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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 28 January 2016 |
| **Meeting venue:** | Room G.04, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 15 December 2015 |
| 12.30pm | New applications (see over for details) |
| 12.30-12.55  12.55-1.20  1.20-1.45  1.45-2.10  2.10-2.35  2.35-3.00  3.00-3.25  3.25-3.50  3.50-4.15  4.15-4.40  4.40-5.05  5.05-5.30 | i 15/CEN/221  ii 15/CEN/250  iii 15/CEN/251  iv 15/CEN/252  v 15/CEN/254  vi 15/CEN/257  vii 15/CEN/259  viii 15/CEN/260  ix 15/CEN/262  x 15/CEN/263  xi 16/CEN/5  xii 16/CEN/9 |
|  |  |
| 5.30-5.55 | Review of approved studies (see over for details) |
|  | i 15/CEN/135 |
| 5.55pm | General business:   * Noting section of agenda |
| 6.00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 01/07/2015 | 01/07/2018 | Apologies |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Apologies |
| Dr Dean Quinn | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Cordelia Thomas | Lay (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Present |
| Dr Melissa Cragg | Non-lay (observational studies) | 01/07/2015 | 01/07/2018 | Apologies |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 01/07/2015 | 01/07/2018 | Present |
| Dr Nora Lynch | Non-lay (intervention studies) | 01/07/2015 | 01/07/2018 | Present |

Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Dr Patries Herst, Dr Melissa Cragg and Dr Angela Ballantyne.

The Chair noted that fewer than five appointed members of the Committee were present, and that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Dr Nora Lynch confirmed her eligibility, and was co-opted by the Chair as member 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 15 December 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/CEN/221** |
|  | Title: | Case description of Staphylococcus lugdunensis infections and susceptibility testing in Canterbury. |
|  | Principal Investigator: | Dr Jared Green |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 January 2016 |

Ms Joanne 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 the study

This study will use a large collection of bacteria kept to review for future generations or emerging infections. Staphylococcus Lugdunensis is gaining notoriety as something of interest as a pathogen and the research team would like to see what the clinical picture is. The lead investigator revised stored isolates and is simultaneously looking at health information from individuals clinical notes as part of the audit and the information can be linked to people originally infected.

The application before the committee today is for an audit in concert with the investigation of the bacterial isolates that will add generalisable knowledge about a health issue. The committee noted that for this observational research aspect of the study that the clinician is using health information without consent for a purpose other than which it was originally collected.

Summary of ethical issues (resolved)

* The committee asked the researcher whether it would be possible to contact the individuals to seek their consent to use their health information. The researcher explained the isolate collection goes back many years to 1999 and that contacting people would be a difficult task as the cases are long closed.
* The committee noted with reliance on ethical guidelines para 6.43 that access to identified or potentially identifiable data for research without the consent from the individuals that the data identifies or makes potentially identifiable may be justifiable when, among other things, it would be impossible in practice to get consent due to the quantity or age of the records and when the public interest in the study outweighs the public interest in privacy. The committee was satisfied given the age of the records that it would not be possible for the researchers to try to seek consent and that the public interest in the outcome of the study would be greater than the risk to privacy. The researcher explained to the committee the safeguards that will be maintained to protect confidentiality of individual’s information and that the study has the goal of advancing health.
* The committee asked whether this organism is associated with rare or idiosyncratic types of disease that when published might signify a rare event. The researcher confirmed that it is not and is associated with infections that might be seen with other forms of staphylococcus.
* The researcher confirmed that this study will not pose any extra risk to researchers or third parties.
* The committee asked whether the Canterbury Health Laboratories has a registered tissue bank. The researcher explained that they deposit tissue with the Otago Medical School, which has a registered tissue bank.

Decision

This application was *approved* by consensus.

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| **2** | **Ethics ref:** | **15/CEN/250** |
|  | Title: | Carboplatin / Paclitaxel +/- Veliparib in Epithelial Ovarian, Fallopian tube and Primary Peritoneal Cancer |
|  | Principal Investigator: | Dr. Robert Matthew Strother |
|  | Sponsor: | Abbvie |
|  | Clock Start Date: | 14 January 2016 |

Dr Strother and Mrs Anne Smith 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 committee asked the researchers to clarify use of ionising radiation in participants as the protocol indicated that participants may have a base line CT and question r.1.13 on page 18 of the application form states that the study will not involve the administration of ionising radiation that is not needed for participants’ normal clinical care. This frequency of radiological assessments differs from what is stated on page 5 of the participant information sheet. The committee asked whether participants in this study are likely to receive more ionising radiation than if they are not in the study. The researchers explained that they would not as patients have imaging done as part of standard of care and that the intervals that patients would receive imaging scans in this study were not over and above that of standard care.
* The committee noted that regarding the anticipated risks involved in this study that the researchers had stated in question r.8.1 on page 23 of the application form and again on page 9 of the participant information sheet that the doctor will monitor for side effects and if it is felt that they become not tolerable then they “may” cease administration of the study drug. The committee asked that the researchers replace the word “may” with “would”. The researchers added that the participants would be monitored and initially treated with a dose reduction for side effects. In the presence of any “significant” toxicity the clinical judgement would be made to stop administering the study drug. The committee asked that the researchers include information about the dose reduction as an option on page 9.
* The committee noted that the answer stated about a participant support person being there to “reinforce” the information presented to the participant in question p.3.2.1 (page 25), may not be the right word as the support person’s role was broader than this.
* For future reference the committee explained that the intent of question p.4.1 on page 26 of the application form is asking if the research addresses an important health issue for Mãori and if so how this study might benefit Mãori. Researchers can provide any known information/statistics about relative prevalence and prognosis in Mãori to the committee to help demonstrate their case and then how the study might benefit. Dr Strother noted that he had not seen any data saying ovarian cancer is more prevalent in Mãori women and that he did not know about prognosis, however. The committee reiterated that that kind of information is useful to include in question p.4.1 in future.
* A BRCA test is required for participation in this study. The committee asked what the usual practice for BRCA testing is. The researchers advised that it varies from location to location but generally if someone young or someone with suspicious symptoms presents then practice is to refer them for BRCA testing. People are referred to genetic counselling services and the same would occur in this study if a participant tests positive for the BRCA gene.

The committee requested the following changes to the participant information sheet and consent form:

* Page 3, under the title ‘Treatment Period’: Schedule #1 and Schedule #2 repeat the same information. The committee recommended that it would be simpler to say that for schedule #2 “participants receive the same treatment as in schedule #1 plus paclitaxel on days 8 and 15 of the 21 day cycle”.
* Page 8, please replace the word “subject/s” with “participant/s”.
* Page 8, eighth bullet point: please reword this statement to read that “You are the only one who can take the medication that has been allocated to you”.
* Page 9, under the title ‘What are the possible risks and benefits of taking part?’ The committee noted that the use of percentages can sometimes not read in a meaningful way. Please reword to clarify how frequent the risks and side effects are.
* Two optional sub-study participant information sheets and consent forms: please include a compensation clause in both sheets. – have a statement about compensation in both rather than refer to main PIS.
* Please remove reference to the support person only signing as a witness. NZ law prevents proxy consent for research.

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 Intervention Studies* *para 6.22*).

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

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| **3** | **Ethics ref:** | **15/CEN/251** |
|  | Title: | ThuLEP Treatment for Symptomatic Enlarged Prostates |
|  | Principal Investigator: | Assoc Prof Peter John Gilling |
|  | Sponsor: | Quanta Systems SPA |
|  | Clock Start Date: | 15 January 2016 |

Ms Rana Reuther 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 the study

This is an open-label study of 20 men over the age of 45 who need surgery for benign prostatic hyperplasia for prostate. A new laser device will be trialled, which is different from the gold standard treatment which may have more risks such as bleeding and clot retention. Primary outcome is bleeding after surgery and researchers will also measure prostate tissue and safety variables.

The reason that the lead investigator (as inventor of the laser technology and expert), is doing the trial is that he is open to different techniques and would like to look at whether there is a better and safer technology available.

Summary of ethical issues (resolved)

* The committee asked why there is not parallel cohort in this study and how the researchers will compare the treatment to be trialled against the gold standard. The researcher advised that they will use historical data and compare 20 men in this group with 20 men from two previous groups.
* The committee was concerned that the study will recruit people from a waiting list and possibly be offering the technique as an inducement to gain quick surgery. The committee asked how big the waiting list is currently. The researchers advised that it is three to six months. When patients are approached by doctors they will not be enticed with a set surgery date. When they have a group of men to operate on will they will set a date. The surgery date may turn out to be not too different from the standard waiting time. When screened they are on the standard waiting list so have opportunity to decide to have the surgery through the public system or as part of the research trial.
* The committee asked whether a study co-investigator will deliver the treatment. The researcher confirmed that while there are co-investigators that the lead investigator only will perform the operation for consistency.
* The researchers advised the committee that they intend to register the trial in a trial registry and are taking steps to do this.
* The committee asked whether QS has links to five industry boards that the lead investigator sits on and the researcher advised that it does not.
* IIEF questionnaire – the committee noted that a title may read better for participants than initials. The committee noted that the questions on this questionnaire are related to sexual function and are relevant. The committee noted however that the opening statement on the questionnaire may need adjustment as it is does not seem appropriate for elderly men having prostate surgery. The committee asked whether there is a way they might remove and include a different statement. This is a validated questionnaire that means something to urologists. The committee noted that the researchers might like to explain to participants that a standard questionnaire is being used but introduce it in a more appropriate way.
* The committee noted that the cover letter submitted with this application noted that the questionnaires may be reformatted. The researcher confirmed that this applied to formatting only and they were not anticipating changing the wording of these standardised questionnaires.
* The committee noted the answer given at question r.1.5 on page 14 of the application form and asked how often the independent group will be looking at data and what they will look at. The researcher confirmed that the data assessor will be a doctor in Milan whom QS has asked to review the data. The Monitoring plan is not yet finalised but it will be done by remote monitoring. The committee sought assurance that all adverse events will be sent and not just selected. The researcher confirmed that the protocol allows for this and that raw data will also be sent.
* The committee noted the answer stated at question r.2.1.1 on page 16 of the application form that the researcher will contact participants directly to discuss involvement in the study. The researcher clarified that they would not contact participants themselves in the first instance and that patients will be given the information by their clinician and given the opportunity to get in touch with the research team if they are interested or can request that a member of the research team contact them.
* For future reference the committee explained that the intent of question p.4.1 on page 23 of the application form is asking if the research addresses an important health issue for Mãori and if so how this study might benefit Mãori. Researchers can provide any known information/statistics about relative prevalence and prognosis in Mãori to the committee to help demonstrate their case and then how the study might benefit. If no information is available then researchers may comment on that. The committee noted the same for question f.1.2 on page 25 which asks the same question in regard to other population groups in New Zealand.
* The committee noted that the answer given at question p.4.2 on page 24 that an “inability to understand the PIS” may be a miswording as this is not a cultural issue for Maori.

Summary of ethical issues (outstanding)

* The committee requested peer review from an expert who is independent of the study team.
* The committee noted the insurance certificate provided from the parent company and was concerned that item 4 which limits coverage to: “damages caused to third parties by malfunction of the machines produced by Quanta System Spa”, seems to offer compensation that is not equivalent to ACC. The researcher advised that she did not notice this and advised that she will follow up with the company to confirm that compensation provided is ACC equivalent.

The committee requested the following changes to the participant information sheet and consent form

* Page 1: please reword the title in lay language.
* Page 1, under the title ‘Why are we doing the study?’: the explanation about why you are doing study did not outline how this treatment differs from the standard of care treatment. The researcher confirmed that there is no difference between technique used for this device and standard of care just the wavelength. Please reword this information to read from a participant’s point of view and note that you would like to see how the new wavelength works. The committee noted that the second paragraph on page 2 that begins: “The purpose of this research…”, might give useful information for this section.
* Page 3, the committee noted the sentence that reads: “You may be reimbursed for some of your travel costs associated with your clinic visit” and noted that travel costs should be both explicit and universal. Please change to state that participants will be reimbursed for their travel costs.
* Page 6, as this is a situation where participants may experience a bleed following surgery, please provide a 24 hour contact number for either Rana Reuther or Prof Gilling. It is not satisfactory to say only to call 111 in a medical emergency.
* Page 6, please provide a Mãori contact name and direct contact details.
* Page 7, statement: “I understand that there may be risks associated with the treatment in the event of myself or my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy”. The researcher confirmed that this was included in error and will remove this statement.

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 Intervention Studies* *para 6.22*).
* Please provide further evidence of scientific peer review of this study from an expert who is independent of this study (*Ethical Guidelines for Intervention Studies, Appendix 1*).
* Please confirm the level of compensation offered in this study is equivalent to at least that offered by the Accident Compensation Corporation. (*Ethical Guidelines for Intervention Studies* *paras 8.3-8.5*).

This information will be reviewed, and a final decision made on the application, by the Chair, Dr Nora Lynch and Dr Cordelia Thomas.

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| **4** | **Ethics ref:** | **15/CEN/252** |
|  | Title: | DHP2016 |
|  | Principal Investigator: | Dr Colin Thompson |
|  | Sponsor: |  |
|  | Clock Start Date: | 14 January 2016 |

Dr Colin Thompson 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 the study

* This study will compare two existing treatment options for diabetic patients. Both treatments are acceptable but it is not known which one is best.

Summary of ethical issues (resolved)

* The committee discussed whether this study needs ethical approval given that there is no change in intervention and the data is collected anyway. The researcher stated that they had received advice that because this is an interventional study then this requires ethical approval.
* The committee asked whether the researchers were intending to exclude Mãori from the study as they had stated at question p.4.2 on page 18 of the application form that there were no cultural issues for Mãori and at question p.4.3 that no formal consultation with Mãori is required. The researchers noted that this may have been in error as they have consulted with Counties Manukau research group. The committee noted for future reference that cultural issues for Mãori include the taking of tissue (blood).
* For future reference the committee explained that the intent of question p.4.1 on page 18 of the application form is asking if the research addresses an important health issue for Mãori and if so how this study might benefit Mãori. Researchers can provide any known information/statistics about relative prevalence and prognosis in Mãori to the committee to help demonstrate their case and then how the study might benefit. If no information is available then researchers may comment on that. The committee noted the same for question f.1.2 on page 19 which asks the same question in regard to other population groups in New Zealand.
* The committee noted that the protocol looks complicated and that it was helpful to see that John Baker’s peer review of the science of this study. The committee asked whether the researchers have discussed the protocol; with other colleagues on the ward, to see how workable or safe the protocol is. The researcher confirmed that the protocol has been discussed by all diabetes physicians at the hospital.

Summary of ethical issues (outstanding)

* The committee asked why the researchers did not intend to seek consent form participants bearing in mind that at week 7 they have enrolled patients. The researchers noted that they can get consent but wondered whether they need to as both treatments are received as standard of care. The committee noted that as participants may be exposed to an extra infusion by taking part in this study, that the researchers are comparing two different treatments, they will be asking staff to participate and that they will be using data to inform research outcomes that it would expect consent to be sought. In this case from staff and from patients.
* The committee agreed to decline the application to allow the research team to submit the application with participant information sheets and consent forms for both staff and patients and invited the research team to resubmit the application for review from this committee.

Decision

This application was *declined* by vote, with 5 for and 1 against, and Dr Dean Quinn dissenting, as the Committee did not consider that the study would meet the following ethical standards:

* The requirement for informed consent. (*Ethical Guidelines for Intervention Studies* *paras 6.8 and 6.22*) and (Health and Disability Commissioner Code of Rights, Right 6, Right to be fully informed).

The committee agreed to decline the application to allow the research team to submit the application with participant information sheets and consent forms for both staff and patients and invited the research team to resubmit the application for review from this committee.

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| **5** | **Ethics ref:** | **15/CEN/254** |
|  | Title: | EEG/fMRI SEDATION STUDY |
|  | Principal Investigator: | Dr Suresh Muthukumaraswamy |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 14 January 2016 |

Dr Suresh Muthukamaraswamy 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 the study

This study will test a new brand of technology that can simultaneously record EEF/fMRI, which are two of the principal techniques currently used to measure human brain function and are currently performed separately. This study will conduct the measures using each of two commonly used anaesthetic drugs, ketamine and midazolam in healthy volunteers to see whether combining the two measurement techniques gives more information than performing the two separately.

Summary of ethical issues (resolved)

* For future reference the committee explained that the intent of question p.4.1 in the application form is asking if the research addresses an important health issue for Mãori and if so how this study might benefit Mãori. Researchers can provide any known information/statistics about relative prevalence and prognosis in Mãori to the committee to help demonstrate their case and then how the study might benefit. If no information is available then researchers may comment on that. The committee noted the same for question f.1.2 which asks the same question in regard to other population groups in New Zealand.
* The researcher explained to the committee that the evidence of consultation with Helen Wihongi at Waitemata and Auckland DHB for a previous trial in patients with treatment resistant depression presented the same and other cultural factors. He confirmed that consultation with Mãori is on an ongoing basis.

The committee requested the following changes to the participant information sheet and consent form

* The committee complimented the researchers of clear and well-written participant information sheets and consent forms. The committee also noted that the pictures included were helpful.
* The committee requested that the researchers proof read the documents for completeness as there were a few missing words.
* Page 1, third bullet point that states: “If you take part in this study you will receive both drugs and a placebo on separate days…” doesn’t belong under that heading. Please include in on page 2 under the title ‘What will my participation in the study involve.
* Page 3: the committee queried whether the researchers might interpret and mention the possible more severe side effects. The researchers noted that this is a balancing act as they don’t want to worry people unnecessarily. They noted that more serious side effect are extremely unlikely and that they don’t want people to worry.
* The committee noted that page 2 states that the researchers will collect urine samples and page 5 states blood and saliva. The committee asked that the researchers clarify which tests will be done as the participants need to know what samples will be collected and what will happen to them.
* Page 4, paragraph 2, under the title ‘Who pays for the study?’: Please remove reference to the completion bonus and reword the task bonus information so that it is clearer for participants the amount of money they may receive.
* The committee noted that the researchers had identified in the application form that the taking of blood samples and genetic information is a cultural issue for some Mãori. DNA marker testing in blood samples this is part of the procedure. Please explain that the DNA marker testing in blood samples is part of the procedure and also what will happen to the samples.
* The committee noted minor variance between what is stated in the protocol and the participant information sheet. The protocol states participants will receive a medical examination at the beginning of the study. The participant information sheet does not mention this. The researcher confirmed that the medical examination will include testing of heart rate, blood pressure and then some questions. Please let participants know that they can expect some limited medical examinations.
* Consent form – please include yes/no boxes only for statements that are truly optional, that is, that a person could still participate if they answer ‘no’.

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 Intervention Studies* *para 6.22*).

This following information will be reviewed, and a final decision made on the application, by Mrs Sandy Gill and Dr Peter Gallagher.

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| **6** | **Ethics ref:** | **15/CEN/257** |
|  | Title: | GED-0301-CD-004 |
|  | Principal Investigator: | Dr James Brooker |
|  | Sponsor: | Celgene Pty Ltd |
|  | Clock Start Date: | 14 January 2016 |

Dr James Brooker was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

* The committee had no major ethical concerns about this study but noted that some questions in the application form have been casually completed.
* The committee noted the answer stated at question r.2.1.1 on page 18 of the application form that participants’ medical records will be treated as confidentially as possible and noted that this statement could have been explained in more depth.
* The committee noted that the researchers had not answered the question at r.2.5 on page 19 of the application form, which sets out the requirement that some health information must be retained for a period of 10 years and asks how long the researchers will store information generated in their study for.
* For future reference the committee explained that the intent of question p.4.1 in the application form is asking if the research addresses an important health issue for Mãori and if so how this study might benefit Mãori. Researchers can provide any known information/statistics about relative prevalence and prognosis in Mãori to the committee to help demonstrate their case and then how the study might benefit. If no information is available then researchers may comment on that. The committee noted the same for question f.1.2 which asks the same question in regard to other population groups in New Zealand.
* Question r.3.11 on page 21 of the application form states that samples will be disposed at the end of the study or if participants withdraw consent for its use in this study and the participant information sheet (page 7) states that samples will be destroyed five years after the end of the study. The answer stated at question r.3.12 on page 21 does imply that samples will be kept for five years at the end of the trial. Page 7 of the participant information sheet states that samples taken in this study will only be used for testing for this study but that should additional testing be required then further consent to do this will be requested. The committee queried whether the researchers intend to do any unrelated research or search for purposes of this study. The samples will be tested for the purposes of this research study only.

Decision

This application was *approved* by consensus.

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| **7** | **Ethics ref:** | **15/CEN/259** |
|  | Title: | EXTEND-IA TNK |
|  | Principal Investigator: | Professor Alan Barber |
|  | Sponsor: | The Florey Institute of Neuroscience and Mental He |
|  | Clock Start Date: | 14 January 2016 |

Prof Alan Barber 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.

Dr Cordelia Thomas declared a potential conflict of interest, and the Committee decided that Dr Thomas would leave the room and would not take part in the discussion or decision making for this application.

Summary of ethical issues (outstanding)

* The committee noted that the immediate ethical issue is that in patients with cognitive deficit that they won’t be able to provide informed consent. This is an issue for all stroke studies where big arteries entering brain from the neck are blocked. 1/3 can give informed consent but others will not. The unit currently treats 12-15 percent with Alteplase.
* The committee noted that New Zealand law draws a distinction between routine clinical care and research and prohibits proxy consent for research (Code of Rights 7(4)). In the presence of a proven alternative treatment that makes it difficult for the committee to give ethical approval where patients can’t consent for themselves.
* The committee noted that this may be different if there was no other alternative treatment and the researchers could argue that it was a life-saving treatment and that it could be seen to be in the “best interests” of the individual. Based on evidence of earlier studies submitted with this application there is evidence to show only potential best interests of an individual. It may be difficult to mount a strong argument, based on a single study in 75 patients that overrides Right 7(4) of the code of rights.
* The researchers noted that in this study clot retrieval aside, the way that they will administer Alteplase and Tenecteplase is exactly the same as that described in the New England Journal article. Confirmatory study of the NE journal study.
* The committee explained that the researchers can do the same study on people that can give consent then they would be able to go ahead. If the research team can do this study in consenting patients and then do the next step in non-consenting patients based on evidence/findings of this study that could be an option.
* The researchers argued that they see the philosophical issue that withholding research in this group of stroke patients who are not able to consent and of whom, 50% end up severely disabled or dead, is unethical. They asked whether the committee might accept a case mounting further evidence from an independent person that 1): this research is in the best interests of the consumer and, 2): this is a vulnerable group of patients who should not be denied the opportunity to be in this research.
* The researchers confirmed that this study has been ethically approved in Australia in a different jurisdiction. 150 patients will be enrolled in Australia.
* The researcher argued that to enrol consenting patients only might skew the results and if so this would be unethical. The committee noted that the NZ contribution proportionally is small (10 participants) and the researchers could still comply with the protocol. Australia is also well a represented population when combined.
* The committee noted the findings of a 2013 Health and Disability Commissioner report, that found that in a case of CVA management, Tenecteplase was confused with Alteplase and was administered at an incorrect dose. The committee noted that the deliverers of the dose don’t always administer it correctly and that they need to be well trained and reminded. Prof Barber will be the only clinician administering the study drugs and reassured the committee that in the emergency department he will be enrolling people and administering the treatment. It was noted that incorrect administering of dose rate may be more of a risk in rural areas with house surgeons.
* The committee agreed to provisionally approve the application to allow the research team to gather up some more evidence that this research is unequivocally in the best interests of each participant. Prof Barber stated that neurology opinion is not divided on this matter and he could get their views. Many medical people are not aware of non-consenting law in terms of treatment and research.

Decision

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

* Views from other clinicians about evidence for experimental treatment being in the ‘best interests’ of each individual participant. *(Code of Health and Disability Services Consumers’ Rights Regulation 1996, Right 7(4))*

This following information will be reviewed, and a final decision made on the application, by the Chair and Dr Nora Lynch.

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| **8** | **Ethics ref:** | **15/CEN/260** |
|  | Title: | Incisional antibiotic prophylaxis in skin cancer surgery |
|  | Principal Investigator: | Mr Jonathan Mathy |
|  | Sponsor: | Counties Manukau DHB |
|  | Clock Start Date: | 14 January 2016 |

Dr Jon Mathy was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

* For future reference the committee explained that the intent of question p.4.1 in the application form is asking if the research addresses an important health issue for Mãori and if so how this study might benefit Mãori. Researchers can provide any known information/statistics about relative prevalence and prognosis in Mãori to the committee to help demonstrate their case and then how the study might benefit. If no information is available then researchers may comment on that. The committee noted the same for question f.1.2 which asks the same question in regard to other population groups in New Zealand. Question p.4.2 asks researchers to identify any cultural issues and the committee noted that the taking of tissue, in this case blood, is a cultural issue for some Mãori regardless of whether or not the tissue will be sent overseas. Whakama may be another issue.
* The committee noted that any research in NZ that involves Mãori requires consultation with a local Mãori consultation research group.
* The committee noted the answer given at question p.3.2.1 on page 20 of the application form in relation to proxy consent for a participant with an EPOA. The committee explained that NZ law prevents proxy consent for adults in experimental research and that the researcher can only include participants in this study who can make an informed decision to be in this study and sign a written consent form. Based on HDC code right 7(4).
* Confounding factors – included in measure as want to show equally represented across both groups. Did include with power analysis. Also collecting data on features with dedicated statistics to determine whether there are additional factors that might impact on the outcome.

The committee requested the following changes to the participant information sheet and consent form

* The researcher confirmed that the submission of documents with tracked changes was in error and that the committee was supposed to get a clean/final copy.
* Page 2, section 6 What will happen during the study?: please replace the word “histology” with another expression. For example – tissue reviewed under the microscope.
* Page 2, section 6 What will happen during the study?: the information about staff removing sutures and saving a trip to the GP is repeated. Please remove the repeated statement.
* Page 2, section 7 ‘What are the benefits of being in the study?’: please reword the statement that there will be no obvious benefit to participants as the study is double-blinded as it is confusing.
* Page 3, section 12 Will you be informed about the results of the study?: the committee asked what is meant by the statement “You will not receive any individual results”. The researcher explained that they expect results to be applicable to the way skin cancer treatment is delivered nationally and internationally. They expect some publicity surrounding the results and at minimum they may manifest as publication in clinical journals and will be more publicly available in public press. It is important that for people who request such information that it is available and the researchers can help them find it. The committee recommended that on the consent form it may be best to ask people whether they want a copy of publically available information, give the details of the lead investigator and invite people to contact him.
* Page 3, section 11 Will your participation be confidential?: it will also be useful to know whether a person has allergies to antibiotics. While every patient gets screened prior, the committee suggested the need to name the antibiotics so that the patient can let the clinician know in the absence of records
* The topical use of antibiotics in the intervention arm has a unique risk of allergy as all individuals outside of the study would not necessarily receive an antibiotic intervention. Please clearly outline what the risk is and who they can seek help should this adverse reaction happen on Page 2, ‘Benefits, Risks and Safety.

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 Intervention Studies* *para 6.22*).

This information will be reviewed, and a final decision made on the application, by Mrs Sandy Gill and Dr Peter Gallagher.

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| **9** | **Ethics ref:** | **15/CEN/262** |
|  | Title: | The REDUCE FMR Trial |
|  | Principal Investigator: | Dr Peter Ruygrok |
|  | Sponsor: | Cardiac Dimensions, Inc. |
|  | Clock Start Date: | 14 January 2016 |

Mrs Jan Burd was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

* The committee noted that patients will have a femoral angiography and then may or may not get the device inserted via jugular venous access. They asked whether the control (non-insertion) procedure was shorter. The researchers confirmed that this is the case and that trying to explain this in lays terms was challenging. The researchers noted that they never rely solely on the information sheet and also sit down and talk through the sheet with the patient. The sheet won’t stand alone in this case and part of the consenting process is to have documented verbal consent and enable the researchers to assess understanding face to face.

Summary of ethical issues (outstanding)

* The peer review submitted with this application is from an expert who works in the same department as the researcher. The researcher believes the review is sufficiently independent in that the reviewer doesn’t have any involvement in the study. The committee advised that it would still like to see an extra peer review from someone not associated with the researchers who can comment on the control group and procedures that they are undergoing.

The committee requested the following changes to the participant information sheet and consent form

* The committee noted that the participant information sheets are both comprehensive and complicated to read while acknowledging that it is a fine line to walk. The committee noted that it could understand a fair part of the language but that it is still a complicated document.
* Page 9, second paragraph: the committee asked whether patients will be able to change their mind about consenting in the study after the device is inserted as Page 1 points out that the study device is not designed to be removed. The researchers stated that this notice will allow the researchers to discuss any health risk associated with withdrawal from the study. They will receive follow up if they do withdraw. Please state on both page 1 and page 9 that if participants decide to withdraw from the study that they will still have the device implanted.
* Page 10: please change approval to being from the Central Ethics committee.
* In 12 months’ time, those without device may then re-join the study and have device inserted if they wish provided they meet all criteria. Patients are aware that they may be in control group. The committee asked how a participant would not know that they had device inserted. The researchers noted that this will be challenging but the likelihood is that procedures involve echo guidance which requires sedation. When sedation is not required participants will have earplugs or music and not hear conversations. The committee questioned the ethics of doing invasive procedures to control/placebo group. Not finally decided whether control group will have trans thoracic guidance which is not invasive to reduce. The data gained of measuring pressures in the heart will still be relevant. Information gained is relevant to all whether the device is implanted or not and will be used to manage treatment.
* Femoral artery puncture to look at pressure except small number of people so some will get a gratuitous puncture. Venous everyone will get a jugular catheter. Measuring pressure how important? If not in trial pleased to have data or just to do invasive thing to controls. That needs to come from the clinician. Whichever way the answer goes doesn’t preclude study but need more information on page 6 as this doesn’t thoroughly cover the issue. One or two vascular procedures helpful to you or don’t need to be done.
* The committee queried whether the compensation information stated in the second paragraph on page 11 of the information sheet is equivalent to at least the level offered by ACC. This is referring to injury that would be covered by the doctor’s indemnity. The researchers stated that they would never require a person to take civil action against the doctors. Please include information that indicates that you have a research office that helps with this process as the civil action statement is stark.

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 Intervention Studies* *para 6.22*).
* Please provide further evidence of scientific peer review of this study from an expert who is independent of this study (*Ethical Guidelines for Intervention Studies, Appendix 1*).

This information will be reviewed, and a final decision made on the application, by Dr Peter Gallagher and Dr Cordelia Thomas.

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| **10** | **Ethics ref:** | **15/CEN/263** |
|  | Title: | TREAT Trial |
|  | Principal Investigator: | Professor Harvey White |
|  | Sponsor: | Research Institute –HCor (Heart Hospital-Hospital |
|  | Clock Start Date: | 14 January 2016 |

Ms Caroline Alsweiler was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

* The committee noted the answer given at question a.6.3.1 on page 10 of the application form stated that ethics approval has already been given. The researcher confirmed that this is a typo.
* The committee noted that the consent must be sought from the participant themselves and that under New Zealand law a legal representative cannot consent to research on their behalf.
* The committee was satisfied that the peer review submitted with this application is from an independent source.

Summary of ethical issues (outstanding)

* Please provide participants with an emergency contact card provided by the study site that has study doctor contact details.

The committee requested the following changes to the participant information sheet and consent form

* Please proof read the document and change the word “subjects” to “participants”.
* In NZ by the sponsor – please clarify who the sponsor is for participants
* Page 3, please include information about the amount of time involved for participation and also what parts of this study are different from standard of care treatment.
* Please indicate the volume of blood being taken for study related procedures rather than standard care should a sample be needed.
* Please include the following compensation clause:
  + *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.   
      
    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.*
* The committee noted that there is no requirement under the Code of Health and Disability Services Consumers’ Rights for people to withdraw from research in writing and the research team cannot rely on the form to be effective withdrawal. Please note on the form that participants can either tell the team or sign the form. Whichever they prefer.
* The committee noted that there is a lack of emphasis on the risk of bleeding given that the participants are on thrombolytic medication and bleeding is a potential side effect. (Page 2, ‘What are the possible risks of participating in this study?’).

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 Intervention Studies* *para 6.22*).
* Please submit a copy of the patient emergency card. (*Ethical Guidelines for Intervention Studies* *para 6.66*).

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

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| **11** | **Ethics ref:** | **16/CEN/5** |
|  | Title: | Interactive Devices and Games for Stroke Recovery |
|  | Principal Investigator: | Dr Brian Robinson |
|  | Sponsor: | Victoria University of Wellington |
|  | Clock Start Date: | 14 January 2016 |

Dr Brian Robinson 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 Peter Gallagher declared a potential conflict of interest, and the Committee decided that he would leave the room and would not take part in the discussion or decision-making for this application.

Summary of the study

This study is a joint collaboration between the Victoria University of Wellington School of Design and the Victoria University Graduate School of Nursing, Midwifery and Health and senior physiotherapists at AUT University in Auckland. It is a ‘usability’ study which will aim to test two things: software and computer controllers in stroke patients as potentially useful rehabilitation aids.

The research team is seeking ethical approval for 4-5 design projects every 3 year for 3 years so for 12-15 projects and around 100 participants. There is not one particular piece of software but students will build on previous students’ work so the software and physical controllers may vary over the three years.

The researchers intend to test in the participant’s home. A design student will explain the device and watch the participant use the device and record the participant using the device with a sensor and photograph/videos and secondly interview the participant and record data.

Summary of ethical issues (resolved)

* The committee asked what 3-4 projects are lined up for this year. Dr Robinson explained that one project involved students developing games guiding an astronaut around a screen that would inform other projects. The overall aim is to create a blanket application to cover these students. Dr Robinson explained that the same game will always be used but a different style of mouse will be tested. The games will be made progressively more difficult to help enhance movement. This game “level 1” will be tested to see whether stroke patients can use the device. The idea is to use upper limb movement to stimulate neural plasticity and students will create a portfolio of games with these devices.
* Supporting design students with stroke patients who are community dwelling. The committee queried whether the design students might need support. Dr Robinson advised that the students will be in their 20s. The students do not have a health background and a physiotherapist will support them in dealing with health issues ethically. Structure set up where both students and people in the community have protocols in place. Focussing purely on upper limb.
* The committee asked whether the participants in this study will have a degree of cognitive impairment and if so how will the research team assess this. Dr Robinson advised that they are anticipating that patients who are unimpaired are the ones who will make contact with the researchers. There is currently no formal screening process and the researchers were not intending to recruit through clinicians.
* The committee asked to see the wording that will be used for the recruitment flyers.
* The committee noted the answer stated at question p.4.3 on page 22 of the application form that consultation with Mãori is not required. The committee reminded the researchers that formal consultation is required MC formal consultation with Mãori is required for all research in New Zealand that involves Mãori. Dr Robinson thought that the answer may have been stated in error and noted for the committee that they had consulted with Professor Rawina Tumaki, Head of the School of Mãori studies regarding the cultural issues of this research programme who had offered useful feedback for the research team. Please provide the name and contact details of a Mãori support person who participants can contact. The committee noted that ‘Whakama’ is a cultural issue for some Mãori and that protocols for behaving in people’s homes need to be observed.
* The committee noted that it is difficult for them to give a blanket approval for the ongoing updates to the software and controllers when they don’t know what they will be. With this in mind the committee agreed to approve the current study protocol but requested that the research team submit each update as a substantial amendment via Online Forms for this committee to consider. Please include updated participant information sheets with each amendment and include updated version numbers and dates on the updated documents.

The committee requested the following changes to the participant information sheet and consent forms:

* Page 2, ‘What will my participation in the study involve?’: The committee noted the statement that the session should take no more than 30 minutes and was concerned that this might set the expectation that participants would have to make this time. In participants who have experienced a severe stroke 30 minutes may be too long to concentrate.
* Page 2, ‘What are the possible benefits and risks of this study?’: the committee noted that the information provided here appeared to be a contradictory and could be confusing for participants. On the one hand it stated that people should do rehabilitation for several hours a day and on the other hand the researchers intend to take the devices away after the session. Dr Robinson confirmed that they are not wanting to use the device as a therapeutic device at this stage but to find out whether it might be useable as a therapeutic device. Please make this clear to participants.
* The committee noted that the research team intend to take and use images but this is not clearly spelt out in the participant information sheet and consent forms. The committee advised that if the researchers are going to use images then they need to tell people clearly and they need to seek consent for that as well.
* The committee asked how the researchers intend to make sure that any photos taken are unidentifiable. Dr Robinson explained that they will use a standard technique of blurring facial images and images of participant’s houses will not be used. Please make this clear to participants.
* The committee asked what kind of device the researchers intend to use to record the images and noted that there are issues of confidentiality associated with recording. Dr Robinson advised that Victoria University of Wellington School of Design cameras will be used and the images taken will be deleted from the cameras. The committee asked that this information be included in the participant information sheet.
* Please submit the wording that will be used for the recruitment flyers.
* Please provide the name and contact details of a Mãori support person who participants can contact.
* Please make clear to participants what will happen in this study – for example, that that students will come to their home and please make clear arrangements for the safety of students. For example that they don’t travel to the house alone and that they take cell phones with them.
* Consent form: please only include yes/no boxes for statements that are truly optional (i.e that a person could still participate if they answer ‘no’).
* Please provide a 24 hour contact number for the lead investigator and for the supervisor for this study. While you are not studying participants with acute problems, students will be going to participants’ homes in the evening and the requirements are that there is a 24 hour contact 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 Intervention Studies* *para 6.22*).

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Dr Cordelia Thomas.

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| **12** | **Ethics ref:** | **16/CEN/9** |
|  | Title: | Effects of maternal pre-eclampsia on offspring metabolism |
|  | Principal Investigator: | Prof Wayne Cutfield |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 14 January 2016 |

Prof Wayne Cutfield, Dr Sarah Goffin and Dr Jose Derraik 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 the study

This is an observational study looking whether there are any long term effects on children of born to mums who had pre-eclampsia. The researchers are interested to know whether pre-eclampsia affects metabolism in childhood and increases the risk of obesity and diabetes in later life.

Summary of ethical issues (resolved)

* Dr Phil Baker will be the point of contact and will initially make contact with mothers of children. The participants are not in the researchers’ hospital care. Once the children are studied their GPs will be informed of the results and how they’ve been interpreted. This is in line with the ethical guideline for Observational studies (para 6.6).
* The committee noted that dealing with head and taking hair samples is tapu for some Mãori and this may be a cultural issue that the researchers encounter. A suggestion was made that the researchers could ask participants to brush their hair and take samples from the hairbrush.
* The committee recommended that the research team rethink asking participants to put the faecal sample in the fridge. Putting the sample in the fridge alongside food could be a cultural issue for some Mãori.

The committee requested the following changes to the participant information sheet and consent forms:

* Page 1, ‘What will my child’s participation in the study involve?’, first bullet point: the requirement to complete the 15 minute questionnaire at home before coming to the visit implies that participants are signing consent before being fully informed. Please reword this statement.
* Page 2, first sentence: please replace the word “it” with “arm” so that it is clear that the child’s arm is wrapped in plastic wrap.
* Page 3, ‘What are the possible benefits and risks of this study?’: Please rewrite the information about feeling anxious even after receiving the cream in a way that won’t make participants feel anxious. For example, having the blood test might hurt a bit.
* The committee noted the exclusion criteria of children in early puberty and asked that if clinicians intend to examine children to determine this point this needs to be included in the participant information sheet.
* The committee asked why the researchers are asking for the parent’s heights and weight in this study for children. The researchers explained that they wanted to look at whether a child’s size is reflective of parents size because influential on a child. The committee noted that taking the parent’s height and weight makes the parent a participant which means that the researchers would need to seek consent from the parent. The committee suggested that the researchers could include this information and seek consent on the parental information sheet and consent form.
* The committee noted the answer given at question r.3.11 on page 18 of the application form that if at the completion of the study participants and their families advise that they wish to have their tissue samples returned to them, then this will be done. Please clearly state this in the participant information sheet and consent forms.
* The committee noted that the researchers may possibly encounter literacy issues depending on area people are from and advised that the researchers check that they can read in a sensitive way. For example, they could ask whether participants would like the researchers to take them through the documents.
* The committee noted that participant information sheet and consent for those who haven’t had pre-eclampsia was not submitted and asked the researchers to provide one.
* Consent Form: please include yes/no boxes only if the statement is truly optional (i.e – that a person could still participate if they answer no).
* The committee noted the answer stated at question p.3.1 on page 22 of the application form that through each pre-eclampsia participant recruited, a friend or relative born from normal pregnancies (of the same age and sex), will also be recruited as controls. Please let participants know that this is how you intend to recruit the control group in the participant information sheet.
* The committee noted the answer stated at question p.3.3.1 on page 23 of the application form that the cost for the trips to the Liggins Institute will be covered with petrol vouchers and free parking will be available. The committee thought that this might cut out people who are less well-off and don’t have access to car and that the researchers may wish to provide costs of a train ticket or taxi ride. The researchers noted that they do this.
* Page 3: Please either delete the statement that “there are no risks for children participating in this study” or include that there is small/minimal risk.
* Child assent form: ‘What happens if I do it?’, first bullet point: please state that mum or dad will put some cream on your arm.
* Child assent form: please modify the use of the word “help” as it is emotive and participants may feel obliged when given this word.

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 Intervention Studies* *para 6.22*).

This information will be reviewed, and a final decision made on the application, by the Chair and Dr Nora Lynch.

## 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:** | 23 February 2016, 12:00 PM |
| **Meeting venue:** | Room G.04, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington, 6011 |

The following members tendered apologies for this meeting.

No members tendered apologies.

The meeting closed at 5.55pm