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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 09 August 2016 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 1pm | Welcome |
| 1.05pm | Confirmation of minutes of meeting of 12 July 2016 |
|  | New applications (see over for details) |
| 1:30pm | i 16/NTA/108  ii 16/NTA/109  iii 16/NTA/124  iv 16/NTA/111  v 16/NTA/112  vi 16/NTA/113  vii 16/NTA/116  viii 16/NTA/118  ix 16/NTA/120  x 16/NTA/121  xi 16/NTA/123  xii 16/NTA/110 |
| 6:30pm | General business: |
| 7:00pm | 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 |
| Ms Susan Buckland | Lay (consumer/community perspectives) | 11/11/2015 | 11/11/2016 | 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 |
| Ms Shamim Chagani | Non-lay (health/disability service provision) | 11/11/2015 | 11/11/2016 | 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 |
| Mr John Hancock (co-opt) | Lay (the law) | 14/12/2015 | 14/12/2018 | Present |
| Ms Rosemary Abbott | Lay (the law) | 15/03/2016 | 15/03/2019 | Apologies |

## Welcome

The Chair opened the meeting at 1pm and welcomed Committee members, noting that apologies had been received from Ms Rosemary Abbot. The Chair welcomed Mr John Hancock, a member co-opted from the Northern B Health and Disability Ethics Committee.

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 12 July 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/NTA/108** |
|  | Title: | PROSPER |
|  | Principal Investigator: | Dr Michelle Wilson |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 26 July 2016 |

Dr Michelle Wilson 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, Dr Christine Cooks, and Dr Kate Parker declared a potential conflict of interest, and the Committee decided to allow Dr Karen Bartholomew to hear fully take part in the discussion. The Committee decided that Dr Christine Cooks and Dr Kate parker were not allowed to discuss or contribute to the decision of The Committee.

Summary of Study

1. The committee commended the researcher on a thoughtful and thorough application, including preceding consultation.
2. The study investigates molecular profiling of patients with advanced gynaecological cancers.
3. The study aims to identify biomarkers that will help clinicians tailor the best treatments and care specifically to individual patients.
4. The study seeks to show that by doing this that genomics can be added to part of routine clinical care of solid tumour patients in New Zealand and improve patient outcomes by doing this.

Summary of ethical issues (resolved)

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

1. The Committee queried what procedures participants would be undergoing that were outside of standard care. The CI explained that patients would be consenting to a mandatory blood donation, researchers accessing their medical records, access and inclusion of laboratory stored tissue samples, genomic profiling, their clinicians receiving the results of their profiling, optional additional biopsy, and optional banking of left over samples for Future Unspecified Use of tissue (at the established and approved Auckland Regional Tissue Bank).
2. The Committee enquired about the use of previously collected tissue for research purposes. The CI explained that they would only use this tissue if there was enough remaining after diagnostic procedures were complete.
3. The Committee asked about the prospective biopsy. The CI explained that this was not part of standard care but for research purposes. While there are risks associated with the procedure they did not want to exclude participants from data sets by not having them undergo a biopsy. The purpose of the biopsy is that tumour profiles change over the course of the illness and treatment and they wanted to capture that.
4. The Committee enquired about how genetic information would be managed, as participants and their families may have different views. The CI explained that they will keep this information de-identified in the database, so as to prevent accidental disclosure, whilst later on the participant and designated family members will be able to have explained to them (study ID reidentifiable) the clinically relevant information where it may have an impact for family or future generations. If they wish they may access genetic counselling support. The committee queried whether the genetic counselling is budgeted in the study or is privately provided given the limited public genetic service capacity. The researchers confirmed that this is research funded.
5. The Committee enquired about cell lines being referred to on pages 11 and 17 of the protocol. The CI explained that this as an administrative error and that cell lines would not be cultivated as part of this study. The CI stated they would remove this from the protocol.

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 there is no time frame mentioned around the future unspecified use of tissue. HDECS do not support an indefinite time frame for this. Please choose a time frame in your protocol and amend the participant information sheet to reflect this.
2. The Committee requested further information on the “public database.” The researcher confirmed that this was not “public” but that it was de-identified information used in research collaborations with similar groups, in order to achieve sufficient numbers for specific research questions. The database was held by the university. The Committee requested further written information is provided to the committee on the databased, and that this is more clearly articulated in the participant information sheet.
3. The Committee queried the study governance vis the Auckland Regional Tissue Bank governance structures. The researcher noted that this was governance around study specific information, data access, research questions, management of incidental findings. The Auckland Regional Tissue Bank would become the governance group once samples were banked and available for other studies. The Committee noted that participants need to understand that future unspecified use may or may not be related to their current illness if this is the case.

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

1. The Committee noted that how information gathered during the course of the study is disclosed to treating clinicians (and GPs) is unclear. Please amend the participant information sheet to include a statement about how this information will be disclosed, and that this will be identifiable information to treating clinicians that may be used to inform care (eg medication selection or clinical trial eligibility).
2. The Committee noted that what exactly is being consented to is unclear in the form. Please amend the information sheet to clearly state exactly what is being consented to by participants. The Committee suggested a table as a way of outlining this eg in a table, and being clear about whether the consent is for previously collected information (eg medical records) or laboratory tissue samples, or for new procedures.
3. Please specify that there will be a follow-up four to six monthly in the participant information sheet, for what duration, what information will be sought at follow up and from where (eg is this patient contact, medical records, GP contact etc).
4. The Committee asked about the retention of study data to date if a participant wanted to withdraw. The CI stated that study data to date of withdrawal will be retained. Please include this information in the participant information sheet.
5. Please include an appropriate compensation clause statement in the participant information sheet.
6. Please add a Māori contact person to the participant information sheet.
7. The Committee enquired about samples being sent overseas. The CI explained that samples would only be sent overseas if there were specific validation tests on genomic results that needed to be performed which could not be done in New Zealand. Please include the Committee’s suggested wording on future unspecified use of tissue in the participant information sheet. This can be found in the template participant information sheet on the HDECS website: http://ethics.health.govt.nz/
8. The Committee enquired about incidental findings and disclosure of this information. The CI explained that these issues would be discussed within the research team as they arose. If clinically significant findings that will cause a clear negative impact then these will be disclosed to participants. The researchers emphasised that any internal discussion around these decisions would be extensive. Please include this in the participant information sheet. Please ensure this statement is distinct from the one around designated family members mentioned in point 8 of these minutes.
9. The Committee noted that information around the optional prospective versus consent to access previous retrospective biopsies and retained tissue was unclear. Please state clearly the implications of study enrolment in the participant information sheet. Please provide information about these procedures.
10. The Committee noted that there may be implications for participants’ health insurance policies, particularly life insurance. Please provide a statement in the participant information sheet suggesting participants discuss participation in the research with their insurance providers in the ACC clause section. The Committee 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.”*
11. The Committee asked about splitting the consent form up, noting consent to future unspecified use. The Committee re-iterated the need to clearly state exactly what participants will be consenting to in the information sheet. Please consider splitting the consent form up so as to have optional, later, components be consented to either in separate sections or on separate sheets. This was suggested so as not to overload participants. The Committee also queried why Auckland Regional Tissue Bank was not named, and if this was to be the FUR storage site then please include this in the information sheet.
12. Please ensure that it is specified to obtain consent for the screening of patient’s previous medical notes and access to notes for follow up. Please specify this in the PIS and have it be separate from the consent to access medical samples.
13. Please remove the final sentence from page six about participants being able to telephone the Northern A HDEC chair.

Decision

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

1. 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 Dr Karen Bartholomew and Mr John Hancock.

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| **2** | **Ethics ref:** | **16/NTA/109** |
|  | Title: | FAST Feasibility Study |
|  | Principal Investigator: | Dr. Seif El-Jack |
|  | Sponsor: |  |
|  | Clock Start Date: | 26 July 2016 |

Dr Seif El was unable to present. Mr Hector Gonzales 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. The Committee noted that the application was very detailed.
2. This study investigates the latest iteration of stent technology. It looks to test the feasibility of a drug coated, fully absorbable stent. This means that the stent will dissolve over time and that there will be no foreign bodies left inside the patient. This particular stent is also different in that is can be bypassed and is also suitable for patients with other complicating disorders such as diabetes and hypertension. Following the stent procedure patients will also have non-standard of care intraprocedural ultrasound. This will be done using the same catheter as standard care, however there will be a sensor at the end of the catheter. In this study they will also use optical appearance tomography which uses infrared light to produce a more detailed image of the interior of patient’s arteries, this is not standard of care either.

Summary of ethical issues (resolved)

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

1. The Committee asked about other site approval and the number of patients enrolled there. The researcher explained that the other site is in Australia and there have been 18 patients enrolled there. This number is due to the strict eligibility requirements.
2. The Committee enquired how the recruitment and consenting process would work. The researcher explained that patients will be screened at all sites for the study. Each site has a delegated researcher. The consent form will always be performed by the site investigators. These people are either cardiologists or a fellow on the cardiology ward. They are are trained in the procedure. Patients who have been to the catheter lab as well as being a patient from the cardiology ward will be targeted. The research team will screen these patients’ electronic medical records. This will be done to ensure all criteria are met whilst at the same time they may have completed tests required by the study. Thus preventing unnecessary procedures.
3. The committee queried the potential for coercion with the study doctor requesting consent. The researcher explained that all of the co-investigators are happy to provide information, as are independent clinicians and the research coordinator, to participants should they want it; and that they are able to provide Māori cultural support if desired. The researchers are specifically required to perform consenting procedures as part of the protocol.
4. The Committee asked about SCOTT review. The researcher explained that as the drug coating the stent is already approved they will not need to seek SCOTT approval. Only the stent is being investigated in this study.
5. The Committee asked about the data safety monitoring group. The researcher explained that data analysis will be performed by a Melbourne branch of an American company. Boston Scientific, the studies’ sponsor, also have an independent, in-house data safety monitoring committee.
6. The Committee asked about how the reporting of serious adverse events might work. The researcher explained that events will be reported to the Melbourne data analysis group, Boston scientific, and the studies’ clinical events committee. The researcher stated that there is an expectation on the researchers to accurately and quickly report all serious adverse events to these groups and that the sponsors actively watch for these.
7. The Committee asked why the study is focused on New Zealand and Australia given that is based in the United States. The researcher explained that the FDA tends to be restrictive about first in human trials and are aware of New Zealand’s high standards for health research. In this case the study started in Australia and now wants to include New Zealand. The aim is to recruit a total of 50 patients worldwide, split between countries, with no more than 30 recruited in New Zealand.
8. The Committee asked about the collection of blood samples. The researcher explained that the only bloods collected would be done so as part of standard care. Not for research purposes.
9. The Committee noted the researcher’s statement that they are unable to remove the statement about the medication’s side effects, although the tables may appear somewhat alarming to participants.

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 peer review for the study is not independent (the clinical director of the cardiology unit at the site). While the committee is aware that the study has had a peer review process through the sponsor company, device trials are required to have independent peer review and it is a responsibility of the investigator to arrange this. Please provide evidence of independent peer review.
2. The Committee noted the researcher’s response to question r.1.6 in the application indicates that the study may be terminated for commercial reasons. Please note that in New Zealand *The National Ethics Advisory Committee’s Ethical Guidelines for Intervention Studies section 6.65* states studies should not be terminated simply for reasons of commercial interest, and sponsors need to be aware of this and participant information sheets reflect this.

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

1. Please include that the study is registered on the Australia/New Zealand clinical trials website in the Participant Information Sheet.
2. The Committee noted that the participant information sheet contains a lot of medical jargon that could be inaccessible or confusing to lay people. The researcher explained that this is sponsor-driven, however the Committee requested that jargon needs to be explained in lay language or simplified. Please amend the information sheet to more clearly explain medical jargon and reconsider the “why is this study being done?” section on page two.
3. Please distinguish between standard care and what are research procedures only in the participant information sheet, including follow up procedures. The Committee suggested using a table to separate the two.
4. Please include a statement about the sending of medical images offshore in the participant information sheet.
5. Please correct the compensation clauses. 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.”*
6. Please include a privacy act reference on page 11 of the information sheet rather than the current American provision.
7. Please state that this study is a first in human for this specific device in the participant information sheet.
8. Please state the absorption times for the drug and stent in the participant information sheet.
9. Please try to remove any legal jargon from the participant information sheet. Please clearly explain in plain English what these statements mean.

Decision

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

1. Please provide evidence of favourable, independent peer review.
2. Please make the required changes and amendments to the participant information sheet.

This following information will be reviewed, and a final decision made on the application, by Ms Shamim Chagani and Dr Brian Fergus.

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| **3** | **Ethics ref:** | **16/NTA/124** |
|  | Title: | DARTS Study |
|  | Principal Investigator: | Mr. Parma Nand |
|  | Sponsor: | Ascyrus Medical LCC |
|  | Clock Start Date: | 29 July 2016 |

Mr Parma Nand could not attend. Mr Hector Gonzales 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. The study investigates the effectiveness of a newly designed stent in the treatment of aortic dissections.
2. The Committee noted that one of the goals for the study is not to add complications from the standard procedures around aortic dissection repairs.
3. The Committee queried how this study arose. The researchers explained that the founder of the study sponsor’s company is a leading cardiac surgeon in the United States. He has designed the stent in order to address current limitations in the treatment of aortic dissection.

Summary of ethical issues (resolved)

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

1. The Committee noted the researcher’s statement that using the stent won’t add complications to standard procedures.
2. The Committee noted that this study is first in human and queried if this device is similar to other standard devices. The researcher explained that this device is the same as other standard devices. The Committee queried why this device was not then being compared against these devices. The researcher stated that this device is functionally the same as other devices, but is longer.
3. The researcher asked The Committee what their recommendations would be for the consenting process. The Committee stated that the researcher would need a clear process and consent form. They would need to develop clear deliverable outcomes. Further, they need to develop their study protocol to incorporate The Committee’s comments. They will need to seek more input from peers.
4. The Committee noted that the sponsor company was relatively new and enquired if they had sponsored any other studies before. The researcher explained that they had sponsored a single previous clinical trial.
5. Please note that in New Zealand *The National Ethics Advisory Committee’s Ethical Guidelines for Intervention Studies section 6.65* states studies should not be terminated simply for reasons of commercial interest, and sponsors need to be aware of this and participant information sheets 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 asked how consenting would work, given that aortic dissection is an acute scenario and intervention would be required relatively quickly. The researcher asked The Committee what their recommendations would be for the consenting process. The Committee stated that the researcher needs to provide a clear process free of coercion and allowing sufficient time to consider the study, well defined participant information sheet and consent form. They will need to seek more input from peers.
2. The Committee noted that the peer review was not independent, it is from the study sponsor (company director). It is the investigators responsibility to provide robust and independent peer review covering the issues in the standard peer review form. Please provide evidence of peer review.
3. The Committee then asked about what specific measureable outcomes are being sought. The researcher admitted that these are not stated in the protocol and as not able to give them.
4. The Committee enquired about the data safety monitoring plans in place and if there was an independent data safety monitoring committee. The researcher explained that they have an independent data safety monitoring committee. Please provide more information on how data safety will be managed in this study, particularly as previous first in human studies of devices like this often take a very cautious case-by-case safety review before proceeding.
5. The Committee noted the poor quality of the information sheet including various typographic issues. Please fix these.
6. Please make sure that the study is listed on the Australia & New Zealand clinical trials website.
7. Please provide more complete protocol document noting clear outcomes, data safety monitoring arrangements, the method, clarification of follow up procedures, an improved participant information sheet/consent form, and quantify the radiation exposure in the participant information sheet.
8. Please explain current best practice treatment against this device in the participant information sheet so participants can make an informed decision.
9. Please provide evidence of Māori consultation.
10. Please provide a CV on the president of the sponsor company.

Decision

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

1. Provide details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies para 6.50).*
2. Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
3. 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.
4. The Committee had concerns over the scientific validity and worth of the study. The *Ethical Guidelines for Intervention Studies (paras 3.5. and 5.5)* state that intervention studies must be of high scientific quality and scientific soundness is ethically important.
5. The Committee noted the lack of a clear study question and measurable outcomes. The *Ethical Guidelines for Intervention Studies (para 5.2)* states that “Investigators should develop clear study questions that identify…the main outcome of interest.”
6. The Committee had concerns over the development of the studies’ protocol. *Ethical Guidelines for Intervention Studies (para 5.41)*
7. The Committee expressed concern over the fact that this is a phase I study. The *Ethical Guidelines for Intervention Studies (paras 5.50 and 5.51)* state that investigators should be familiar with the recommendations made by the Expert Scientific Group on Phase I Clinical Trials 2006 document.
8. The Committee was concerned over the lack of clarity around the risks and benefits of the study. The Committee felt that these were not stated clearly enough in order for them to provide a fair assessment or for participants to provide informed consent. *Ethical Guidelines for Intervention Studies (paras 3.11 and 4.12)*
9. The Committee was concerned about the potential vulnerability of participants and that this had not been addressed. *Ethical Guidelines for Intervention Studies (para 5.28)*

The Committee welcomes the Researchers to resubmit this application having addressed the above issues.

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| **4** | **Ethics ref:** | **16/NTA/111** |
|  | Title: | The REACTOR trial. Randomised Evaluation of Active Control of Temperature versus ORdinary temperature management. |
|  | Principal Investigator: | Dr Paul Young |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 26 July 2016 |

Dr Paul Young was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The Committee asked The CI to summarise the study. The CI summarised as follows: They want to investigate an active approach to temperature control versus standard care in intensive care unit patients who do not have acute brain pathologies. This study is to confirm that there is a physiological temperature response, to inform a further study powered to determine impact on 90 day mortality rates.
2. The CI identified the non-consensual nature of the study as the ethical issue, as well as the fact that there is no patient screening until they present. The researcher and research group of ICU clinicians have conducted many similar trials and have developed a protocol to address the key issue of delayed consent and family input and assent, this has been provided to the committee. They intend to follow methods used in previous studies where they will treat patients and explore wishes from family. Once able they will seek to obtain informed consent from the participant for inclusion of their data as soon as possible.
3. The CI stated that there have been preliminary studies published looking at this temperature control approach and they plan to aggregate with them in order to look at outcomes. Following this there will be a stronger case for future research.

Summary of ethical issues (resolved)

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

1. The Committee enquired about the differences between standard care and the study setting. The CI explained that in standard care a patient’s fever is generally tolerated by clinicians unless they become high (eg more than 38 degrees). In this study they seek to intervene as soon as a patient’s temperature exceeds the normal level. In the other arm temperature management is same as standard care. The Committee was satisfied with this explanation with the provision that this is clearly stated in the participant information sheet.
2. The Committee asked, as patients will initially be enrolled without informed consent, how will the best interest criteria of Right 7 (4) of the Code of Health and Disability Services Consumers’ Rights. The CI explained that in both arms of the study receive standard care, there is no experimental treatment occurring in this study. Temperature management is in the participants’ best interests and staff will be monitoring them closely. Thus there is equipoise and in both arms patients will benefit. The researcher also commented that the intervention is an active control (more than current temperature control methods).
3. The CI stated that if clinicians did not think that enrolment in the study was in a patient’s best interests then they will not include them in the study.
4. The Committee enquired about any patient group consultation that had occurred. The CI stated that while they had not done any regarding non-consenting research. However Wellington Intensive Care Unit has 25 current trials running; staff are not inexperienced or unfamiliar with patients’ needs or concerns. The CI noted that patients and their families are generally supportive of improving standard treatments for the future.
5. The Committee asked about what will be done with the data of those patients who recover and decline to participate. The CI stated that they will ask these patients about their wishes and then follow them.
6. The Committee asked if the CI had considered splitting the participant information sheet into three separate sheets (participant consent, participant consent to include information when recovered, and family assent). The CI explained that they had received advice to combine three sheets into a single sheet from their locality and prefer this approach.
7. The Committee asked about the identified additional risk of bladder core temperature monitoring (catheterisation of patients). The CI explained that this is not experimental and can be part of standard clinical care if judged necessary, and that catheterisation was very common in this setting in usual care. There are other methods of core temperature monitoring available and this will be determined by the clinician..
8. The Committee asked about Māori consultation about non-consent. The CI stated that this study has been submitted to the Māori research advisory group.
9. The Committee asked how ascertaining families’ views will work. The CI explained that they will try to ascertain the views of relatives but within reason in terms of timing. Enrolment will occur if it is unreasonable to try to seek the views of relatives, however these views will be sought as soon as practically possible.
10. The Committee asked if the consent form will be gone through with relatives and how this will work. The CI explained that the form will be gone through with the family and then with the patient (when possible). The Committee suggested the CI consider a separate form for family members (noting 9 above).

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

1. Please thoroughly check the participant information sheet for clarity and any typographic errors.
2. Please provide an alternative information sheet for family members.

Decision

This application was *approved* *with non-standard conditions* by consensus.

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| **5** | **Ethics ref:** | **16/NTA/112** |
|  | Title: | The NZ PrEP study: A demonstration project |
|  | Principal Investigator: | Dr Sunita Azariah |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 28 July 2016 |

Dr Sunita Azariah and Dr Peter Saxton 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. The study investigates whether or not the use of the HIV prophylaxis drug, PrEP, can reduce the rate of new HIV infections in a high-risk population of Takatāpui, gay or bisexual men in New Zealand.
2. The Committee noted that the drug can serve as a preventative with two randomised controlled trials showing an 86% reduction rate in at-risk populations.
3. The Committee asked about the goals of the study. The CI explained that they want to look at how the local population and environment accepts the use of the drug in New Zealand.

Summary of ethical issues (resolved)

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

1. The Committee noted the design of the study and the drug’s mechanism. The CI explained that while the drug is licensed in the United States it is not licensed here.
2. The Committee asked the researchers to explain the recruitment process. The CI explained that study information will be available through a purpose-built website. This information will be linked with the New Zealand AIDS foundation website and the same information will be available on the Foundation’s website. The aim is to recruit those who use the CI’s service, the people who use this service are already classified as high-risk. If an individual’s history does not meet the criteria then they will not be included. This history will be recorded as part of normal clinical care. After seeking this history the CI will seek to recruit patients. Any testing for HIV or related illnesses will be done as part of standard clinical care. After potential participants receive standard care they will be provided with a participant information sheet and consent form and the study will be explained to them. After this participants will be asked if they are willing to undergo the non-standard blood test. If they are willing then they will be rebooked for the test. Once the blood test has been performed then any participants who are diagnosed will be referred down the standard care pathway. After this then the nurse will go through the consent process with participants, part of which includes the provision that they will remain in the Auckland area. After participants are enrolled then they will see a peer educator about safe sex practice and receive a prescription. There will be a follow-up phone call at one week and a consultation at one month with a repeat HIV test.
3. The Committee asked what will happen if patients develop HIV during the study. The CI explained that participants will be advised to ring the study nurse if they develop any of the symptoms mentioned in the participant information sheet. If a participant is diagnosed then they will be told to stop taking the medicine and be booked onto the standard care pathway. The Committee asked if they will have access to the drug as part of standard care. The CI explained that they will and that it is funded.
4. The Committee noted that there had been a spike in HIV cases. The CI explained that this has been due partly due to increased incidence but also due to increased testing.
5. The Committee asked how will the potential harm of the drug being available to a high risk group be managed. Participates taking the drug may feel inclined to increase their risk behaviours. The CI stated that this phenomenon has been noted in previous studies and will be monitored. Due to the increased monitoring of the study any sexually transmitted infections will be identified and treated sooner. Thus reducing risks to patients and their partners.
6. The CI explained that by participating in the study sexually transmitted infection rates may decline in population groups as these will be identified and treated sooner. However there may also be a reduction in condom use. There are pre- and post- study methods in place to manage this.
7. The Committee asked how the stigmatisation of participants via the recruitment process will be managed and if there had been consultation around this issue. The CI explained that the NZ AIDS Foundation and Bodypositive NZ had been involved in the protocol design process and in informing the community. These organisations are aware of the risk in increasing infection rates. The CI has noted stigmatisation that occurred in the United States as a result of patients taking PrEP and has designed a way of framing the taking of the drug as a positive choice. The CI noted that a large portion of the community accept and welcome the implementation of PrEP.
8. The Committee asked who funds the study. The CI explained that Gilead Science is providing the funding for everything except the behavioural survey. The Committee asked if they benefit from the study or have control over publication. The CI stated that they do not and have a letter confirming this.
9. The Committee was satisfied that this is not a sponsored trial and that ACC compensation would be available, dependent on participant eligibility. The CI confirmed they had checked with Medsafe and that this is the case.
10. The Committee enquired about the level of intimate detail contained in the questionnaire for participants. The CI explained these kinds of direct questions are standard in New Zealand. Previous studies using these questions have received ethics approval.

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

1. The Committee queried the length of the study. The CI explained that the study will last for 96 weeks. Please include this information in the participant information sheet.
2. Please clarify the recruitment process in the participant information sheet to make it easier to understand.
3. Please place more emphasis on condom use in the form. Otherwise participants may engage in high risk behaviours.
4. Please rephrase the wording around the 86% efficacy of PrEP in the information sheet to provide more clarity.
5. Please remove yes/no boxes for items that are not truly optional on the consent form.
6. Please change wording around future unspecified use in the application process. Please change this to reflect that it is actually seeking a future unspecified use.
7. Please remove the reference to an HDEC approved auditor from the information sheet.
8. Please state that Gilead Science is the sponsor in the participant information sheet.
9. Please combine consent forms into a single document.
10. Please lay out exactly what participants are consenting to in a clear manner.

Decision

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

1. 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 Charis Brown and Mr John Hancock.

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| **6** | **Ethics ref:** | **16/NTA/113** |
|  | Title: | Treatment of mild-moderate Impetigo |
|  | Principal Investigator: | Dr Alison Leversha |
|  | Sponsor: |  |
|  | Clock Start Date: | 28 July 2016 |

Dr Alison Leversha 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 remain present, but not participate in the discussion or decision making processes.

Summary of Study

1. The study aims to add screening for impetigo onto an already extant rheumatic fever screening process in place in low decile schools. They will assess the efficacy of standard wound care versus that of an antibiotic cream. The schools and students are familiar with the screening process and were concerned about skin infections as rheumatic fever rates have been found to be low.
2. The Committee asked for incidence rates of impetigo. The CI explained that around 25% of children will have skin infections.

Summary of ethical issues (resolved)

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

1. The Committee queried how consent would be obtained. The Ci explained that parents consent for their child when their child goes to school. If any form of treatment is required then they call the parents and seek consent.
2. The Committee asked how parents wanting to time to think about their choices would be managed. The Ci explained that parents will be able to think about this overnight. Parents coming into the school to collect medicine will be able to discuss with staff.
3. The Committee asked about the stigmatisation of self-identifying. The CI explained that this is not an issue. In previous school-wide initiatives there have been no stigmatisation issues. Being tested is normalised in schools as all students have to undergo the tests. There are not set times for screening or appointments as nurses are present at the school for time blocks.
4. The Committee asked if there is a higher risk factor by having different interventions with different difficulties of administration. The CI explained that they have an intervention point where study participation will be stopped. The CI noted that the wounds respond to treatment with or without antibiotics; hence one of the aims of the study being to establish the efficacy of the cream.
5. The Ci explained that they had consulted with PHARMAC regarding antibiotic resistance. Thus the study is important if they can show equivalence before antibiotic cream becomes useless. If total resistance occurs then there will be no conventional medical option for GPs.
6. The CI noted that as some patients delaying in presenting they can use the photographs to work out a chronological point where the drugs should not be used.
7. The Committee asked how time of school will be managed. The CI stated that students will not be spending time off school if they are diagnosed. The Committee asked how, given that there are other factors that can cause school absence, time off school will be recorded as this is a stated aim of the study. The Ci explained that randomisation of participants will help offset this.
8. The Committee asked about bacterial resistance management. The CI stated that treatment failure is an outcome; measured by photograph and clinical assessment.

Summary of ethical issues (outstanding)

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

1. Please ensure data is kept for 10 years following participants reaching the age of 16. *(Health (Retention of Health Information) Regulations 1996).*
2. The Committee asked about how reuse of medication will be managed as some groups will seek to reuse medicines. Please ask participants to return the tube.
3. Please provide the patient questionnaire.
4. Please consider reviewing the study once the number of participants reach 100 to check response rates and confirm that there are no safety issues for the participants.

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

1. Please include a Māori contact in the information sheet.
2. Please add an ACC statement to the information sheet.
3. The Committee noted the quality of the assent form. Please remove the tick boxes for items that are not truly optional.

Decision

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

1. 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*).
2. Please provide the patient questionnaire.

This following information will be reviewed, and a final decision made on the application, by Dr Kate Parker and Dr Brian Fergus

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| **7** | **Ethics ref:** | **16/NTA/116** |
|  | Title: | MS1819-SD phase IIa clinical trial for EPI caused by CP and/or distal pancreatectomy. |
|  | Principal Investigator: | Dr Richard Stubbs |
|  | Sponsor: | INC Research®, Inc. |
|  | Clock Start Date: | 28 July 2016 |

Dr Richard Stubbs was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The Committee noted that the CI is looking at an alternative to the current standard of care for the treatment of chronic pancreatitis. The alternative has been shown to be effective but there are no testing doses.
2. The CI explained that there are various issues with using animal-extracted enzymes such as the theoretical possibility of disease transmission. The dosing of currently-used extracts is variable, difficult to standardise, and the extracts deteriorate over time. It has been noted that the current maximally tolerated dose does not provide sufficient fat absorption. The community consensus is that the standard of care needs to be improved. A pure lipase has been chosen as the gut is capable of absorbing other substances that pancreas deficiency can cause difficulty absorbing.

Summary of ethical issues (resolved)

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

1. The Committee asked about the duration of the washout period. The CI explained that there is no harm necessarily; participants’ bowel movements will be more regular. Some participants may not be on any medicines or dietary supplements for the treatment of their conditions. No harm is anticipated for not being on medicines.

Summary of ethical issues (outstanding)

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

1. The Committee noted the large financial compensation figure for study participationThe CI clarified that the compensation is scaling and is in-line with what other early-phase projects have provided to their participants. The Committee considered the issue of the total sum forming an inducement to participate. To mitigate this risk they requested the researcher remove the ten thousand dollar figure but instead provide the compensation per hour rate or session and time commitment figures. This way participants can calculate the full figure if they wish. The Committee further asked how the compensation’s coercive factor would be managed. The CI stated that this is not intentional. Participants will be giving up 25 days of their life and will be required to collect all of their stool. In order to get patients to do this a payment is necessary. Whilst it is attractive it will also help cover lost earnings and other issues that could arise as part of study participation.
2. The Committee noted that there is a washout period in the participant information sheet and asked if during this time participants would be taking their standard medicine. The CI explained that they would not be taking their medicine during this time as this will be the time where fat malabsorption levels are measured. The CI stated that there are no significant problems anticipated with this time period. Please amend the participant information sheet to clearly state this.
3. The Committee asked about the washout period and what it entailed. The CI explained that participants will include a high fat diet. In order to pass screening participants must absorb 25% of fat or less. Please state this clearly in the participant information sheet.
4. The Committee noted that the participant information sheet states that samples will be sent to a central lab and queried how confidentiality would be managed. The CI explained that these samples will be de-identified. The lab will not be able to identify them, only the researchers. Please clearly state this in the participant information sheet as well as the locations of these labs.
5. Please remove the name space from the diaries collected by the sponsor as this would be disclosure of identifiable health information.

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

1. Please amend the participant information sheet so as to more clearly state eligibility criteria.
2. Please note that in New Zealand *The National Ethics Advisory Committee’s Ethical Guidelines for Intervention Studies section 6.65* states studies should not be terminated simply for reasons of commercial interest, and sponsors need to be aware of this and participant information sheets reflect this.
3. 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.”*
4. Please remove the mention of HDEC approved auditors from the participant information sheet. HDECs do not appoint auditors.
5. Please correct the emergency phone number to the New Zealand one.
6. Please state that ethics approval was gained from Northern A HDEC not Northern B.

Decision

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

1. 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 Christine Crooks and Dr Brian Fergus.

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| **8** | **Ethics ref:** | **16/NTA/118** |
|  | Title: | He Kura: Asthma in Schools PHASE 2 (Asthma Trial) |
|  | Principal Investigator: | Mrs Bernadette Jones |
|  | Sponsor: |  |
|  | Clock Start Date: | 28 July 2016 |

Mrs Bernadette Jones and Dr Tristram Ingahm was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study seeks to address gaps in asthma education in children, and realise the potential opportunity of schools to intervene to reduce the burden of asthma. There needs to be support for children in schools for when they need to take their medication. School staff do not currently have the education and support for how to look after the children.
2. The Committee noted that this is the second phase of the study. The CI confirmed this noting that phase one was the research and development of the He Kura toolkit. Phase one involved research in schools and consultation.

Summary of ethical issues (resolved)

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

1. The Committee asked about the consent provisions in the study.The CI explained that school Board of Trustees will be consenting to the intervention occurring in the school and to teachers and children participating in the toolkit intervention. Parental consent to participate in the school intervention will not be sought. Some parents will be invited to participate in qualitative evaluation about the programme (questionnaire, interview or focus group). Parents will be asked to consent to these methods. Teachers will also be asked for individual consent for interviews. The consent from the Board of Trustees is clear what time requirement is involved for teachers and the school in the intervention and the evaluation, but that teachers will be free not to participate if they choose.
2. The Committee queried the proposal in the protocol for the release of individual data on absences, educational attainment, knowledge improvement and self-management. The Principal Investigator reported that the data would not be individual but would be proportions provided by the school. However the CI noted that the researchers would receive individual data, on children with asthma and children without, but that this would be de-identified numbers of children. The Committee noted that this may be small numbers of children and so the children might be identifiable even of the names are not provided to researchers. The Committee also queried the scientific validity of a pre- and post- assessment of these variables given that there may be a number of confounding factors, including the identification of more children with asthma by the intervention, background rates of asthma, housing issues, circulating viral illness or other factors that may impact these measures. The researchers stated that they were aware of this but believed that the study design of pre- and post-analysis of these variables was appropriate.
3. The researchers were asked how educational attainment will be measured. The CI explained that they will perform an annual measure by looking at those with asthma and see how they are performing on standard school collected measures.
4. The Committee asked about the purpose of the school attendance measure and why they haven’t sought consent for this. The CI stated that these students would not be identified and in the past they have found that there has been underrepresentation of students with absences. Schools will provide a dataset that shows the total number of absences but will not be identifying students or specifying reasons. The school will simply look at the number of absences before and after the implementation.
5. The Committee asked about the health referral of students who have been identified as having asthma noted in the protocol. The CI explained that this is a safety measure. The Committee asked who would be referring the students. The CI explained that they will provide guidelines to families about diagnosis and schools will be asked to identify their referral pathways. The researchers would not be referring individual children.
6. The Committee enquired about newsletter articles about the school participating in the study being the only notification parents have of the school and their children’s involvement in the study. The CI explained that the schools would like to notify families of the study through this mechanism. The Committee noted that information in this ad that some children may be identified with asthma as part of the intervention, and also that the study would be looking at whether there was any impact on school attendance and performance.
7. The Committee noted that there are three separate information forms for teachers and parents and asked if teachers could refuse to participate. The CI confirmed they are free to refuse to participate.
8. The Committee asked if Non Māori children will be involved in the study. The CI explained that the program is Māori-focused but available to all children.
9. The Committee asked if the schools re doing the de-identification of data and that all data would be completely de-identified. The CI confirmed this was the case.

Summary of ethical issues (outstanding)

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

1. Please provide more information around how the requirements of the Privacy Act will be met when sharing individual student school data.
2. The Committee asked about information channels and the process under which information would be de-identified by schools and then passed on to the research team. The Committee expressed concern at the Privacy Act implications, as the process involves the school passing on personal information of students to the researchers. The Committee requests information/documentation that confirms that this arrangement complies with the provisions of the Privacy Act. This documentation should ideally be in the form of legal or policy advice from a duly qualified person or organisation, such as confirmation from the Office of the Privacy Commissioner, for example.

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

1. Please provide more detailed information about the studies’ methods in the participant information sheet.

Decision

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

1. Please provide information from each agency about how the privacy act implications of disclosing de-identified data of a very small population will be managed.
2. Please provide more policy or legal advice addressing The Committee’s concerns.
3. Please provide more information on your study design including responses to questions raised during the peer review process.

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

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| **9** | **Ethics ref:** | **16/NTA/120** |
|  | Title: | Prediction of a response to treatment during first episode psychosis |
|  | Principal Investigator: | Associate Professor Bruce Russell |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 29 July 2016 |

Miss Valentina Morgera was present in person and Associate Professor Bruce Russell was present via teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates whether or not treatment-resistant psychosis can be identified early by testing patients’ biomarkers following first-episode psychosis.
2. Participants will be recruited through inpatient or community centres. They will undergo a psychiatric assessment, so their symptoms can be scored. Participants will undergo an electroencephalogram whilst performing simple computer tasks.
3. Participants will also be asked to provide blood samples; once after 2 weeks and once after 3 months. This second visit may be brought forward if clinicians are considering changing their medications. Treatment response will be noted.
4. The Committee noted that there will be around 100 participants.

Summary of ethical issues (resolved)

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

1. The Committee noted that the terms in the participant information sheet are complex and if they have considered simplifying these in light of the studies’ population. The CI explained that in their experience patients understand the terms used in the participant information sheet.
2. The Committee enquired about the timeframe feedback form the peer review. The student explained that the study will extend past the due date for their thesis. Thus their thesis work will not be completed with as much information as the studies’ final form will have, the CI takes responsibility for completing the study.
3. The Committee asked about the age cut off for the study, age 18-45, and why this was in place. The CI explained that psychosis in those over the age of 45 is usually due to different causes that are outside the scope of the study.
4. The Committee asked about the taking of blood samples for future unspecified research. The CI explained that these will be stored for future research looking for potential genetic susceptibilities to schizophrenia, the epigenetics of schizophrenia, or pharmacogenetic issues surrounding schizophrenia. These samples will not be used in this study.
5. The Committee asked about blood samples being returned to participants or destroyed. The CI explained that this is in case participants do not want to have their blood samples stored for an extended period of time.
6. The Committee asked about the vulnerability of participants. The CI explained that these people will have been referred from community centres and will be less vulnerable than might be supposed, and should have the right to be included in research that is relevant to them. If patients are identified as too vulnerable then they will be excluded from participating in the research. Only patients able to consent for themselves, in the judgement of the clinician, will be included.
7. The Committee asked about the safety of conducting this research at the same premises as other studies. The CI explained that there is no identified risks. Participants may bring their key worker and there will be a trained psych nurse present.
8. The Committee noted that threshold for informed consent is higher for future unspecified research (please see the requirements for informed consent in the Future Unspecified Research Guidelines: http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0) and asked how the researchers will ensure they meet this, and ensure participants have sufficient time and resources to fully consider the implications. The CI explained that it is very rare for participants to be unable to consent. Clinicians will give their opinions as to if individual patients are able to consent. If individual cases might preclude a patient from being a participant then these cases will be examined.
9. The CI explained that they had consulted with a service user reference group who have given feedback. Further they will ensure that the future unspecified component is clearly communicated in the participant information sheet and verbally. Participants will be encouraged to take as much time as they need whilst they consider consenting to this, and will have the opportunity to withdraw consent.
10. The Committee asked about the discussion and introduction of the study. The CI explained that clinicians will know about the study and if they identify a potential participant they will invite the researchers who can provide the information. The Committee noted that this was different to what was stated in the application. The CI clarified that the project will initially be presented to patients by a clinician and when they meet with researchers they will have already seen the information sheet once.
11. The Committee asked about the inclusion criteria around first-episode psychosis and if this meant that patients have had a first episode and then ongoing issues. Alternatively could this be taken to mean that there are a range of issues covered by the first episode umbrella as individual cases could vary? The CI stated they are interested in the response to treatment. Major concerns are length of the episode, as the length correlates with brain damage. By performing this study they are looking to identify individuals who should be shifted onto different medications if determined to be treatment resistant sooner. This will help avoid drawn out periods of medicines that are not beneficial.
12. The Committee asked about drug induced or short term psychosis. The CI explained that participants in this population will have been living with psychosis for a while and short-term psychosis will be excluded. This will allow for external factors such as environment stressors or medications to be ruled out as causes.
13. The Committee queried whether data would be discarded on withdrawal, or kept up to the point of withdrawal. Please clarify in the participant information sheet.
14. Please clarify whether the normal controls also need blood tests and future unspecified use?

Summary of ethical issues (outstanding)

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

1. Please provide information that the population can be consented that matches the minimum requirement for future unspecified use from HDECS (see Guidelines for Future Unspecified Research), for example consideration of return of results, incidental findings, commercial relationships, re-contact.
2. 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)*

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

1. Please clearly state that the study is part of Valentina’s PHD thesis in the participant information sheet.
2. Please remove yes/no boxes from the consent form for all items that are not truly optional.
3. Please be more specific in the participant information sheet about why participants have been chosen. Please clearly reflect this in the section about inclusion criteria.
4. Please amend the information sheet to state that participants will have to come back twice.
5. Please clarify what it is that participants are consenting to in the consent form and information sheet. Especially around future unspecified use of tissue, currently the form is blanket consent for any research. The researchers stated that it would be research on mental health issues or schizophrenia, if this is the case then it is broad consent and requires specification.
6. Please correct typos eg “time spam” page 3.

Decision

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

1. Please make the required changes to the participant information sheet and consent forms.
2. Please provide evidence that the population can be consented for future unspecified use of tissue.

This following information will be reviewed, and a final decision made on the application, by Ms Shamim Chagani and Dr Brian Fergus

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| **10** | **Ethics ref:** | **16/NTA/121** |
|  | Title: | Margins Project |
|  | Principal Investigator: | A/Prof Ian Campbell |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 July 2016 |

Associate Professor Ian Campbell was present by teleconference for discussion of this application. Dr Melissa Edwards and Ms Jenni Scarlet where present in person for the discussion of this application.

Potential conflicts of interest

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

Dr Charis Brown identified a conflict of interest for this application. The Committee resolved to allow her to remain present for, but not participate in, the discussion or decision.

Summary of Study

1. The study aims to establish the optimal margins for excision following confirmation of breast cancer. The researchers propose to perform a retrospective cohort study of twenty thousand women by combining registries. They need to use large amounts of data so that they can control for confounding variables. They are looking to examine reoccurrence and mortality data based on margins of excision.

Summary of ethical issues (resolved)

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

1. The Committee queried the NHI number linkage of identifiable medical information and additional medical records. The CI explained that this is done to link with the national minimal data set to get comorbidity information. They also stated that they want to access a more complete set of mortality data.
2. The Committee asked about accessing mortality data. The CI stated that they wish to ensure that they have up to date and complete data for recent patients and that some patients may be missed without this, although several registers already update data from the mortality collection routinely.
3. The Committee enquired about hospital data and comorbidity. The CI stated that they are wanting to look at discharge information on comorbid diseases, and that the purpose of this is to ensure appropriate consideration of important confounders to the research question.
4. The Committee asked if the researchers intend to access further medical records. The CI stated that they do not need this information.
5. The Committee asked if the women providing the data are aware that the linking of identifiable data may occur. The CI stated that they might not be aware, as the registers are opt off.
6. The Committee noted that the Auckland and Wellington registers have approved the data linkage for mortality data.
7. The Committee queried if this study only examines women who have had breast preservation surgery. The CI confirmed this and stated that those who have had a mastectomy will not be included.
8. The Committee queried if the comorbidity data was vital. The CI explained that it is an important variable as comorbidity impacts surgical decision making.

Decision

This application was *approved* by consensus.

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| **11** | **Ethics ref:** | **16/NTA/123** |
|  | Title: | Prucalopride in postoperative ileus |
|  | Principal Investigator: | Associate Professor Ian Bissett |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 29 July 2016 |

Dr Tony Milne 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. The study investigates a new potential way of managing postoperative ileus. Currently there is no definitive treatment or medication for this condition. This study is looking to test a drug that has been shown to be effective in patients with constipation.
2. The Committee commended the quality of the application.

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 what the current standard of care is for postoperative ileus. The CI explained that patients are instructed to stop eating food and are put on IV fluids. Any other potential complicating factors, such as opiate-based medications are also adjusted. The CI stated that in this study no patients will miss out on standard care.
2. The Committee queried how participants will be recruited for this study. The CI explained that they will examine operation lists. Following this patients will be asked if they want to discuss the study with researchers. If they agree they will discuss with researchers, they will also have time to call family or whanau. The CI stated that it is not necessary to obtain consent on the same day as the study is discussed with patients in pre-admission clinic. They will have up to two weeks before the operation occurs, thus they will have plenty of time to take the form home and choose to consent, or revoke consent, later.
3. The CI explained that the study drug increases parasympathetic nerve activity as it’s’ method of action.
4. The Committee enquired about data safety monitoring committees and if there are rules for withdrawing patients from the study. The CI explained that they have these and another investigator is experienced in managing these issues.
5. The Committee asked about adverse events and if these would cause the data safety monitoring committee to review the continuance of the trial. The CI confirmed that this was the case and would occur following any major adverse events.
6. The Committee asked about the mention of increased surgical complications in the placebo arm. The CI explained that the drug reduces postoperative ileus which also lowers risk of other postoperative complications The main complications being examined in this study are those of prucalopride.
7. The Committee asked about trials of the drug in other countries. The CI stated that both China and the United States have shown the drug to be effective.
8. The Committee stated that serious adverse events should be notified to MEDSAFE and the data safety monitoring committee for the study.
9. The Committee asked if mortality in the intervention arm will be reviewed more often than six months. The CI stated that all serious adverse events will be reviewed.
10. The Committee noted that there is a preoperative dose of the drug. The CI explained that the drug is an anti-inflammatory and that these drugs are often given pre-surgery to reduce chances of ileus.

Summary of ethical issues (outstanding)

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

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

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

1. Please clarify the study procedures, currently states just taking the medication, however there are additional blood tests, a breath test, phone follow up and follow up review of medical records. A table or list may assist in clarification.
2. Please state the unblinding process in the participant information sheet.
3. The CI stated that there would be no storage of samples or future unspecified use. Please remove the wording around samples stored for future use in the consent form and information sheet
4. Please remove the consent form clause around agreeing to keeping of data for another study.
5. Please clearly state the requirements that are beyond those of standard care in the information sheet.

Decision

This application was *approved with non-standard conditions* by consensus.

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| **12** | **Ethics ref:** | **16/NTA/110** |
|  | Title: | Evaluation of the Safety of N1539 Following Major Surgery |
|  | Principal Investigator: | Dr John Currie |
|  | Sponsor: | Recro Pharma |
|  | Clock Start Date: | 26 July 2016 |

Ms Eileen Bisley and Ms Heather Logan were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates a new method of administering the drug N1539 as pain relief following major surgery. Currently the drug is administered orally. This study seeks to assess the efficacy of administering the drug intravenously.
2. The CI stated that it is important to do this study as individuals can react differently to medicines and NSAID drugs can be hard on the gut.

Summary of ethical issues (resolved)

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

1. The Committee queried if the researchers had sought SCOTT approval. The CI explained that they have but have not yet received it. Once it is obtained the sponsor company will provide it to HDECS in the form of a letter.
2. The Committee asked what the standard of care is for patients in this trial. The CI explained that patients in this trial will be having major surgery and thus will be under a general anaesthetic. Once this wears off they will either be given opiates or NSAID drugs. NSAIDs are commonly used for orthopaedic surgeries.
3. The Committee sought clarification that all patients will get pain relief. The CI stated that all patients will get pain relief and that if they are on the study drug they will not get other NSAIDs.
4. The CI stated that participants will get opiates and Panadol as well as either the NSAID or placebo.
5. The Committee sought clarification around the rules for additional doses mentioned in the participant information sheet. The CI explained that participants will be able to come back to the hospital up to seven days after discharge for additional doses under the supervision of the study doctor.
6. The Committee asked if Māori consultation has taken place. The CI explained that it had and they are still on an approval letter.
7. The Committee enquired about the use of eye masks to physically blind patients. The Ci explained that this was the standard procedure in the United States arm of the trial and that this may have been kept in for consistency of results.
8. The Committee asked about a 100 day screening period. The CI explained that there will be a 21 day screening period.

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 information sheet states that the study can be stopped for commercial reasons. The *Ethical Guidelines for Intervention Studies* *para 6.65* state that HDECS do not support the termination of studies for purely commercial reasons.
2. Please register the study on the clinical trials website, this is required by law in New Zealand.
3. 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*).
4. Provide details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies para 6.50).*

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

1. Please clarify if samples will be sent to Singapore or the United states for testing. Please amend the participant information sheet to clearly state where the samples are going.
2. The Committee asked if nanocrystals are part of the technology. The CI stated that yes, they are. Please include this in the information sheet.
3. The Committee noted that the participant information sheet mentions that samples will be sent to a central lab but not used for genetic testing. However genetic testing may occur. The CI explained that there will be no genetic testing in this study dlete, have already said earlier there was no genetic testing Please remove the references to genetic testing from the information sheet.
4. The Committee noted that the study is a randomised, double blind, placebo controlled trial. Those on the placebo will get less than standard care as they will be part of a group who do not get NSAIDs to avoid potential double ups of medications. The Committee also noted that the CI will not know who is on the placebo. Please include this as a risk in the participant information sheet in the ‘what does participation in this research involve’ section on page four.
5. Please place information about pregnancy and illegal drug use under their own headings in the information sheet.
6. Please remove the paragraph about agreeing to an approved HDEC auditor from the consent form.
7. Please address the inconsistent statements around the testing of urine for illegal drugs on pages three and eight. Please remove the section from page eight about these tests being used against participants in legal proceedings.

Decision

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

1. Evidence of SCOTT approval or other relevant evidence of independent review.
2. Evidence of data safety monitoring arrangements
3. Please make the required changes to the participant information sheet and consent forms

This following information will be reviewed, and a final decision made on the application, by Dr Charis Brown and Dr Karen Bartholomew

## General business

1. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 13 September 2016 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

The following members tendered apologies for this meeting.

* Dr Christine Crooks, Ms Shamim Chagani, and Ms Susan Buckland.

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 7:00pm