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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 03 April 2018 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:10pm | Confirmation of minutes of meeting of 06 March 2018 |
| 12:30pm | New applications (see over for details) |
|  | i 18/NTB/50  ii 18/NTB/49  iii 18/NTB/55  iv 18/NTB/56  v 18/NTB/59  vi 18/NTB/60  vii 18/NTB/61 |
| 4:25pm | General business:   * Noting section of agenda |
| 4:30pm | 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 | Present |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Present |
| Mrs Jane Wylie | Non-lay (intervention studies) | 20/05/2017 | 20/05/2020 | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 06 March 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/NTB/50** |
|  | Title: | Access to Services |
|  | Principal Investigator: | Mr Dorian Gray |
|  | Sponsor: | Oranga Tamariki, Ministry for Children |
|  | Clock Start Date: | 22 March 2018 |

Dorian Gray and Tai Leofo and two other investigators were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This project is in response to a finding from an expert advisory panel finding that children in state care are not always accessing services they need in a timely manner. The project will investigate another way to get these services to children in need.
2. All children coming in to care receive a gateway assessment as a standard part of the process, this project is trialling direct purchasing model to allow additional services to be provided to children if it is identified at the gateway assessment that this service is required.
3. Part of this project is to trial the direct purchasing model in two DHBs and to evaluate this trial.

Summary of ethical issues (outstanding)

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

1. The Committee noted that this project was poorly explained in the application, and a protocol was only provided for the evaluation aspect of the study. The Committee accepted that these two aspects of the project can be separate, and have separate documentation, but it must be clear to the HDEC what they are being asked to approve. The Committee noted that even if an aspect of the project may not be within HDEC scope of review on its own, if it is part of the larger project, which is being submitted for HDEC review, then full details of this should be included with the HDEC application.
2. The Committee noted that the information sheet for social workers is not suitable as a Research Participant Information Sheet, which is required if the social workers are participants in this study. The Committee noted that a HDEC template is available to guide the development of Participant Information Sheets and Consent Forms for this study. People are entitled to make free and informed decisions about their participation in a study (Ethical Guidelines for Intervention Studies paragraph 6.8).
3. The Committee noted that it is unclear if children in this project are active participants or if the project only involves the use of their data. The Committee stated that this would be clearer if a suitable study protocol was provided. The Committee stated that the trial of the direct purchasing model could significantly impact what services are provided to children. All studies should be conducted according to written protocols (Ethical Guidelines for Intervention Studies paragraph 5.41).
4. The Committee noted that if the children in the trial are also participants, a suitable Participant Information Sheets and Consent/Assent Forms must be provided. The Committee noted that current documentation seemed to limit what social workers can tell children and their families about the project, however, if they are participants in a study they should be provided with full information about the project unless a good reason exists to withhold information from participants.
5. Please ensure the documents for this project, especially those that are participant facing, clearly explain that this project is testing and evaluating a method of service purchasing.
6. The Committee noted that the evidence of scientific peer review provided is not suitably independent. Scientific soundness is ethically important. Projects without scientific merit needlessly expose participants to risk and misuse their time, and waste resources (Ethical Guidelines for Intervention Studies paragraph 5.5). Please provide evidence of favourable independent peer review of the study protocol (Ethical Guidelines for Intervention Studies appendix 1).
7. The Committee expressed that they did not believe the proposed cultural consultation for this study is adequate. The Committee suggested that the HRC Guidelines for Researchers on Health Research Involving Māori could provide more information on a suitable process.
8. The Committee requested further information is provided on what data will be collected, accessed, used, and stored for the purposes of this project. The Committee requested that further information is provided on whether the data will be used or stored in an identifiable form, and how this data would be managed throughout the project. Investigators should make arrangements for protecting the confidentiality of study data (Ethical Guidelines for Intervention Studies paragraph 7.2).
9. The Committee questioned whether the consultancy firm that is being contracted for the evaluation aspect of the project will have access to identifiable data and what justification can be provided for this.
10. The Committee questioned the purpose of accessing National Data Sets, suggesting that this is to look at outcomes.
11. The Committee questioned the primary and secondary outcomes for this study and how these will be measured. Investigators should develop clear study questions that identify the participant population, the intervention and the main outcome of interest (Ethical Guidelines for Intervention Studies paragraph 5.2).
12. The Committee noted that it appeared that verbal consent was intended to be sought for this project, however, consent for research participation should be recorded in writing. Additionally, processes must be detailed for obtaining assent from child participants and consent to be obtained from their parent or legal guardian.

Decision

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

* Investigators should develop clear study questions that identify the participant population, the intervention and the main outcome of interest (Ethical Guidelines for Intervention Studies paragraph 5.2).
* The study design should be the one best suited to answer the study question, while minimising harm, maximising benefit and meeting other ethical standards (Ethical Guidelines for Intervention Studies paragraph 5.4).
* Projects without scientific merit needlessly expose participants to risk and misuse their time, and waste resources (Ethical Guidelines for Intervention Studies paragraph 5.5).
* Please provide evidence of favourable independent peer review of the study protocol (Ethical Guidelines for Intervention Studies appendix 1).
* All studies should be conducted according to written protocols (Ethical Guidelines for Intervention Studies paragraph 5.41).
* People are entitled to make free and informed decisions about their participation in a study (Ethical Guidelines for Intervention Studies paragraph 6.8).

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| **2** | **Ethics ref:** | **18/NTB/49** |
|  | Title: | CGA patient experience study |
|  | Principal Investigator: | Ms Rosemary Hoyt |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 March 2018 |

Ms Rosemary Hoyt 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 older haematology patient’s experiences and perceptions in the use of a comprehensive geriatric assessment (CGA).
2. This study is being conducted for the purpose of a Master’s qualification.

Summary of ethical issues (resolved)

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

1. The Committee expressed concern regarding the size of the project and its suitability for a Master’s project. The Committee questioned if data is being collected that is not directly relevant to the Master’s project. The Researcher explained that they are primarily interested in the interview transcripts and other data that is used (such as the linking of pharmacy records) is part of the CGA.
2. The Committee questioned if participants would be able to receive their individual results, such as the results of the CGA. The Researcher confirmed they would be offered this.
3. The Committee questioned who is conducting the CGA. The Researcher explained that she will be conducting these and is experienced in the aspects required from her clinical experience.
4. The Committee questioned how long after the CGA the interviews will be conducted. The Researcher explained that it would be within 2 weeks.
5. The Committee questioned if participants may have a recent cancer diagnosis. The Researcher explained that although the CGA is recommended for newly diagnosed patients, in this study all participants will have completed their treatment already.
6. The Committee questioned who the study sponsor is, the Committee suggested that it is the University as they have primary responsibility for the conduct of the study as this is being done by a student researcher.
7. The Committee queried if the CI will conduct an extensive physical exam on each participant, as this appears to be part of the CGA. The Researcher explained that they are used to conducting these kinds of physical exams in their clinical role, and for this study the information will primarily be based on a discussion with the participants and the participant’s medical records.
8. The Committee questioned if participation could take more than an hour and if participants could take a break during the assessment if they wanted to. The Researcher explained that they could, but as the study is primarily investigating patient experiences of the CGA they want to conduct it in a way that is similar to how it would be in clinical practice.
9. The Committee queried and confirmed that study data will be stored for 10 years.
10. The Committee questioned if the study supervisor has access to identifiable study data. The Researcher confirmed that they would not have access to identifiable data.
11. The Committee questioned if a management plan would be sent to participants’ GPs following the CGA. The Researcher confirmed that if anything concerning is identified in the CGA a management plan would be sent to that participant’s GP.

Summary of ethical issues (outstanding)

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

1. The Committee questioned whether participants will be reimbursed for additional travel costs associated with attending the study visits that are additional to standard care. The Researcher explained that they did not intend to reimburse participants for travel costs. The Committee stated that participants should not incur any costs from study participation and they would expect that participants reasonable travel costs are reimbursed or at least some reimbursement is offered to participants to thank them for their time. The Researcher explained that they currently do not have any funding for this reimbursement but will pursue this further.
2. The Committee noted that the study may involve conducting site visits to participants’ homes, and this requires suitable site safety protocols to protect both the participants and the researchers. The Committee requested a site safety protocol is provided, noting that the researcher’s DHB likely has one that can be adapted for the study. Please ensure that this site protocol includes information on cultural guidelines for home visits.
3. The Committee noted that in their view, older participants are more likely to have impaired ability to provide informed consent to study participation and questioned the proposed process for determining whether participants have sufficient capacity to provide consent, and for supporting those with diminished capacity to make an informed choice. The Researcher explained that they will be able to tell from speaking with participants if they are able to provide consent and will make the decision in the same way they would for any patients.
4. The Committee requested information is provided on how participants with diminished capacity will be supported to provide informed consent. People who have diminished competence to make decisions about their participation in a study are entitled to make informed decisions to the extent appropriate to their level of competence (Ethical Guidelines for Intervention Studies paragraph 6.25).

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

1. Please use the University header on the Participant Information Sheet, to make it clear it isn’t a hospital study. The Committee noted that this could be added in addition to the current hospital header.
2. Please clarify in the Participant Information Sheet and Consent Form that if participants agree to be in the study, their GP will be informed and provided with a management plan if required. Currently it appears that this is optional, however, it should be required for this study.
3. Please state in the Participant Information Sheet that if participants say something concerning that other health professionals may be informed.
4. Please revise the second sentence of the Participant Information Sheet to clarify the intended meaning.
5. Please add a specific Māori cultural support contact person to the Participant Information Sheet, this should include their name and position.
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 revise the Participant Information Sheet to remove all typographical errors.
8. Please clarify in the Participant Information Sheet whether participants will be reimbursed for additional travel costs associated with the study.
9. Please clarify in the Participant Information Sheet that the CGA could take longer than an hour.
10. Please ensure that the correct approving HDEC is provided, this study is reviewed by the Northern B Health and Disability Ethics Committee.
11. Please state in the Participant Information Sheet the options for where the study interviews can be conducted.

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 form, taking into account the suggestions made by the Committee (Ethical Guidelines for Intervention Studies paragraph 6.22).

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

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| **3** | **Ethics ref:** | **18/NTB/55** |
|  | Title: | MASTERSTROKE |
|  | Principal Investigator: | Dr Douglas Campbell |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 March 2018 |

Dr Douglas Campbell, Davina McAllister, Dr Deng, and Sarah Dandyand were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study is a RCT involving very unwell participants, the majority of whom will be unable to provide informed consent to study participation.

Summary of ethical issues (resolved)

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

1. The Committee commended the quality of the form proposed to be used to recruit participants unable to provide informed consent.
2. The Committee discussed with the researchers the proposed processes for participants who have capacity to provide consent or regain this capacity after the study intervention has been performed. The Committee stated that they are satisfied with the proposed processes.
3. The Committee questioned whether 24 hour support was available routinely in other DHBs. The Researcher explained that it is not usually available but will be available for this study, and is funded by the study.
4. The Committee questioned whether sufficient funding is available for the study, expressing their concern that the study may begin and not have enough funding to continue. The Researcher explained that they are applying for more funding but think that they can fully run the study, with adjusted timeframes, without this funding as the patient volume has increased since they began designing the trial and they can continue at only one study site if required.
5. The Committee noted that in future more care should be taken to answer questions in the application form in lay language as in this case far too technical information was included.
6. The Committee noted that references to ‘implied consent’ should not be included in future applications as this is not intended in the study and implies something unacceptable.
7. The Committee questioned what is meant by the statement in the application form that participants and their families will be informed if the study CI is involved in their care. The Researcher explained that this is in relation to disclosing potential conflict of interests.
8. The Committee questioned what happens if they are unable to keep participants within the set blood pressure limits. The Researcher explained that this is an important part of the feasibility aspect of the study.
9. The Committee discussed with the researchers the cultural considerations in the study, noting that this was relatively well addressed, although the DHBs cultural support unit is not mentioned in the application form.

Summary of ethical issues (outstanding)

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

1. The Committee stated that it is not possible for HDECs to approve an application unless it is consistent with New Zealand law, including the right not to be subjected to medical or scientific experimentation without that person's consent (section 10 of the New Zealand Bill of Rights Act 1990). Research involving participants who are not competent to consent must be undertaken in accordance with Right 7(4) of the Code of Health and Disability Services Consumers’ Rights. In addition to requirements regarding ascertaining the views of the consumer and other suitable persons, Right 7(4) of the Code requires that any health services provided without the informed consent of the consumer must be in the best interests of the consumer. This means that there must be some benefit, or potential benefit, to the participant beyond what they would receive if they were not participating in the research.
2. The Committee questioned whether the researchers believe study participation could meet the best interest test. The Researcher explained that previous observational studies have shown that having tighter blood pressure control is beneficial for these patients, and this study involves very tight blood pressure control compared to standard care and can be expected to provide clinical benefits to study participants.
3. The Committee expressed that they did not feel that the expected clinical benefits from study participation were well explained in the study protocol and would appreciate further written evidence is provided about the expected clinical benefits to individual participants.
4. The Committee questioned whether participants’ families or friends would be consulted with before their enrolment in the study, as per Right 7(4). The Researcher explained that they will be consulted with if they are available in the short time frame before enrolment, they will also be informed of the participants’ participation if they become available after the participant is enrolled. The Committee requested that a suitable family/friends information pamphlet is provided to help them understand the study.
5. The Committee questioned what blood pressure target they would be trying to keep participants at and how this was determined. Please provide more information on this.
6. Please amend the form used to recruit participants unable to provide informed consent to state the ‘views’ of the suitable persons who were consulted, instead of recording the ‘outcome’ of the discussion.
7. The Committee noted that a formal Data Safety Monitoring plan should be provided for this study. Provide details of the Data Safety Monitoring plans (Ethical Guidelines for Intervention Studies para 6.50).
8. Please confirm who the study sponsor is. The Committee noted that for HDEC purposes the sponsor is defined as the person or organisation with responsibility for the initiation, management and financing arrangements of a study.
9. The Committee requested clarification of whether study data may be available for use in future studies, please also clarify whether this data will be identifiable.

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

1. Please amend the Participant Information Sheet to indicate that 50 participants will be recruited in New Zealand, not worldwide.
2. Please revise the Participant Information Sheet to remove all typographical errors, including “the their discretion” and ‘before calling if you”.
3. Please remove technical jargon from the Participant Information Sheet, such as ‘recanalisation’.
4. Please provide an option on the Consent Form for participants to decline any further involvement and to allow withdrawal of existing data.

Decision

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

* Please address the outstanding ethical concerns detailed above.
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

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| **4** | **Ethics ref:** | **18/NTB/56** |
|  | Title: | Improving Quality of Life Through Preference Based Teaching |
|  | Principal Investigator: | Mrs Jocelyn Davis |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 March 2018 |

Mrs Jocelyn Davis and Angela Arnold-Saritepe were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study involves investigating whether support workers can be supported to provide preference based teaching to their disabled clients to teach them how to do a daily task to increase their independence.

Summary of ethical issues (resolved)

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

1. The Committee questioned how participants will be recruited. The Researcher explained that they intend to partner with health care providers to identify patients who may benefit from the study, and if they are interested the researcher will obtain informed consent.
2. The Committee raised concerns about the risks of power imbalance and participants feeling pressured to provide certain answers that their support worker would like to hear in the questionnaires. The Researcher explained that these questionnaires will be strictly confidential and not shared with the support workers at all, they will also be collected without the participant’s name.
3. The Committee questioned whether the CI is suitably qualified to lead the research project. The CI’s supervisor explained that the CI is suitably qualified and experienced and will be well supported.
4. The Committee questioned whether recording data was a fair use of the support workers time. The Researcher explained that the time involved is minimal.
5. The Committee noted that study data should be stored for 10 years.

Summary of ethical issues (outstanding)

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

1. The Committee questioned how the daily tasks to be taught will be chosen. The Researcher explained that they will be chosen by the disabled person and their family, in conjunction with the support worker. The Committee suggested that because of the requirements for observing the training it would be important to have some restrictions on the kinds of daily tasks that would be taught, to help protect the dignity of the disabled person. The Researcher agreed and suggested some restrictions that could be added to the study protocol.
2. The Committee questioned how the consent process will be managed, given that many participants will be unable to provide informed consent. The Researcher explained their plan to obtain consent from participants where possible, and when necessary to obtain consent from their family on their behalf.
3. The Committee stated that it is not possible for HDECs to approve an application unless it is consistent with New Zealand law. Research involving adult participants who are not competent to consent must be undertaken in accordance with Right 7 (4) of the Code of Health and Disability Services Consumers’ Rights. In addition to requirements regarding ascertaining the views of the consumer and other suitable persons, Right 7(4) of the Code requires that any health services provided without the informed consent of the consumer must be in the best interests of the consumer. This means that there must be some benefit, or potential benefit, to the participant beyond what they would receive if they were not participating in the research. The Committee asked the researcher is they believed these requirements could be met by this study, or if the study would be limited to only adults able to provide informed consent. The Researcher agreed to limit adult participants to those able to provide informed consent.
4. The Committee noted that for child participants, parents or legal guardians are able to provide consent on their behalf.
5. The Committee requested that the study protocol is updated to reflect the adjusted inclusion criteria, to ensure that no adult participants who are unable to provide their own informed consent are recruited in to the study.
6. The Committee noted that supported decision making should be utilized for participants with diminished capacity, who have sufficient capacity to provide a sufficient degree of informed consent. People who have diminished competence to make decisions about their participation in a study are entitled to make informed decisions to the extent appropriate to their level of competence (Ethical Guidelines for Intervention Studies paragraph 6.25).

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

1. Please clarify in the Participant Information Sheets that the small sample size may mean that confidentiality cannot be maintained, although personally identifiable information will be removed from published information.
2. Please give more information in the Participant Information Sheet about what the study is about and what is involved in participation. Please set the context for the study in the Participant Information Sheet and explain what the activities are likely to be, what preference mapping is, and what kinds of daily tasks the training could be used for.
3. The Committee requested the compensation wording is added to the Participant Information Sheet 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.”
4. Please ensure the correct ethics committee is referenced in the Participant Information Sheet, the reviewing HDEC is the Northern B Health and Disability Ethics Committee.
5. Please remove statements from the Participant Information Sheet about expectations of improving quality of life and that participants are ‘chosen because they are ideal candidates…’.
6. Please clarify in the Participant Information Sheets what happens if either the client or the support worker withdraws from the study.
7. Please add contact details for a suitable Māori cultural support person to the Participant Information Sheet.
8. Please provide suitable information sheets and assent forms. This includes an information sheet and consent form for parents of child 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), and a suitable simple information sheet and assent form for child participants unable to provide their own informed consent.

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 form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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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| **5** | **Ethics ref:** | **18/NTB/59** |
|  | Title: | EV-ICD Pilot Study (MDT17034) |
|  | Principal Investigator: | Dr Ian Crozier |
|  | Sponsor: | Medtronic Australasia Pty Ltd |
|  | Clock Start Date: | 22 March 2018 |

Dr Ian Crozier 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 a new implanted defibrillator, that it is hoped will overcome some of the difficulties associated with current devices.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether this study includes emergency surgery patients who have limited time to consider their study participation. The Researcher confirmed that all participants will be elective surgery patients who will have days to weeks to consider their participation.
2. The Committee discussed the study travel restrictions. The Researcher explained that this is because participants cannot have device support if they travel away from the study site.
3. The Committee noted that it is important in this study that a sufficient number of Māori participants are recruited.

Summary of ethical issues (outstanding)

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

1. The Committee noted that the MPS certificate provided has expired and requested an up to date one is provided.
2. The Committee noted that the insurance certificate provided from the study sponsor is not study specific, please provide an updated insurance certificate that is aligned with the study’s Clinical Trial Number.
3. The Committee noted that the peer review is not suitably independent. Please provide evidence of favourable independent peer review of the study protocol (Ethical Guidelines for Intervention Studies appendix 1).
4. The Committee questioned whether participants would be assured ongoing follow up if they withdraw from the study after the device is implanted, or if the study sponsor stops the study early for any reason. The Researcher explained that if participants want the device removed or turned off then this can be done, although it wouldn’t be recommended. The Researcher also confirmed that if participants want to withdraw from the study but keep the device they would still receive follow up and if the sponsor decided to stop the study participants would still receive ongoing follow up. The Committee requested assurance from the sponsor that ongoing support will be provided, even if it is decided to halt the study early.
5. The Committee noted their preference that information about study participants is not provided to the sponsor in an identifiable form. Please confirm that identifiers will be removed before data is sent to the sponsor.
6. The Committee questioned whether the training plan for surgeons is sufficient. Please have a surgeon confirm if they believe the proposed training is enough.
7. The Committee noted that reimbursing participants in the form of a voucher is suitable, however suitable reimbursement must be provided for participants who do not drive themselves.

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

1. The Committee noted that the HDEC Participant Information Sheet template should be used to revise the Participant Information Sheet to ensure all necessary information is included.
2. The Participant Information Sheet currently contains a lot of information about standard care. Please revise the Participant Information Sheet to only include study specific information. For example, information about the risks of standard care should not be provided in the study Participant Information Sheet.
3. Please remove the interpreter box from the Consent Form, this should be replaced with a statement about the availability of interpreters as required.
4. The Committee noted that the table of potential adverse events on page 8-9 of the Participant Information Sheet is not suitable and should be revised or removed.
5. Please clarify in the Participant Information Sheet the options for if participants decide to withdraw from the study, including if the device can be removed.
6. Please clarify the requirements for travel restrictions in Participant Information Sheet.
7. Please clarify in the Participant Information Sheet that there is quite a commitment involved in study participation, such as longer follow up visits than standard care.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please respond to the outstanding ethical concerns detailed above.

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

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| **6** | **Ethics ref:** | **18/NTB/60** |
|  | Title: | Sensor Performance Under Free-living Conditions Comparing Guardian™ Sensor 3 With Capillary Glucose Monitoring |
|  | Principal Investigator: | Dr Martin de Bock |
|  | Sponsor: | Telethon Kids Institute |
|  | Clock Start Date: | 22 March 2018 |

Dr Martin de Bock was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (outstanding)

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

1. The Committee questioned whether the study is being conducted primarily for the benefit of the manufacturer of the device being tested. The Committee noted the following relevant questions.
   1. Who is initiating the study?
   2. Who is designing and planning the research questions that the study will ask?
   3. Will the PI or other investigators receive remuneration from the manufacturer or distributor?
   4. Is the manufacturer or distributor putting any unreasonable restrictions or delays on the timely publication of the results of the study?
   5. Is the manufacturer or distributor providing any funding and/or materials for the study?
2. The Committee expressed their view that this study is being conducted primarily for the benefit of the manufacturer and consequently suitable insurance and indemnity certificates must be provided.
3. The Committee noted that study participation is quite burdensome and requires a large number of additional finger pricks. The Researcher explained that participants will be used to these finger pricks as part of their standard care. The Committee stated that although this may be true, there is an ethical difference between burdens imposed on patients for their care, and those only required for study participation, this is especially important when study participants are children. The Researcher stated they could reduce the number of finger pricks required for child participants, and the number of sensors they are required to wear would be limited to a maximum of two. Please adjust the study protocol to reflect this.
4. The Committee questioned the need for the study to include very young children. The Researcher explained that this is because the condition is commonly diagnosed in childhood. The Committee expressed their view that unless very young children are necessary for the study, which does not seem to be the case for this study, they should be excluded.
5. Research should only be done with children if comparable research with adults could not answer the same question and the purpose of the research is to obtain knowledge relevant to the health needs of children (Ethical Guidelines for Intervention Studies appendix 2). Where a study with a vulnerable group is conducted, it should involve the least vulnerable people in that group (eg, older rather than younger children) (Ethical Guidelines for Intervention Studies paragraph 5.30). The Committee requested that the study inclusion criteria are adjusted to only include those children necessary to answer the study question.
6. The Committee noted that child participation in the sub-study must also be justified. The Researcher explained that they viewed child participation in the sub-study to be important as they believed that children would have different responses to exercise and should be included in the sub-study. The Committee requested written justification for their inclusion in the sub-study, including justification for the age groups intended to be included.
7. The Committee questioned the justification for including children under 14 years old when the device manufacturer’s investigators brochure states that it should not be used on children under 14. The Committee requested justification for this is provided.
8. Please provide 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. 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.”*
2. The adolescent Participant Information Sheet and Consent Form currently states that it is for participants aged 13-20, however, any participants aged 16 or older must provide their own informed consent and should be provided with the adult Participant Information Sheet and Consent Form. Please adjust the forms to reflect this.
3. Please ensure all participants, including children, are told the number of finger pricks required in the study.
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. Guidance on assent can be found at <http://ethics.health.govt.nz/guidance-materials/assent-guidance>.
5. Please state in the assent forms that children do not need to participate in the study even if their parents want them to, and they can stop participation at any time.
6. Please state in the Participant Information Sheet that data will be stored for 10 years after the participant turns 16.
7. Participant Information Sheets must be clearer about any restrictions that exist for exercise and swimming when wearing the device.
8. Please clarify in the Participant Information Sheet how close the device needs to be to the transmitter/sensor device, please also clarify if participants will use their own mobile device or be provided with a study specific one.
9. Please add more information to the Participant Information Sheet about study data being sent to the study sponsor, including what this means for participants with regard to data ownership and commercial benefits.
10. Please provide a suitable Māori cultural contact person in the Participant Information Sheet.
11. Please ensure New Zealand English is used in the Participant Information Sheets, such as ‘Mum’ instead of ‘Mom’.

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 form, taking into account the suggestions made by the Committee (Ethical Guidelines for Intervention Studies paragraph 6.22).

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

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| **7** | **Ethics ref:** | **18/NTB/61** |
|  | Title: | Anaesthetists Be Clean (the ABC study). |
|  | Principal Investigator: | Professor Alan Merry |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 22 March 2018 |

Dr Derryn Gargiulo and Professor Alan Merry was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

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

1. The Committee questioned the study intervention. The Researcher explained that the primary intervention in the study is the filter, as part of a bundle including other hygiene standards, which is commercially available and used in other procedures but not used for all patients due to the cost involved. The Researcher further explained that it is important in their view to investigate the whole intervention bundle as individually each intervention has been established as best practice.
2. The Committee questioned whether there were any risks involved to participants, for example from it being harder to inject with the filter. The Researcher explained that the filter can be bypassed if needed, however they did not believe it presented a risk to participants.
3. The Committee questioned who the participants in the study are. The Researcher explained that the anaesthetists are the primary participants in their view, as they are trying to change their practice. The Committee noted that patients are also participants in this study, as one of the primary outcome measures is collected about participants.
4. The Committee questioned whether the study data could identify if a specific clinician is a problem. The Researcher explained that the data being collected would not show this kind of information.
5. The Committee questioned if patient data would be used in this study in an identifiable way. The Researcher explained that they will need to collect individual patient data in an identifiable form as some of the primary outcome measures, such as days alive out of hospital, cannot be reported in larger data sets.
6. The Committee questioned whether adding a study site every 6 months was too slow and would delay getting benefits to participants. The Researcher explained that the reason for doing the study over a longer period of time is to see if the proposed changes can be continually made over a long period of time, to see if they are practicable as changes to standard care.
7. The Committee questioned how the filters will be paid for. The Researcher explained that they are being donated by the manufacturer.

Summary of ethical issues (outstanding)

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

1. The Committee questioned whether consent would be obtained from all participants. The Researcher explained that they did not intend to obtain consent from anaesthetists or patients, as this is primarily a quality improvement project. The Committee explained that as this has been submitted as a research project it must meet the Ethical Guidelines for Intervention Studies, including paragraph 6.8 which states *‘people are entitled to make free and informed decisions about their participation in a study’* and 6.19 *‘People are entitled to refuse to participate in intervention studies and to withdraw their consent to participate. They may make either of these decisions whenever practicable and without experiencing any disadvantage’.*
2. Additionally, paragraph 6.16 states that *‘the purposes of consent are normally best served by decision-making that occurs prior to a participant’s inclusion in a study. Any exception requires justification to an ethics committee on grounds that prior consent is one or both of the following:*
   * *impracticable (eg, for studies in emergency care or community intervention studies)*
   * *undesirable (eg, when any delay of the intervention(s) to be studied would harm the person).‘*
3. The Committee questioned whether consent could and should be sought from anaesthetists. The Researcher explained the practical difficulties associated with seeking their informed consent, however, they expressed that it may be possible to obtain their consent. The Committee agreed that if it is practically possible then individual consent should be sought in writing from each anaesthetist. Please provide a suitable Participant Information Sheet and Consent Form for this purpose.
4. The Committee questioned whether consent could and should be sought from patients. The Researcher explained that in their view it is impractical to obtain consent from individual patients as the study changes hospital practice, a large number of patients will be included, and it would be difficult to ensure the bundle was not applied to an individual patient as the study involves getting whole anaesthetic departments to agree to change their standard practice. The Researcher further explained that the interventions pose no risks to patients and are all considered best practice individually, although not currently standard care primarily due to the cost of the filter.
5. The Committee agreed that obtaining consent from individual patients is impractical and in their view the inclusion of these participants without consent meets the requirements of paragraph 6.16 of the Ethical Guidelines for Intervention Studies.
6. The Committee noted that their understanding is that for patient participants the Code of Health and Disability Services Consumers' Rights (The Code) also applies, specifically Right 7, the right to make an informed choice and give informed consent, which states:
   * *(1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.*
   * *(6) Where informed consent to a health care procedure is required, it must be in writing if—* 
     1. *the consumer is to participate in any research*
7. The Committee noted that Right 6 of The Code, the Right to be fully informed, states at (1)(d) states *‘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’.* Additionally, paragraph 6.17 of the Ethical Guidelines for Intervention Studies states that *‘People are ethically entitled to be informed about their participation in a study, whether their participation occurs with their consent or without it. Any exception requires justification to an ethics committee on grounds that informing participants is impracticable and/or undesirable’.* The Committee noted that it is preferable that participants are at least informed of their study participation, however, an exemption to this may be able to be approved if it is consistent with the requirements of The Code.
8. The Committee stated that it is not possible for HDECs to approve an application unless it is consistent with New Zealand law, in addition to the requirements of The Code, the New Zealand Bill of Rights Act 1990 states in section 10 that people have the right not to be subjected to medical or scientific experimentation without that person's consent.
9. The Committee explained that the HDEC Standard Operating Procedures require that researchers and sponsors are responsible for ensuring that their health and disability research is conducted lawfully. HDECs need to be satisfied that any research approved by the Committee is consistent with NZ law. An HDEC may not approve an application that is inconsistent with NZ law, even if that application is consistent with ethical guidelines.
10. In relation to the above points, the Committee requested that the researchers seek legal advice regarding the legality of the proposed study.
11. The Committee questioned why the study proposes to recruit twice as many participants than the power calculation indicated was necessary. The Researcher explained that it is difficult to do an accurate power calculation for this study as the effect size is unknown. The Researcher explained that they are very keen to avoid under-powering the study as this has been cited as a problem with previous studies and they want the results of their study to be strong. The Committee requested that further statistical peer review is sought to justify the proposed study size.
12. The Committee requested that a formal interim safety analysis is added to the study protocol. Every intervention study should have appropriate oversight of the conduct of the study to ensure the safety of the participants and the integrity and validity of the study data (Ethical Guidelines for Intervention Studies paragraph 6.38).

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

1. Please provide a suitable Participant Information Sheet for anaesthetists.

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 provide an information sheet and consent form, taking into account the HDEC template as a guide (Ethical Guidelines for Intervention Studies paragraph 6.22).

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

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. Mrs Stephanie Pollard explained to the Committee that although she did not report a conflict of interest at the previous meeting when reviewing 18/NTB/40 that since that meeting she has developed a conflict of interest. The Committee agreed it was suitable for Mrs Stephanie Pollard to participate in the consideration of this application at the previous meeting, although she will not be involved in any future considerations around this application.
3. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| --- | --- |
| **Meeting date:** | 01 May 2018, 08:00 AM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

1. **Problem with Last Minutes**

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

The meeting closed at 4:30pm.