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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 11 October 2016 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 1:00pm | Welcome |
| 1:15pm | Confirmation of minutes of meeting of 13 September 2016 |
| 1:30pm | New applications (see over for details) |
|  | i 16/NTA/165  ii 16/NTA/157  iii 16/NTA/158  iv 16/NTA/159  v 16/NTA/160  vi 16/NTA/162  vii 16/NTA/163  viii 16/NTA/164  ix 16/NTA/156  x 16/NTA/166  xi 16/NTA/167  xii 16/NTA/169 |
| 6:30pm | General business:   * Noting section of agenda |
| 6:40pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Brian Fergus | Lay (consumer/community perspectives) | 11/11/2015 | 11/11/2018 | Present |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 13/05/2016 | 13/05/2019 | Present |
| Dr Christine Crooks | Non-lay (intervention studies) | 11/11/2015 | 11/11/2018 | Present |
| Miss Tangihaere Macfarlane | Lay (Consumer/community perspectives) | Co-opt NTB | Co-opt NTA | Present |
| Dr Kate Parker | Non-lay (observational studies) | 11/11/2015 | 11/11/2018 | Present |
| Dr Charis Brown | Non-lay (intervention studies) | 11/11/2015 | 11/11/2018 | Present |
| Ms Rosemary Abbott | Lay (the law) | 15/03/2016 | 15/03/2019 | Present |

## Welcome

The Chair opened the meeting at 1:00pm and welcomed Committee members. The Chair noted that two members, Mrs Susan Buckland and Mrs Shamim Chagani, have completed their terms on the Committee.

The Chair noted that fewer than five appointed members of the Committee were present, and that it was necessary to co-opt members of other HDECs in accordance with the SOPs. Miss Tangihaere Macfarlane confirmed their eligibility, and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 13 September 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/NTA/165** |
|  | Title: | The Benzathine Penicillin G Formulation Preferences Study |
|  | Principal Investigator: | Dr Dianne Sika-Paotonu |
|  | Sponsor: | Victoria University of Wellington |
|  | Clock Start Date: | 29 September 2016 |

Dr Dianne Sika-Paotonu 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 the preferences of children and teenagers who receive Benzathine Penicillin G for Rheumatic Fever.
2. Currently this formulation is given as a monthly injection that the researchers believe is disliked by the children and leads to reduced compliance with the treatment as they do not attend appointments.
3. This study will involve interviewing the children who receive this treatment, their family and whanau, and the clinicians who administer the treatment to investigate their preferences for administering this treatment.
4. The Committee commended the quality of the participant information sheets, consent form, and assent form.

Summary of ethical issues (resolved)

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

1. The Committee noted that the application indicated that a Māori advisory group would be established for this study, the Committee questioned the membership of this group. The Researcher explained that as a number of the named investigators for this study are of Māori and Pacific heritage they would be on the advisory committee, and others will also be consulted. The Researchers raised that it was important to have Māori and Pacific representation on the research group as many of the participants will be Māori or Pacifica.
2. The Committee questioned whether Pacifica will be broken down to more specific ethnicities when ethnicity is collected. The Researcher stated that this was their intention.
3. The Committee questioned how long the study transcripts would be retained for after the study. The Researcher explained that they intend to retain the data for 10 years after the end of the study. The Committee agreed this was suitable.
4. The Committee questioned who would provide informed consent to participation as the parents forms seemed to cover the wider Whanau also. The Researcher explained that as the interview tool for adults would be completed together that only one member of the Whanau would provide written informed consent and the rest of the Whanau would provide implied consent by engaging with the interview process. Children will provide assent to their participation and complete the child interview tool.
5. The Committee questioned whether the answers provided by one Whanau would be linked to their child’s answers, and similarly for their clinician’s answers. The Researcher explained that they wouldn’t be, the responses from Whanau and clinicians could relate to any of the children in the study.

Summary of ethical issues (outstanding)

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

1. The Committee questioned whether the Well Home service mentioned in the information sheet is standard of care. The Researcher confirmed that it is. The Committee requested that references to standard care are revised or removed from the Participant Information Sheet as it is unclear what aspects are part of the study.
2. The Committee stated that although they think that the IPad tool is suitable for the population group that the current version of the tool provided contains significant bias, such as calling the injection ‘sore’ and may influence the child’s response. The Researcher agreed and explained that they are already working on an updated tool. The Committee requested that this is provided.
3. The Committee felt that the medical terms used in the IPad tool may confuse the children participants and requested that this is modified to ensure that it is clear what children are referring to when they complete the interview tool.
4. The Consent form refers to photos being taken, however this is not the case for this study, please revise to remove this reference.
5. Please proof read the Participant Information Sheets and Consent Forms to ensure accurate language is used as some sentences are confusingly written, such as the final sentence on the first page of the Participant information Sheet.
6. The Committee noted that some older participants may be able to provide their own informed consent and should have a suitable consent form provided. 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>.
7. Please provide the updated IPad tool for children.
8. Please revise the Participant Information Sheets and Consent Forms to ensure they reference the correct approving committee as they currently contain a reference to the Central HDEC and a reference number for a study approved by the Central HDEC. They should refer to the Northern A HDEC and contain the correct reference number.

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 para 6.10).

This following information will be reviewed, and a final decision made on the application, by Ms Rosemary Abbott and Dr Karen Bartholomew.

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| **2** | **Ethics ref:** | **16/NTA/157** |
|  | Title: | ITACS |
|  | Principal Investigator: | Dr Shay McGuinness |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 September 2016 |

Dr Shay McGuinness 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 whether IV Iron administered to anaemic patients pre-surgery is associated with improved outcomes post-surgery.
2. Although it is understood that if IV Iron is given to a population group they become less anaemic, it is not clear whether this has any impact on their outcomes post-surgery.

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 it is standard care to give IV Iron to these patients. The Researcher explained that there is an IV Iron clinic set up for this purpose, however, very low numbers of eligible patients attend this clinic and receive IV Iron. This study will investigate whether this clinic is worthwhile, provides benefit, to justify the costs and provide evidence to attempt to get more patients to the clinic.
2. The Committee questioned whether patients who were offered enrolment in this study, which involves a placebo arm, could decline participation and just receive IV Iron at the clinic. The Researcher said this would be an option for potential participants that would be explained to them and if they wanted certainty that they would receive IV Iron they could go directly to the clinic outside of the study as this should be available to them as part of standard care.
3. The Committee questioned how clinicians would be blinded in this study as they will see the participants’ blood test results as part of standard care. The Researcher agreed that it would be difficult to maintain clinician blinding, however, some patients who receive IV Iron will not have improved iron levels and this will help maintain the blinding.
4. The Committee questioned why participants are asked pre-surgery to guess which study arm they were assigned to. The Researcher explained that this is because some participants are expected to have reduced symptoms from their anaemia if they are in the IV Iron group and may be able to guess their allocation, this question is asked to determine whether blinding was able to be maintained. The Researcher clarified that study blinding being broken would not mean that the participant’s surgery was altered or delayed.
5. The Committee noted that the study is NHMRC funded. The Researcher also explained that a HRC grant application is in process.
6. The Committee noted that the application form indicated no potential cultural issues, however, this study involves the use of tissue for extra blood testing. The Researcher explained that although they are aware of the potential cultural issues surrounding the use of tissue they did not believe this applied to this study as the blood being tested would be collected as standard of care. The Committee explained that this is still use of tissue for the study as there are study specific tests on the blood.
7. The Committee questioned whether there was a break between being informed about the study and attending the IV Iron clinic. The Researcher explained that potential participants will be sent information in advance and then attend a standard meeting 6 weeks pre-surgery where they would be offered formal enrolment in the study. If participants consent to being in the study they can attend the IV Iron clinic the same day or return at a later date for this.

Summary of ethical issues (outstanding)

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

1. The Committee questioned whether any comments from the peer review process are available as currently they just have a funding approval letter. The Researcher confirmed that the HRC comments are now available. The Committee requested that this is provided.

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

1. Please add Māori cultural support contact numbers to the Participant information Sheet.
2. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
3. Please revise the Participant Information Sheet to improve clarity regarding what is involved in participation, specifically to make it clear that there is only 1 study specific visit and all of the procedures are done at this one visit.
4. Please clarify in the Participant Information Sheet whether the study is being conducted in Australia, New Zealand, and Europe, or just New Zealand and Australia.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (Ethical Guidelines for Intervention Studies para 6.22).
* Please provide the HRC Peer Review comments.

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

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| **3** | **Ethics ref:** | **16/NTA/158** |
|  | Title: | The feasibility of assessing changes in muscle strength in children with Cerebral Palsy following Chiropractic care. |
|  | Principal Investigator: | Mrs Jenna Salmons |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 29 September 2016 |

Mrs Jenna Salmons 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

* This feasibility study investigates the potential benefits from chiropractic care for children with Cerebral Palsy.

Summary of ethical issues (resolved)

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

* The Committee questioned whether participants would be familiar with the strength measuring machine from their standard care. The Researcher stated that they should be.
* The Committee questioned whether ethnicity data would be obtained. The Researcher explained that as this is a feasibility study with only 6 participants they will not collect ethnicity data.
* The Committee questioned how participants for this study would be recruited. The Researcher explained that the Cerebral Palsy register has agreed to email an advertisement to its members who can then contact the researcher if they are interested in participating. The Committee agreed this was suitable.
* The Committee questioned the status of Māori consultation. The researcher stated that they are currently working through the process with AUT.
* The Committee questioned why with such a small feasibility study there is a control group. The Researcher explained that they considered doing a cross over design but thought that the burden on participants would be too high if they were required to attend two study visits. The Researcher stated that their intention is to do a larger trial later and this project is to determine if a difference between the groups can be measured.

Summary of ethical issues (outstanding)

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

* The Committee requested that the information sheet for child participants is revised to be more child friendly and to confirm that it is suitable for children with Cerebral Palsy.
* The parent Participant Information Sheet is not currently written in lay language, please revise this.
* Please revise the Participant Information Sheet to remove possibly coercive sentence in the section regarding the voluntary nature of participation.
* Please remove the statement from the Consent Form regarding colour blindness, autism etc. as they are not relevant to eligibility. If any are related to eligibility they can be retained but must also be stated and explained in the Participant Information Sheet.
* Child participants should sign their own assent form rather than signing the parent’s consent form. Please provide a suitable child assent form.
* The Committee noted that the photos in the child information sheet are a bit scary and suggest that these are replaced with more suitable photos or images.
* Please state in the parent information sheet that this study is being conducted for a Master’s project.
* Please remove any mention of benefits from the Participant information Sheet as this is a non-therapeutic study.
* The committee noted that study data must be kept for 10 years after the participant turns 16, please ensure this is clear in the Participant Information Sheet.
* Electrical stimulation is currently mentioned in the child information sheet but not the parents’ information sheet. Please revise to include this information in both.
* Please ensure consistency of the names used for study groups between documents, for example the treatment group is sometimes referred to as the active group.
* Please explain random allocation in the parents’ information sheet.

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).

This following information will be reviewed, and a final decision made on the application, by Ms Rosemary Abbott and Dr Kate Parker.

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| **4** | **Ethics ref:** | **16/NTA/159** |
|  | Title: | The ACT-F Trial: Does active follow-up of invitation lead to higher participation in bowel screening by Māori, Pacific and Asians? |
|  | Principal Investigator: | Dr Peter Sandiford |
|  | Sponsor: | Auckland and Waitemata District Health Boards |
|  | Clock Start Date: | 29 September 2016 |

Dr Peter Sandiford was present by teleconference and Dr Nina Scott 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.

Dr Karen Bartholomew declared a potential conflict of interest, and the Committee decided to allow her to stay in the room but not participate in the discussion or decision making for this application.

Dr Charis Brown declared a potential conflict of interest, and the Committee decided to allow her to fully participate in the discussion and decision making for this application.

Summary of Study

1. The Committee commended the high quality well written application.
2. This study will investigate whether active follow up is beneficial at improving participation rates in the bowel screening programme.
3. This study will not obtain consent from participants as it involves delaying the standard follow up process for some participants (by 8 weeks) to determine whether the follow up makes a difference in the rates of return of bowel screening kits. This study is being done to investigate whether the costs associated with the active follow up are justified by an increase in participation rates.

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 many participants would be involved in the study. The Researcher confirmed it would be about 7000, 3500 in each study arm.
2. The Committee questioned whether it would be possible for the follow up programme to use text rather than calling to reduce costs. The Researcher explained that a number of contact details for patients are incorrect and they currently need to phone them.
3. The Committee questioned whether the researchers had considered altering the study design as suggested in the peer review. The Researcher explained that they feel that a non-inferiority design is suitable, however, depending on the analysis of the results the study may be able to be used to determine superiority.

Decision

This application was *approved* by consensus.

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| **5** | **Ethics ref:** | **16/NTA/160** |
|  | Title: | A pilot randomised control trial (RCT) of group Cognitive Behaviour Therapy (CBT)to assist prisoners with symptoms of Traumatic Brain Injury (TBI). |
|  | Principal Investigator: | Ms Tracey Mitchell |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 September 2016 |

Ms Tracey Mitchell was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study is being conducted as part of the CI’s PhD. The PhD candidate’s supervisor was not present for consideration of this application.
2. This study will investigate whether a Cognitive Behaviour Therapy (CBT) and Mindfulness programme can benefit prisoners with Traumatic brain Injury (TBI).

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 what the eventual outcome was hoped to be if this programme was successful. The Researcher hoped that the programme would be rolled out throughout New Zealand correctional facilities.
2. The Committee questioned whether the study intervention needed to be given by a trained psychologist. The Researcher explained that they deliberately picked a programme that could be given by trained nurses, allowing the CI to give the programme.
3. The Committee questioned whether this model was already used with TBI patients. The Researcher explained that it has been used in adolescents with TBI but not with prisoners before.
4. The Committee sought clarification regarding the randomisation process for the study and whether all participants would receive the study intervention. The Researcher explained that the control group is a wait list control and all participants will eventually get the study intervention.
5. The Committee questioned the recruitment process for this study. The Researcher explained that the study would be advertised on the prison intranet and prisoners would be able to sign up through this system if there were interested, then their health information would be checked to confirm they have TBI as prisoners may say they do to be accepted on the programme when they do not meet the inclusion criteria. Participants who meet the inclusion criteria will meet with the CI to provide informed consent.
6. The Committee questioned whether all participants will complete the questionnaire and the interview. The Researcher explained that all participants will complete the questionnaire but the interview is optional.
7. The Committee questioned the plan to support prisoners who are released before completion of the study intervention. The Researcher explained that the participants will not be able to continue with the intervention post release and will just be referred to standard health services.
8. The Committee questioned how confidentiality would be maintained as the intervention is provided in a group therapy setting. The Researcher explained that participants in group sessions at the prison sign a confidentiality agreement that has proven successful in this setting in the past.

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 their concern about the potential conflict of interest as the CI is employed by the prison as the head of healthcare. The Committee explained that this raised two specific concerns for them; first, that it could introduce scientific bias to the results as the CI would be analysing study data and giving the intervention programme and would therefore not be blinded to participants’ group allocation; second, the risk of coercion of prisoners as the CI doing recruitment, analysing results, and delivering treatment is their healthcare professional in prison and they may feel compelled to comply in an attempt to not appear uncooperative.
2. The Committee questioned how these conflict of interests would be managed. The researcher suggested that they could have another nurse provide the study intervention. The Committee stated that this would only be suitable if the CI remained blinded to group allocation, but it seemed difficult to do this in a prison setting where the CI is involved in the healthcare of all participants. The Committee requested that the CI discuss this further with her supervisors to develop a suitable method for reducing scientific bias from her conflict of interest.
3. The Committee questioned whether it would be possible to conduct the study in a different prison. The Researcher explained that as her study was being run in the prison she worked in which is run by Serco she is able to do it by going through the Serco ethics committee, but to do it in another prison would require approval from Corrections’ National office. The Committee requested further confirmation that this is not required for the study to be conducted in her prison, confirmation from Corrections would be ideal, as it would be ideal for the study to have the same approval as it would if she did not work for the prison.
4. The Committee requested more information on how the conflict of interest and possible coercion of recruiting prisoners who receive healthcare from the CI would be managed. The Committee noted that prisoners may feel obligated to consent to participation to appear cooperative.
5. The Committee questioned whether app participants would be capable of providing informed consent due to their brain injury. Please clarify how this will be determined and confirm that only participants able to provide their own informed consent will be enrolled in this study.
6. The Committee questioned whether participants will be able to consult their family and whanau before agreeing to be in the study, as participants not in a prison would be able to. The Researcher stated that most prisoners see their family weekly and could talk about it with them then. The Committee stated that it was their view that this was unsuitable as this time with family is limited and should not need to be used to discuss study participation. The Committee requested that another avenue is provided for participants to speak with their whanau about this study.
7. Please provide a copy of the advertisement that will be used to recruit participants on the intranet.
8. Please provide information on how data will be monitored during this study.
9. The Committee noted that it appears that this study involves an element of deception, in that participants are not informed that their behaviour is being monitored. The Committee understands that this is likely because if participants know their behaviour is being monitored they may behave differently, however, this must be explained to the Committee and a process must be in place to inform participants at a suitable time of what has occurred and why.

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

1. The Participant information Sheet currently over emphasises the expected benefits from participation. Please revise this form to ensure bias is reduced as it is not yet known whether participants can expect a benefit.
2. Please revise the ‘cost of participation’ section in the Participant information Sheet.
3. Please add more information to the Participant Information Sheet regarding the risks of participation, for example that the therapy may be distressing.
4. Please provide a Māori cultural support contact in the Participant information Sheet that the participants will be able to access.

Decision

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

* The Committee noted that there are a number of scientific and ethical issues in the study as currently proposed that must be rectified before the study can continue.
* The Committee felt that the current study design does not adequately control for bias primarily due to the CI’s direct involvement in all aspects of the study and a lack of blinding. To make an optimal contribution, intervention studies must be of high scientific quality, and their ethical issues must be well understood and addressed. (*Ethical Guidelines for Intervention Studies* para. 3.5).
* Although the Committee understands that deception may be required for the study design the application did not contain sufficient information regarding how the ethical issues surrounding deception would be addressed.
  + When an investigator believes deception or concealment is scientifically justified, the following criteria apply. (*Ethical Guidelines for Intervention Studies* para. 6.31)
    - There are no suitable alternative methods.
    - Participants are not exposed to increased risk of harm.
    - The extent of deception or concealment is defined in the study protocol.
    - Adequate and prompt disclosure is made, and debriefing is provided, as soon as appropriate and practicable.
    - Participants are entitled to require the withdrawal of study data that were obtained from them without their knowledge or consent.
    - The deception or concealment will not compromise the relationship between the community and the investigators or research.
    - The investigator justifies the deception or concealment to an ethics committee.
* The Committee noted that prisoners are a potentially vulnerable group, however, this application did not include sufficient information on how the ethical issues surrounding inclusion of this group will be mitigated. The primary issue surrounding the participation of inmates in research has always been whether inmates have a real choice whether to participate in research, or whether their situation prohibits the exercise of free choice. A secondary issue is whether confidentiality of participation and of data can be adequately maintained in the prison. (*Ethical Guidelines for Intervention Studies* Appendix 2).

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| **6** | **Ethics ref:** | **16/NTA/162** |
|  | Title: | Long term outcomes following Traumatic Brain Injury (TBI) in Childhood |
|  | Principal Investigator: | Dr Kelly Jones |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 29 September 2016 |

Dr Kelly Jones was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study involves recruiting participants from an earlier study (a 7 year follow up of the BIONIC study) for a later phase follow up.
2. Participants are children and young adults who have had Traumatic Brain Injury (TBI), and healthy control participants. The study is investigating their long term outcomes.
3. Some 400 children will be followed up.
4. Parents have already consented to ongoing contact.

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 the children in this study may be unable to provide assent due to their TBI. The Researcher stated that the participants only have minor TBI and will be competent to provide assent.
2. The Committee questioned whether ethnicity data would be collected for both the children and their parents. The Researcher confirmed it would. The Committee noted that the demographic form needs to be updated to reflect this.

Summary of ethical issues (outstanding)

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

1. The Committee questioned why the study did not initially propose to get consent or assent from the child participants, only their parents. The Researcher explained that as all information would be provided from the parents they felt that the parents are the participants in the study. The Committee explained that as the parents are being asked to provide information about their children, and consent to the researchers accessing a range of data about the children and contact the child’s teacher, that the child themselves should be informed of the study and agree to the parents providing this information about them.
2. The Researcher explained that the consent process for this study is verbal over the phone and they were concerned about the practicalities of obtaining assent or consent from children over the phone. The Committee understood that this may raise difficulties for the study, however, all participants aged 16 years or over must provide their own informed consent to information about them being used for research, and participants under 16 who are competent to provide informed consent should not have their parents’ consent on their behalf, they must also provide their own informed consent. The Committee also explained that participants aged under 16 years who are not able to provide their own informed consent should be offered information about the study and provide assent to their inclusion.
3. The Committee questioned whether teachers in this study would provide consent to their participation. The Researcher explained that if the parents had agreed to the researchers contacting the teachers that the teachers should not need to provide consent also as they are not really participants in the study. The Committee stated that as the teachers are being asked to share confidential information about the children, including their grades and a behavioural report that they should be informed about what their participation involves, their rights, and the purpose of the study. However, consent could be implied by the teacher filing out the questionnaire if this is accompanied by an information sheet. The Researcher stated that they could provide a covering letter with the teacher questionnaire explaining the study. The Committee said this would be suitable and requested that this is provided.
4. The Committee requested further clarification is provided about the consent protocols for this study, including who will provide informed consent and who will provide assent and how this will be recorded. Please keep in mind Right 6 of the HDC Code of Rights (the right to be fully informed) 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. If assent will not be obtained from younger children for their teachers to be contacted and their private information accessed please provide justification for this.

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

1. Please clarify in the information sheet for parents that they are agreeing to their child’s teacher being contacted.
2. Please provide a suitable cover letter for teacher participants explaining the study.
3. The Committee noted that the information sheet for control participants indicated a chance to win a $500 prize. The Committee requested that if a prize is retained as a method of recruitment that it should be reduced in size and a specified amount not given in the information sheet.
4. Please ensure the information sheets clearly explains what medical and/or private records (including private educational records) will be accessed by the researchers. Please note that as the school is the holder of some of the information and may refuse to release this information under the Privacy Act or the Education Act.

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 para 6.10).
* Please provide more information about the informed consent process for this study, including which participants will provide informed consent and which participants will provide assent.

This following information will be reviewed, and a final decision made on the application, by Dr Christine Crooks, Ms Rosemary Abbott, and Dr Brian Fergus.

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| **7** | **Ethics ref:** | **16/NTA/163** |
|  | Title: | Levels of cognitive dysfunction in service users of community mental health teams at Counties Manukau Health |
|  | Principal Investigator: | Dr Melodie Barr |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 September 2016 |

Dr Melodie Barr 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 will investigate the level of cognitive impairment in clients of the Community Mental Health service in Counties Manukau. Anecdotally clinicians in this area report seemingly high rates of impairment in this group but it is not known how prevalent or severe these issues are. This study intends to take a random sample of these clients to give snapshot of the level of impairment to ensure that appropriate services are being provided.
2. The Committee commended the quality of the Māori consultation response.

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 all participants will be able to provide their own informed consent. The researcher confirmed that they will, and although some will be under the mental health act, their responsible clinician will be able to confirm their ability to provide informed consent.
2. Please ensure that all health information is stored for a minimum period of 10 years (Health (Retention of Health Information) Regulations 1996).
3. The Committee questioned whether individual participant’s results will be available to their treatment team to inform their treatment. The Researcher confirmed that it will be and that this will be a direct benefit to participants.
4. The Committee questioned how the potential conflict of interest of the CI also being a treating clinician will be managed. The Researcher explained that they will only be the treating clinician of some participants and other psychologists will be available to facilitate the testing process.
5. The Committee questioned why information such as years of schooling will be recorded. The Researcher explained that it is because there is an expected correlation between cognitive ability and education level.
6. The Committee questioned the recruitment process for the study. The Researcher stated that potential participants will be randomly selected and then their treating clinician will approach them about the study and get their consent to put the researchers in touch with them, then formal consent will be obtained by the researchers. Please amend the study protocol to reflect the recruitment process.
7. The Committee noted that from the application it appeared that 2 clinicians would be doing the assessment, they questioned whether the participant would be assessed by 2 clinicians at one time. The Researcher clarified that there are two clinicians work sharing the assessment and each participant would only be assessed by 1 clinician.

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 study data will be de-identified when analysed by the researchers.
2. Please provide a copy of the assessment tool that will be used in this study.

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

1. The Committee noted that currently verbal consent is intended to be recorded, however consent should be recorded in writing if possible. The Researcher agreed to obtain written informed consent. Please provide a suitable consent form for this.
2. Please add a Māori cultural support contact number to the Participant Information Sheet.
3. The Committee noted that the Participant information Sheet indicated that the IPad camera could be used to record participant reactions and that this sounded like they will be taking photos of the participant’s face. The Researcher explained that they meant that the IPad camera could be used to take photos of the tasks the participants have completed on paper (such as drawing shapes). Please clarify this in study documents.

Decision

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

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

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

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| **8** | **Ethics ref:** | **16/NTA/164** |
|  | Title: | Prelude Study |
|  | Principal Investigator: | Associate Professor Andrew Holden |
|  | Sponsor: | Cagent Vascular |
|  | Clock Start Date: | 29 September 2016 |

Andrew Hill and Donna Katae 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 first in human trial of a new kind of scoring balloon that aims to open blood vessels with less damage as it helps the vessel to tear in a controlled way.
2. Scoring balloons are not new although this specific balloon is different to the others available as it has a number of tiny serrations rather than a few large ones.

Summary of ethical issues (resolved)

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

1. The Committee noted that the manufacturer and study sponsor is a new start-up company and questioned whether the researchers felt the company is appropriate to be conducting a first in man trial of this device. The Researcher confirmed that they are comfortable with the study sponsor.
2. The Committee questioned whether the researchers are familiar with using other scoring balloons. The Researchers confirmed they are familiar and comfortable with these devices and their use, and although this is a new device it is a variation on currently available technology.
3. The Committee questioned whether participants’ CT scans would be sent overseas. The Researchers confirmed they would be and noted that participants rarely had a problem with this as it was not tissue.
4. The Committee questioned whether the 30 day and 6 month follow ups are standard care. The Researcher confirmed they are.
5. The committee asked the Researcher whether safety assessments would be done between participants. The Researcher stated that they have no specific agreement with the study sponsor, but any safety issues will be clearly apparent and they will stop the study if they have safety concerns.
6. The Committee noted that New Zealand will likely start before the other sites and questioned whether the 10 participants being recruited in New Zealand may be recruited before the other sites start. The Researcher explained that they did not expect to complete recruitment before the other sites began the study as it would take between 6 and 9 months to recruit 10 participants.
7. The Committee questioned how many participants were expected to be Māori in this study. The Researcher stated approximately 2 of the 10 participants will be Māori, but that this is not a study requirement.
8. The Committee questioned the status of Māori consultation. The Researcher stated it has been submitted.
9. The Committee questioned whether the study device remains in participants after the study. The Researcher stated that it does not, it is inserted then the procedure is done and then the device removed.

Summary of ethical issues (outstanding)

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

1. Please correct the study sponsor name on the Participant Information Sheet.
2. Please revise the Māori cultural support contact information as it is currently spelled incorrectly.

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* *para 6.22*).

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| **9** | **Ethics ref:** | **16/NTA/156** |
|  | Title: | The EMBLEM UNTOUCHED Study |
|  | Principal Investigator: | Dr Margaret Hood |
|  | Sponsor: | Boston Scientific |
|  | Clock Start Date: | 29 September 2016 |

Dr Warren Smith 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.

Dr Brian Fergus declared a potential conflict of interest, and the Committee decided to allow him to stay in the room but not participate in the discussion or decision of this application.

Summary of Study

1. This study investigates whether a change in the programming for an implanted defibrillator reduces the rates of unnecessary and inappropriate shocks given to patients.

Summary of ethical issues (resolved)

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

1. The Committee asked for clarification regarding what was meant by changing the programme settings. The Researcher explained that the sponsor has changed the algorithm that decides when the defibrillator provides a shock to a participant.
2. The Committee questioned who would recruit participants. The Researcher confirmed that the study CI would recruit participants. The Committee noted their preference that participants re recruited by someone else, such as a study nurse, to minimise the conflict of interest present by the researcher also being the treating clinician. The Researcher agreed to consider the possibility of consent being obtained by the EP nurse as they do not have a specific study nurse.
3. The Committee questioned whether the expected risks of the adjusted programming are acceptable to the Researcher. The Researcher stated that they feel the risks are acceptable as this is similar to what other devices do already.

Summary of ethical issues (outstanding)

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

1. Please clarify in the Participant information Sheet what is standard care and what is study specific. The Researcher noted that the only change from standard of care is which programming the defibrillator has and all follow up is standard of care.
2. Please reduce the jargon in the Participant Information Sheet.
3. Please remove the statement from the information sheet about stopping the study or commercial reasons as studies should not be stopped for the commercial benefit of the sponsor.
4. 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.”*
5. The Committee questioned whether a sponsor rep will always be present during study procedures, as indicated in the Participant Information Sheet. The Researcher clarified that they may or may not be present. Please revise the information sheet to be clear that they may be present, not will be present.
6. Please clarify in the Participant Information Sheet whether study data will be sent overseas.
7. Please confirm and clarify in the Participant information Sheet whether data will be identifiable when provided to the study sponsor, the Committee noted their preference that the data is at least partially de-identified before being sent overseas.

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* *para 6.22*).

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| **10** | **Ethics ref:** | **16/NTA/166** |
|  | Title: | Community water supplies: ensuring microbial safety for disease prevention |
|  | Principal Investigator: | Dr Liping Pang |
|  | Sponsor: | Institute of Environmental Science Research |
|  | Clock Start Date: | 29 September 2016 |

Dr Liping Pang and Dr Joanne Hewitt 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 involves faecal samples being accessed to extract Norovirus, these faecal samples were collected to investigate a Norovirus outbreak and will be used to test the suitability of water filtration systems at removing the virus.
2. There is no human DNA or RNA extraction and the residual waste is destroyed in the usual manner
3. Tests on water filtration systems will be done with surrogate viruses not active viruses.

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 the confidentiality of the patients whose faecal samples will be used will be protected. The Researcher explained that although the faecal samples have some identifiers, once the virus is extracted the identifiers will be removed.
2. The Committee questioned whether the faecal sample donors consented to their use in research. The Researchers stated they did not explicitly but this is for public health surveillance.

Decision

This application was *approved* by consensus.

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| **11** | **Ethics ref:** | **16/NTA/167** |
|  | Title: | A study of RO7020531 in healthy subjects and patients with chronic hepatitis B |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | Covance NZ Ltd |
|  | Clock Start Date: | 29 September 2016 |

Professor Ed Gane, Mary Ellis-Pegler, and Roselyn Shash 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 ethical issues (resolved)

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

1. The Committee questioned whether any information on potential drug interactions was available. The Researcher stated that none was available for this specific drug but other similar drugs have no notable drug-drug interactions.
2. The Committee noted that some participants will get every-other-day dosing but the information sheet states that weekly dosing was better tolerated in animal testing. The Researcher explained that they felt that the levels being given in the study will be well within safe limits and every-other-day dosing is used for efficacy.

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 they are uncomfortable approving an umbrella protocol that covers Phase 1 with healthy volunteers and Phase 2 with Hepatitis B patients as the safety information is not yet known for the first phase in humans. The Researcher stated that they appreciated why the Committee may be concerned and noted that although they do not usually do this they feel it is more appropriate in this case as the tests in healthy volunteers will not only show safety but also efficacy.
2. The Committee noted that as they already need to wait for the results from the first phases to move on to later phases that it seems acceptable to submit a separate application for HDEC review before proceeding with later phases. The Researcher confirmed that there would be at least 14 days between study phases.
3. The Committee noted that after the first phase of testing the researchers will have more information (e.g. side effects, safety, and dosing) to include in the information sheets for the later phases, requiring them to be revised and submitted for Committee review before proceeding with these later phases of the study. The Researcher agreed that any updated safety information would be included in the information sheets as standard, and if this information was substantial it would be submitted for HDEC review as an amendment.
4. Please provide more information on the process for proceeding with different phases of the study, such as what data monitoring will be done and what information will be provided for HDEC approval before proceeding with the later phases of the study. The Committee stressed their concern about umbrella protocol and the request to approve all phases of the study under one application before sufficient information is available about the results of the early phase human trials.

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

1. The Committee questioned why the healthy volunteers would be paid for their participation but not the Hepatitis B patients, who are not expected to receive a therapeutic benefit. The Researcher stated that this is incorrect, all groups are paid but the Hepatitis B patients are paid less as they do not need to attend overnight study visits. Please revise the information sheet for Hepatitis B patients to reflect the reimbursement amount.
2. Please revise the Future Unspecified Use of Tissue information sheet to clearly state what tissue will be stored, where it will be stored, and how long it will be stored for. The Committee suggested that the HDEC template is consulted to ensure that this form contains all of the required information.
3. 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.”*
4. Please clarify in the information sheets where study samples will be sent, specifically whether they will be sent overseas.
5. Please revise the Participant Information Sheet for healthy volunteers, currently this form includes phrases regarding the care participants receive not being altered due to their participation or not in this study. However, these statements are not relevant for a study involving healthy volunteers.

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 Brian Fergus and Dr Kate Parker.

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| **12** | **Ethics ref:** | **16/NTA/169** |
|  | Title: | Pain Free TRUS B |
|  | Principal Investigator: | Mr Nicholas Buchan |
|  | Sponsor: | Canterbury Urology Research Trust |
|  | Clock Start Date: | 29 September 2016 |

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 ethical issues (outstanding)

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

1. The Committee emphasised their disappointment that the Participant Information Sheet was not adjusted to be suitable for New Zealand participants before being submitted for HDEC review.
2. The Committee questioned who would recruit participants for this study. Please clarify the recruitment process including justifying how potentially conflict of interests will be managed if the treating clinician will also be recruiting participants for the study as participants may feel pressured to agree to participate.
3. The Committee requested more information on the peer review process, specifically requested the comments by the peer reviewer if they are available.

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

1. The Participant Information Sheet must be revised to be suitable for New Zealand participants, for example all reference to Australian regulations must be replaced with the relevant New Zealand references. The Committee strongly suggests that a new information sheet is developed from the HDEC template.
2. Please clarify in the Participant Information Sheet whether health information obtained during the study will be de-identified before being sent overseas or shared with others.
3. The Committee were uncertain whether this study is commercially sponsored, being conducted primarily for the benefit of the manufacturer of the item being tested, as the inhaler manufacturer has some control over the publication of study results. Please confirm and add the suitable ACC STATEMENT to the Participant Information Sheet.
4. Please clarify in the Participant Information Sheet whether data will be made available for future research in an identifiable form.
5. The Participant information Sheet needs to be revise to improve the overall readability for lay participants.
6. Please add a section to the Participant Information Sheet about how confidentiality will be maintained.
7. Please see the HDEC template for the required contact information to include in the Participant Information Sheet and ensure this information is added.

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 concern detailed above.

This following information will be reviewed, and a final decision made on the application, by Ms Rosemary Abbott and Dr Charis Brown.

## 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:** | 15 November 2016, 01:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

1. **Problem with Last Minutes**

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

The meeting closed at 6:40pm