sheet and Consent Form include suitable headers with the site logo.
4. Please add study contact numbers to the Participant Information Sheet, including details of a suitable person to provide Māori cultural support, as per the HDEC template.
5. Please clarify in the Participant Information Sheet how long data will be retained for.
6. Please revise the Participant Information Sheet to ensure readability of all sentences, the Committee noted that the following sentence must be revised ‘You told us or people you know told us you were interested in taking part in the research’.
7. Please add involvement in other research on living with dementia as an exclusion criteria to the Participant Information Sheet.

Decision

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

* Please respond to the outstanding ethical concerns detailed above.
* 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).*

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

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| **5** | **Ethics ref:** | **18/NTB/88** |
|  | Title: | Effect of warm humidified CO2 insufflation on de-airing |
|  | Principal Investigator: | Dr David McCormack |
|  | Sponsor: | Fisher and Paykel Healthcare(FPH) |
|  | Clock Start Date: | 24 May 2018 |

Lotte van den Heuij and a co-investigator from FPH were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a 3-arm double blind randomised controlled trial of methods to de-air the heart at the conclusion of aortic valve replacement surgery. The current standard of care at Waikato is using room air, although some units use dry, un-warmed CO2.
2. This study is sponsored by Fisher and Paykel Healthcare to test their humidifier and also test the use of CO2 as compared to standard of care. It is postulated that both CO2 and warmth will reduce micro bubbles in the circulation which can cause neurologic compromise.

Summary of resolved ethical issues

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

1. The Committee noted that the period covered by the insurance certificates provided differs from the proposed study period, adequate insurance coverage must be in place for the entire duration of the study.
2. The Committee queried the proposed timeline for the study, noting that it appears to require 2/3rds of aortic valve replacement patients are recruited in the study which may be overly optimistic. The Researcher explained that they have quite high recruitment rate at the study site and believe it will be met.
3. The Committee queried if the sample size calculation accounted for multiplicity of comparisons given there are 3 arms and two primary outcomes (2 different time points).
4. The Committee queried if the perfusionist is already familiar with the study device. The Researcher confirmed that they are comfortable with the device.
5. The Committee questioned whether morbid obesity should be defined and added to the exclusion criteria for the study, given the response to question r.1.1 in the application form regarding potential difficulty of reducing CO2 levels if they become too high in the very obese. The Researcher confirmed that the anaesthetists will apply their judgement as per standard for the surgery to exclude participants as required.

Summary of outstanding ethical issues

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

1. The Committee queried the status of Māori consultation for the study, noting that this consultation is a standard requirement for studies involving Māori participants (Ethical Guidelines for Intervention Studies paragraph 4.9).
2. The Committee queried how participants will be identified and approached. The Researcher explained that in advance of the surgery a research nurse will identify potential participant and they will be able to consider participation up to the point of surgery. Please revise the protocol to reflect that all participants will hear about the study well in advance. The investigator should choose a method of approaching participants that meets applicable ethical and scientific standards (*Ethical Guidelines for Intervention Studies* paragraph 6.2).
3. The Committee requested evidence that a biostatistician has considered the possible effect of multiplicity on the results given the multiple comparisons inherent within the primary outcome. Please provide this as further evidence of favourable independent statistical peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
4. The Committee noted that the evidence of peer review provided is from a consultant from Fisher and Paykel Healthcare. Please provide further evidence of independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
5. Please provide a copy of suitable indemnity for the study’s co-ordinating investigator.
6. The Committee queried the interim analysis planned and requested further information was provided on the internal review team.

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

1. Please include a land line for Katiaki Maori contact in the Participant Information Sheet.
2. Please remove mention of consent by a legal representative from the Participant Information Sheet as this does not apply in New Zealand.
3. Please review the Participant Information Sheet to remove all typographical errors, including removing the apostrophe from “arrhythmia’s”.
4. The Committee noted that the information presented that 32-83% of cardiac surgeries cause neurologic complications which may persist for up to 5 years, is supported by references which are more than 20 years old. This information has the potential to frighten patients about to have surgery. The Committee stated that if this information is to be included it is important that it is correct. Please ensure that the statistics provided in the Participant Information Sheet align with the standard statistics provided during informing participants for standard care.
5. Please revise the section in the Participant Information Sheet about benefits and risks. The statement that there are no risks to the use of CO2 is inconsistent with the disclosure of the small risk of hypercapnia and acidosis in question r.1.1 of the application form. There is always some risk when you use a new intervention and in this case 2 of the 3 arms are using CO2 which is not usually used.
6. Please remove the participation advantage statement from the Participant Information Sheet as this is not necessarily so.
7. The statement on page 5 about the right to remove samples is inconsistent with the statement on page 3 that there are no samples. Please revise this to ensure accuracy.
8. The Committee queried the Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement is used if the study involves the use of tissue, however it is unclear whether this is the case. “*You may hold beliefs about a sacred and shared value of 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.”*
9. Please add a suitable header to the Participant Information Sheet with the study title and hospital logo.
10. Please revise the Participant Information Sheet for lay readability, including replacing the terms ‘insufflation’ and ‘dissipate’, the exclusion criteria must also be re-medicalised.
11. Please remove content related to another study from the Consent Form, this currently has information with an incorrect date, refers to ‘bacterial load in my wound’, and ‘bacterial sample’.
12. 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.
13. Please revise the statement about sending a summary of the study results to participant’s GP’s as in this case it is more appropriate to send the results to the participant directly if they wish to receive them.
14. Please revise the wording of the risk/benefit section of the Participant Information Sheet as it differs from the information provided to participants.
15. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured as a result of treatment given as part of this study, which is unlikely, you* ***won’t*** *be eligible for compensation from ACC. However, compensation would be available from the study’s sponsor, [x], in line with industry guidelines. We can give you a copy of these guidelines if you wish. You would be able to take action through the courts if you disagreed with the amount of compensation provided. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* paragraph *6.22*).
* 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 Maliaga Erick and Dr Nora Lynch.

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| **6** | **Ethics ref:** | **18/NTB/90** |
|  | Title: | Outcomes following Traumatic Brain Injury |
|  | Principal Investigator: | Mrs Hemisha Patel |
|  | Sponsor: |  |
|  | Clock Start Date: | 24 May 2018 |

Mrs Hemisha Patel 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 investigates how people are recovering after traumatic brain injury.
2. Participants will be posted an invitation letter and Participant Information Sheet, this will be followed by a phone call where consent will be obtained and a survey will be conducted.

Summary of resolved ethical issues

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

1. The Committee queried the purpose of the study. The Researcher explained that a number of studies have been done for the immediate outcomes from TBI, but longer term outcomes (6 months) have not been investigated. Further, this study is investigating more serious brain injury as participants are recruited from the ICU, rather than more minor TBI as associated with sport (for example).
2. The Committee queried how participation differs from standard care. The Researcher explained that patients are discharged from ICU and then either cared for in the ward or by the Auckland brain Injury Unit having rehab until they are fully discharged, as per standard care. This study adds an additional follow up with the participant by phone.

Summary of outstanding ethical issues

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

1. The Committee queried the proposed consent process for the study. The Researcher explained that they will be approaching the participant’s EPOA to obtain consent. The Committee stated that consent should not be obtained from someone else on behalf of participants who are unable to consent, instead a supported decision making process should be undertaken, unless it is possible to include the participant’s without their consent under right 7(4) of the HDC Code of Rights.
2. The Committee raised concerns about the proposal to speak with the participant’s EPOA in the event that the participant is unable to provide their own informed consent. The Committee stated that the study should only include participants’ who are able to provide their own informed consent. Investigators should obtain the prior informed consent of study participants (Ethical Guidelines for Observational Studies paragraph 6.10).
3. The Researcher queried the possibility for using data without consent to determine capacity to consent, before approaching participants. The Committee explained the difficulties of using data without consent.
4. The Committee noted that it may be possible to partner with the Auckland Brain injury Unit to determine capacity to consent prior to approaching potential participants, however, this would need to be investigated further and a protocol developed. The Researcher explained that the Auckland Brain Injury Unit cannot conduct the study tests as the timeframes do not line up.
5. The Committee raised concerns about conducting this research by phone.
6. The Committee stated that a script will need to be developed for conducting the phone interviews.
7. The Committee queried the process for recording consent, noting that this must be carefully documented and recorded. Evidence of free and informed consent should ordinarily be obtained in writing When written consent is culturally unacceptable or good reasons exist for not recording consent in writing (such as in the case of telephone interviews), the procedures used to seek free and informed consent should be documented. (Ethical Guidelines for Observational Studies paragraph 6.26-6.27).
8. The Committee noted that some potential participants may be uncomfortable to be approached in writing and then by phone by someone they have never met, who was not directly involved in their care, who knows more about them than they do about her and who comes cold-calling asking about their deficits. The Committee questioned how this would be addressed.
9. The Committee noted that no covering letter for recruiting participants has been included, noting that this is important as the approach to participants will need to be carefully designed. The investigator should choose a method of approaching participants that meets ethical and scientific standards (*Ethical Guidelines for Observational Studies* paragraph 6.5).
10. The Committee noted that participants may become upset during study participation, having just ticked off a list of things they can no longer do (over the phone). The Committee questioned how this risk will be mitigated, noting it is possible participants could disclose potentially concerning information (such as suicidal thoughts).
11. The Committee stated that the study protocol should be updated and a data management protocol provided. The data management protocol should include information on the following:
    * + the purpose(s) of the data collection,
      + how data will be collected and by whom, including any training required for data collectors
      + the proposed use(s) of participants’ data, including any future use(s),
      + details of the form (i.e., identifiable, re-identifiable or non-identifiable) in which participants’ data will be collected, accessed, used and stored at the different stages of the research and the measures proposed to remove identifying details
      + who will access the participants’ data
      + plans for how consent will be sought for data collection and use
      + the length of time participants’ data will be retained
      + how the privacy and confidentiality of participants’ data will be protected,
      + procedures for dealing with any breaches of privacy and confidentiality,
      + plans for any commercial use of participants’ data and proposals for benefit sharing, including intellectual property issues
      + whether participants’ data will be transferred to other countries
      + whether participants’ data will be transferred to other
      + participants’ rights to correct their data
      + procedures for withdrawing participants’ data
      + procedures for destroying participants’ data
      + details of proposed approaches for any community engagement
      + what measures will be adopted to ensure transparency
12. The Committee raised concerns about participant’s feeling compelled to participate in the study as the recruitment method is likely to make them feel that it would be rude to not answer the questions, especially as the phone call may appear to be from the hospital, as without a carefully crafted script the phone call could seem like routine follow-up rather than something extra and entirely optional.
13. The Committee queried what suggestions were made by Waikato DHB Māori Research Committee during cultural consultation.
14. This study involves accessing health information without consent, to identify and recruit participants. 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.*
15. 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. It is the applicant’s responsibility to justify the use of health information without consent, and to explain how these requirements are met.

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

1. The Committee noted that the Participant Information Sheet for participants able to provide informed consent is lacking information in some areas.
2. The Participant Information Sheet must explain who the researchers are and how they have identified potential participants.
3. The Participant Information Sheet should request consent to access participant’s hospital records, currently it just informs the participant that this will be done.
4. Please clarify in the Participant Information Sheet what will happen to study data, currently it states that ‘the data will be saved for 1 year following the study and then will be anonymised’ but it is unclear what is meant by this. The Participant Information Sheet should detail where the data will be stored, how identifiable the data will be during this storage period, who will have access to the data, and when it will be destroyed.
5. Please clarify in the Participant Information Sheet how privacy and confidentiality will be protected in publication and presentation of the study data.
6. Please add study contact numbers to the Participant Information Sheet, including details of a suitable person to provide Māori cultural support, as per the HDEC template.

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 forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies* paragraph *6.10)*
* The investigator should choose a method of approaching participants that meets ethical and scientific standards (Ethical Guidelines for Observational Studies paragraph 6.5).
* Evidence of free and informed should ordinarily be obtained in writing. When written consent is culturally unacceptable or good reasons exist for not recording consent in writing (such as in the case of telephone interviews), the procedures used to seek free and informed consent should be documented. (Ethical Guidelines for Observational Studies paragraph 6.26-6.27).
* 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(*Ethical Guidelines for Observational Studies* paragraph 6.43)*:*
  + 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.

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| **7** | **Ethics ref:** | **18/NTB/93** |
|  | Title: | BGB3111\_BGBA317\_Study\_001 |
|  | Principal Investigator: | Dr David Simpson |
|  | Sponsor: | Pharmaceuticals Solutions Ltd |
|  | Clock Start Date: | 24 May 2018 |

No member of the research team was present for discussion of this application.

Potential conflicts of interest

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

Mrs Stephanie Pollard declared a potential conflict of interest and the Committee decided to allow her to remain in the room but not participate in the consideration of the application.

Summary of Study

1. This is a phase 1 dose escalation followed by dose expansion study. The aim of this project is to investigate the effects of combination of BGB3111 and BGBA317 in patients with Bcell lymphoid malignancy (lymphoma).
2. The New Zealand study only involves the expansion cohort using a dose that has already been determined in the first part of the study (multiple ascending dose) conducted elsewhere.

Summary of resolved ethical issues

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

1. The Committee noted that any study data or samples being sent overseas should have identifiers removed and replaced with a study specific code.
2. The Committee noted that participants do not need to withdraw from the study in writing, verbal withdrawal is sufficient in New Zealand.

Summary of outstanding ethical issues

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

1. The Committee noted that studies should not be terminated simply for reasons of commercial interest or public relations (*Ethical Guidelines for Intervention Studies* paragraph 6.65). The Committee stated their preference that this option is removed from study documentation, and noted that if the study is terminated early for any reason consideration must be given to reducing the disadvantages from this for participants, such as by offering post trial access for participants on compassionate grounds.
2. The Committee requested clarification regarding whether the study sites have sufficient capacity to hospitalise participants if tumour lysis syndrome occurs.
3. The Committee queried what is meant by statements about the Māori committee being able to stop the study.
4. The Committee noted that they expect this study will be approved by SCOTT. If this is not the case please provide evidence of favourable independent peer review of the study protocol, as the peer review currently provided is not suitably independent (*Ethical Guidelines for Intervention Studies* Appendix 1).
5. Please clarify if the Data Safety Monitoring Committee are independent of the study sponsor (*Ethical Guidelines for Intervention Studies* paragraph 6.50).
6. The Committee queried how potential participants will be identified for study participation.

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

1. The Committee noted that if any New Zealand participants will receive the additional 24/hour intensive monitoring that a suitable Participant Information Sheet must be provided for this.
2. The Committee noted that some participants would require more invasive testing and a separate Participant Information Sheet would need to be provided for these participants.
3. Please remove the list of possible treatments from the Participant Information Sheet as in this expansion cohort it should be known what participants will be receiving.
4. Please remove the statement from the Participant Information Sheet about the inclusion criteria of being expected to live more than 4 months.
5. The Committee stated that the information about the reasons for additional testing for CNS participants differs between the Participant Information Sheet and protocol. Please clarify this, as currently it states that this testing is for drug levels, but if this is the case it seems unlikely that a baseline measure (before drugs are given) is necessary.
6. There are a number of tests which are specific to those with CNS lymphoma. It is suggested that these are extracted from the body of the Participant Information Sheet and all put under a heading ‘For CNS lymphoid disease only’. The alternative is to prepare a separate Participant Information Sheet for CNS lymphoma.
7. Please remove the statements from the Participant Information Sheet about participants potentially being unable to access information about them as this is an open study so compromising blinding is not relevant. Further, in New Zealand participants are always able to access information about them, although this may result in them being withdrawn from the study (if it breaks blinding, for example).
8. Please separate information on Future Unspecified Use of Tissue from the main Participant Information Sheet and create a separate PIS for Future Unspecified Use of Tissue.
9. It is unclear in the Participant Information Sheets whether the genetic research will investigate relapse and whether sampling of tumour DNA is mandatory at baseline. Please clarify this in the Participant Information Sheets.
10. Please remove the information about standard of care from the Participant Information Sheet.
11. Please remove the references to American laws from the Participant Information Sheet. These should instead refer to the relevant New Zealand laws.
12. Please remove the references to blinding from the Participant Information Sheet as this study is not blinded.
13. Please clarify what government agencies in addition to research regulatory agencies could access study data, as stated in the Participant Information Sheet.
14. The optional genetic Participant Information Sheet should not repeat information from the main Participant Information Sheet. Please only include additional information in this form.
15. Please add a table of study procedures lined up against study visits to the Participant Information Sheet to help participants keep track of what is required during the study.
16. The Committee noted a preference to have risks communicated as ‘1 in 10 people’ rather than 10% as participants are better able to understand risk when it is conveyed in absolute figures.
17. Please add a ‘what will happen to my samples' heading to the Participant Information Sheet to highlight this information.
18. The Committee noted that notifying the participant’s GP should usually be mandatory, if it is not optional please remove the tick box from the Consent Form.
19. Please clarify the various option boxes about archival tumour vs. fresh sample in the Consent Form, specifically clarifying what the implications for participants are.
20. In the optional genetic Participant Information Sheet please be more precise about where samples will go, rather than stating they will be sent to a ‘central lab’.
21. Please ensure it is clear in the Participant Information Sheet which aspects of study participation apply to which participants.
22. Please remove references to participants passing away from the Participant Information Sheet, the Committee stated that these can be phrased in a more sensitive way.
23. Please add study contact numbers to the Participant Information Sheet, including details of a suitable person to provide Māori cultural support, as per the HDEC template.
24. Please revise the Participant Information Sheets to remove all typographical errors.
25. In the Participant Information Sheet please reduce the verbiage around commonly understood tests such as ECG, ECHO, ultrasound and venepuncture
26. Please give headings or bullet points to “Rights” section which spans pp.22-25
27. Please clarify if flu vaccine is an exclusion and if not modify statement on p.5.
28. Please clarify if another biopsy is required for study participation.
29. Please ensure all Participant Information Sheets and Consent Forms have correct header information, including removing all typographical errors and adding the word ‘optional’ to the header.
30. Please change wording "gotten worse" to "become worse".

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* paragraph *6.22*).
* 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 Mrs Kate O’Connor.

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| **8** | **Ethics ref:** | **18/NTB/94** |
|  | Title: | Ventilatory limitation during exercise |
|  | Principal Investigator: | Mr Ryan Welch |
|  | Sponsor: |  |
|  | Clock Start Date: | 24 May 2018 |

Mr Ryan Welch 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 study investigates breathlessness during exercise in adolescence. This is common and often diagnosed and treated as asthma, however this diagnosis may be often incorrect as another explanation for breathlessness during exercise may be more suitable, such as physiological limitations in air flow.
2. This study will investigate how common breathing limitation is in adolescence, what the mechanisms are, and the changes that occur over time.
3. The study has two parts, a cross-sectional lung testing to compare function between groups of 60 male and female of following ages: -12 to14 -15-19 -20-24, and one longitudinal testing of 12-14 year olds as they age.

Summary of resolved ethical issues

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

1. The Committee queried whether the study would take too long to complete for the researcher’s PhD. The Researcher confirmed he will be doing his PhD part time, which will give sufficient time to complete the study.
2. The Committee queried the recruitment method for the study. The Researcher clarified that they go through schools and sports clubs who then give the information to the participants to take home and discuss with their parents.
3. The Committee discussed the suitability of the BMI process for the study and agreed it is suitable.
4. The Committee noted that they are disappointed that the researcher’s supervisor declined to attend the ethics committee meeting, as a general rule the Committee request that for student research that the student’s supervisor attend the meeting.
5. The Committee noted that Māori consultation is required for this study, and this process should identify cultural issues such as the touching of the head and research involving the breath.

Summary of outstanding ethical issues

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

1. The Committee noted that the outcome measures are not well set out in the protocol and details of the proposed descriptive analysis are missing. The Committee suggested that a statistician is consulted. To make an optimal contribution, intervention studies must be of high scientific quality (*Ethical Guidelines for Intervention Studies* paragraph 3.5).
2. The Committee raised concerns about the proposed recruitment methods for the study. Currently potential participants/parents contact the researcher for a Participant Information Sheet or get one from a presentation. Potentially they may mail back a signed consent to participate in the study without a chat through, although they can ring and talk. Their consent then triggers an emailed questionnaire which is seeking information about other diseases which may render them ineligible, it also collects other info, this is sent back to "determine eligibility". However, eligibility cannot be fully determined until the first appointment as a lung function test (FEV1/FVC) is needed to complete the inclusion criteria. Because of these reasons the Committee stated their view that there is no point in trying to do the consent and screening without a face to face meeting. The Committee suggested that instead the researchers could increase the eligibility information in the advert to include exclusion due to musculoskeletal limitations that prevent use of a treadmill and certain chronic diseases. Then the first appointment could be a combined session to obtain informed consent in person, complete screening by FEV1/FVC and checklist and undertake testing. Participants could be invited to ring the researcher beforehand to check if they think they may have a condition which makes them ineligible and be warned in the Participant Information Sheet that they may not be enrolled if screening throws up an exclusion. The Researcher agreed to revise their consent processes to reflect this methodology. The investigator should choose a method of approaching participants that meets applicable ethical and scientific standards (*Ethical Guidelines for Intervention Studies* paragraph 6.2).
3. The Committee noted that the principal outcome measure(s) that will be used to accept or reject the hypotheses and the metrics that will be used to compare them across ages and over time need greater clarification within the protocol before the study begins. The Committee strongly suggest consultation with a biostatistician now, and to amplify the relevant section in the protocol.
4. The Committee queried where the testing will be conducted. The Researcher clarified they will be conducted at Greenlane clinical centre. The Committee queried if the travel costs would be reimbursed. The Researcher confirmed that parking would be funded. The Committee noted that participants should be reimbursed for study related costs, such as petrol for travel to study appointments (especially in the longitudinal study), otherwise this may open economic inequities and harm study results. Please confirm that suitable arrangements will be made.
5. The Committee questioned the possibility of incidental findings and how these would be addressed, the Committee noted that the research may flush out a young person who actually has another reason for exercise breathlessness such as an undiagnosed atrial septal defect or asthma. Please adjust the protocol to account for this possibility.
6. The Committee queried if a statistician has reviewed the study protocol, and requested that this is done as further evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).

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

1. Please add a space on the Visit Information Sheet to write the date and time of the appointment and please also include the researcher contact details to facilitate participants getting in touch in case of injury/illness or delay.
2. Please add an option to the Consent Form for participants to receive a summary of the study results.
3. Please integrate the consent for the CPET to the Participant Information Sheet to ensure that the risks of study participation are clearly and consistently explained.
4. In the Participant Information Sheet please de-medicalise the paragraph on page 2 which describes the tests. For example, use 'lung' instead of pulmonary, and get rid of 'dynamic cardiopulmonary lung volumes'.
5. Please state early in the Participant Information Sheet that this study is being conducted for a PHD.
6. In the Participant Information Sheet please advise participants of right to see and correct information collected on them
7. Please advise participants how data on them is stored, e.g. in a password protected dedicated database on hospital computer
8. Please add study contact numbers to the Participant Information Sheet, including details of the HDC, as per the HDEC template.
9. Please remove the word ‘adolescent’ for the Participant Information Sheet for participants aged 16 or over, these participants are adults.
10. In the Participant Information Sheet for participant’s aged 16 years or over, please clarify that their data will be stored for 10 years, not 10 years after their 16th birthday.
11. Remove the phrase from the Participant Information Sheet for young people that implies that the form is ‘dumbed down’.
12. Please separate the Participant Information Sheet, Consent Form and Assent Form for parents and young people 12-15years.
13. Under 'What to do to participate' on the assent form, change 'guardian' to 'you and your guardian' (and preferably use parent/guardian).
14. Please check Assent form to remove all typographical errors.
15. Please revise the Participant Information Sheet to remove all typographical errors, including ensuring that all terms are spelt consistently throughout the documents.

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 Mr John Hancock.

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| **9** | **Ethics ref:** | **18/NTB/83** |
|  | Title: | Implementation of a risk assessment tool to enable targeted SUDI prevention care. |
|  | Principal Investigator: | Dr Christine McIntosh |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 24 May 2018 |

No member of the research team was present for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is an intervention study trialling the implementation of a safe sleep calculator as a universal SUDI risk assessment tool within the first 2 weeks of life, to better identify families of vulnerable babies, to better target interventions
2. High risk cases will be offered another intervention ('care bundle' which is not part of this application as the researchers consider it part of good clinical care).
3. The application does not intend for parents to be consented to research, but instead will be asked: “This tool will help us to know the level of risk of sudden expected death in infancy (SUDI) for your baby and it will help us to work out what we can do together to give the best protection for your baby. Is it ok if I ask you some questions?”.
4. The second part of the study is undertaking focus groups with health care providers and families in the community. Their comments will be used to tweak the programme.
5. The Committee supported the research project and noted that this is an important area for research, however, the study protocol and other documentation must be improved.

Summary of outstanding ethical issues

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

1. The Committee stated that it is unclear from the research application submitted as the protocol, whether this application covers just Stage 2 or the design phase as well. If it is just Stage 2, please submit a protocol which is aligned with this application so it is clear what the Committee are being asked to approve.
2. The Committee queried how many participants would be involved in the focus groups, where will they be held, who is leading them, and how participants will be identified and selected.
3. The Committee requested a more detailed idea of the questions to be discussed during the focus groups.
4. The Committee questioned who the focus group participants will be, specifically which health care providers and what kind of members of the community.
5. The Committee noted that an argument has been mounted for enrolling parents/babies in the ‘SUDI calculator evaluation before 2 weeks' study without their consent or awareness that they are in an implementation research project, and that their data is to be used and matched to other health data harvested from a variety of sources. The argument advanced is that the project is low risk and that getting consent will 'a add complexity and negatively impact on implementation'. The Committee raised concerns about this argument as the calculator will be used by a midwife or nurse who will be in contact quite a bit of time over the pregnancy and first 2 weeks.
6. The Committee queried why the clinician administering the calculator cannot offer a simple explanation and Participant Information Sheet and get consent. The argument advanced makes no mention of the concept of participant autonomy, just because it is low risk and the researchers think it is good for participants does not take away their right to choose whether to be involved. The proposal may be in breach of HDC Right 6.1 (d) “Every consumer has the right to be notified of involvement in research" and “people are entitled to make free and informed decisions about their participation in a study” (Ethical Guidelines for Intervention Studies paragraph 6.8).
7. 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. It is the applicant’s responsibility to justify the use of health information without consent, and to explain how these requirements are met.
8. The Committee queried the training programme for the nurses/midwives who will do the SUDI calculator and inform the parents of the significance of a high risk result and course of action.
9. The Committee queried how the "pre and post intervention SUDI comparison" will be done as there is no documentation of doing a second SUDI score.
10. The Committee queried how possible harm and distress to families with a history of SUDI will be managed.
11. The Committee queried how the number of proposed participants (7300) had been determined, noting that it seemed to be excessive for a implementation study and reduced participant numbers may improve the researchers’ ability to obtain informed consent while still allowing the study questions to be answered.
12. The Committee queried the justification for not obtaining consent from the parent participants. The Committee noted that under Right 6 and 7 parents have a right to be informed and consent to their participation in the study. The Committee noted that they are informing the parents of the use of the calculator, this seems to be a good opportunity to consent them.
13. People are entitled to make free and informed decisions about their participation in a study (Ethical Guidelines for Intervention Studies paragraph 6.8).
14. It is preferable that participants provide in writing their consent to participate in an intervention study (Ethical Guidelines for Intervention Studies paragraph 6.15).
15. The Committee noted that the current study design does not meet the features of informed consent described in paragraphs 6.22-6.23 of the Ethical Guidelines for Intervention Studies.
16. The Committee raised concerns about the specialised care bundle, noting that if study participants will be referred to it then the Committee need to review this and determine its appropriateness. Alternatively, the Committee must be assured that this is current standard of care and suitable.
17. The Committee raised concerns about the cultural aspects of the study, noting that rates of SUDI are higher in Māori and pacific infants.
18. The Committee raised concerns with the quality of peer review provided. Please provide further evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).

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

1. The Participant Information Sheet currently does not include sufficient information. Please add information about why the participant was chosen, how long the focus groups last, where they will be held, what will be discussed (in more detail than currently given), participant’s rights to withdraw, compensation for time and transport, storage of audio and transcripts (including where they will be stored, for how long, and who will have access).
2. Please review the Participant Information Sheet to remove all typographical errors, including run-on words.
3. Please add study contact numbers to the Participant Information Sheet, including details of a suitable person to provide Māori cultural support, as per the HDEC template.
4. The Committee noted that the Participant Information Sheet indicated that no one will be identified, however it is intended to take photos of the focus group. Please adjust the Participant Information Sheet to better reflect how, and to what degree, participant’s privacy will be protected.
5. The Consent Form provided is inadequate. Please revise this form, the Committee suggested the use of the HDEC template as a guide.
6. The Consent Form needs to include a place for the researcher explaining the study to sign to indicate their view that the participant has been explained the study, understands what is involved, and is freely providing informed consent.

Decision

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

* People are entitled to make free and informed decisions about their participation in a study (Ethical Guidelines for Intervention Studies paragraph 6.8).
* It is preferable that participants provide in writing their consent to participate in an intervention study (Ethical Guidelines for Intervention Studies paragraph 6.15).
* The Committee noted that the current study design does not meet the features of informed consent described in paragraphs 6.22-6.23 of the Ethical Guidelines for Intervention Studies.
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* paragraph *6.22*).
* Please respond to the outstanding ethical concerns detailed above.

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| **10** | **Ethics ref:** | **18/NTB/101** **(CLOSED)** |
|  | Title: | MK3475-587(00)Extension Study for Participants With Advanced Tumors in Pembrolizumab Trials. |
|  | Principal Investigator: | Prof Matthew Strother |
|  | Sponsor: | Merck Sharp & Dohme (Australia) Limited |
|  | Clock Start Date: | 24 May 2018 |

No member of the research team was present for discussion of this application.

Potential conflicts of interest

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

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

Decision

This application was *provisionally approved* by consensus.

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| **11** | **Ethics ref:** | **18/NTB/96** |
|  | Title: | Usability Assessment of Evatherm 2 |
|  | Principal Investigator: | Dr Robert Martynoga |
|  | Sponsor: | Fisher & Paykel Healthcare |
|  | Clock Start Date: | 24 May 2018 |

Dr Robert Martynoga was present by teleconference, and Geoff Bold with a team from Fisher & Paykel Healthcare 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 clinical usability assessment of a new reusable breathing circuit. The application proposes that the breathing circuit will be placed on participants who require breathing support in the Intensive Care Unit and High Dependency Unit.
2. Three questionnaires on the usability of the breathing circuit will be completed by: the ICU Technician team, each time they set up a circuit, the bedside nurse at the end of each shift, and the Sterile Services Unit each time a circuit is cleaned and sterilized. The research will continue for three years.
3. The application proposes to not obtain informed consent from participants as the researchers claimed that if informed consent was required, the participant would be required to undergo an additional circuit change (from their current circuit to the Evatherm 2 circuit) which would introduce additional unnecessary risk.

Summary of outstanding ethical issues

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

1. The Committee stated that for an application to be approved the HDEC must be convinced that the study meets all applicable ethical and legal requirements.
2. The Committee noted that the application does not identify patients as participants, however they are participants in this study, as are the clinicians involved in completing questionnaires about the usability of the device.
3. The Committee queried if consent could potentially be obtained from patient participants. The Researcher explained that these patients would be too unwell to provide informed consent.
4. The Committee noted that the HDC Code of Rights does not seem to be met by this study, specifically the following rights:
   * *(6)(1)(d) Every consumer has the right to the 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*
   * *(7)(1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent.*
   * *(7)(4) Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where—*
     + *(a) it is in the best interests of the consumer; and*
     + *(b) reasonable steps have been taken to ascertain the views of the consumer; and*
     + *(c) either,—*
     + *(i) if the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or*
     + *(ii) if the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.*
5. Additionally, the Ethical Guidelines for Intervention Studies state that ‘People are entitled to make free and informed decisions about their participation in a study’ (paragraph 6.8).
6. The Committee explained that, as presented, the study does not meet the requirements of the HDC Code of Rights or the Ethical Guidelines for Intervention Studies.
7. The Committee noted that to conduct the study on participants unable to provide informed consent that an argument would need to be presented that the study is in the best interests of participants, and that the other requirements of Right 7(4) are met (such as obtaining the views of people interested in the welfare of the participant). This has not currently been explained.
8. Further the Committee noted that studies should not be performed with vulnerable groups if they can be adequately performed with other groups. Where a study with a vulnerable group is conducted, it should involve the least vulnerable people in that group. (Ethical Guidelines for Intervention Studies paragraph 5.30). The Committee noted that this requirement must be met even if the requirements of the HDC Code of Rights are met.
9. The Committee queried if the study could be conducted in a less vulnerable participant group. The Researcher stated that they may be able to conduct the study in elective cardiac surgery patients who could provide consent in advance of their surgery. The Committee stated that they would welcome a future application for a study in this less vulnerable population group who would be able to provide fully informed consent.
10. The Committee noted that the clinical participants, such as the nurses, would also need to provide fully informed consent to their study participation, as they are being asked to provide feedback on the usability of the device. The Committee noted that the guidance on the Ethical Guidelines for Intervention Studies regarding employees as a potentially vulnerable group of participants should be considered before submission of a future application.

Decision

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

* People are entitled to make free and informed decisions about their participation in a study (Ethical Guidelines for Intervention Studies paragraph 6.8).
* Studies should not be performed with vulnerable groups if they can be adequately performed with other groups. Where a study with a vulnerable group is conducted, it should involve the least vulnerable people in that group. (Ethical Guidelines for Intervention Studies paragraph 5.30).

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| **12** | **Ethics ref:** | **18/NTB/97** |
|  | Title: | Usability Assessment of Gallus Mask |
|  | Principal Investigator: | Dr Robert Martynoga |
|  | Sponsor: | Fisher & Paykel Healthcare |
|  | Clock Start Date: | 24 May 2018 |

Dr Robert Martynoga was present by teleconference, and Geoff Bold with a team from Fisher & Paykel Healthcare 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 clinical usability assessment of a new non-invasive ventilation mask.
2. The mask will be placed on participants who require ventilatory assistance without endotracheal intubation, and a questionnaire on how easy the mask was to set up and use will be completed by the bedside nurse at the end of each shift.
3. The application proposes to not obtain informed consent from participants as the researchers claimed that if informed consent was required, the participant would be required to undergo an additional circuit change (from their current mask to the Gallus) which would introduce additional unnecessary risk.

Summary of outstanding ethical issues

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

1. The Committee stated that for an application to be approved the HDEC must be convinced that the study meets all applicable ethical and legal requirements.
2. The Committee noted that the application does not identify patients as participants, however they are participants in this study, as are the clinicians involved in completing questionnaires about the usability of the device.
3. The Committee queried if consent could potentially be obtained from patient participants. The Researcher explained that these patients would be too unwell to provide informed consent.
4. The Committee noted that the HDC Code of Rights does not seem to be met by this study, specifically the following rights:
   * *(6)(1)(d) Every consumer has the right to the 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*
   * *(7)(1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent.*
   * *(7)(4) Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where—*
     + *(a) it is in the best interests of the consumer; and*
     + *(b) reasonable steps have been taken to ascertain the views of the consumer; and*
     + *(c) either,—*
     + *(i) if the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or*
     + *(ii) if the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.*
5. Additionally, the Ethical Guidelines for Intervention Studies state that ‘People are entitled to make free and informed decisions about their participation in a study’ (paragraph 6.8).
6. The Committee explained that, as presented, the study does not meet the requirements of the HDC Code of Rights or the Ethical Guidelines for Intervention Studies.
7. The Committee noted that to conduct the study on participants unable to provide informed consent that an argument would need to be presented that the study is in the best interests of participants, and that the other requirements of Right 7(4) are met (such as obtaining the views of people interested in the welfare of the participant). This has not currently been explained.
8. Further the Committee noted that studies should not be performed with vulnerable groups if they can be adequately performed with other groups. Where a study with a vulnerable group is conducted, it should involve the least vulnerable people in that group. (Ethical Guidelines for Intervention Studies paragraph 5.30). The Committee noted that this requirement must be met even if the requirements of the HDC Code of Rights are met.
9. The Committee queried if the study could be conducted in a less vulnerable participant group. The Researcher stated that they are not aware of a less vulnerable group of potential participants, as this device would not frequently be used in elective surgery patients. The Committee noted that the inclusion of this vulnerable group must be justified in any future applications.
10. The Committee noted that the clinical participants, such as the nurses, would also need to provide fully informed consent to their study participation, as they are being asked to provide feedback on the usability of the device. The Committee noted that the guidance on the Ethical Guidelines for Intervention Studies regarding employees as a potentially vulnerable group of participants should be considered before submission of a future application.
11. The Committee noted that ethnicity would likely be an important factor to record with the study results, to account for different nose shapes in different ethnicities, and this should be included in the future.

Decision

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

* People are entitled to make free and informed decisions about their participation in a study (Ethical Guidelines for Intervention Studies paragraph 6.8).

## 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:** | 03 July 2018, 12:00 Noon |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

The following members tendered apologies for this meeting.

* Mrs Jane Wylie
* Mrs Leesa Russell

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 6:30pm