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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 16 September 2014 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Avenue, Christchurch |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 19 August 2014 |
|  | New applications (see over for details) |
|  | i 14/STH/119  ii 14/STH/128  iii 14/STH/129  iv 14/STH/131  v 14/STH/132 |
| 3.00pm | General business:   * Noting section of agenda |
| 3.15pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Raewyn Idoine | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Angelika Frank-Alexander | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Sarah Gunningham | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Nicola Swain | Non-lay (observational studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Mathew Zacharias | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Dr Devonie Waaka | Non-lay (intervention studies) | 01/07/2013 | 01/07/2016 | Present |
| Dr Fiona McCrimmon | lay (the law) | 01/09/2014 | 01/09/2015 | Present |
| Associate Professor Mira Harrison-Woolrych | Non-lay (observational and intervention studies) | 01/09/2014 | 01/09/2015 | Present |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

The Committee welcomed the new members Dr Mira Harrison-Woolrych and Associate Professor Fiona McCrimmon. The members introduced themselves.

## Confirmation of previous minutes

The minutes of the meeting of 19 August 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/STH/119** |
|  | Title: | NEROMODULATION AS A TREATMENT FOR ALCOHOL ADDICTION |
|  | Principal Investigator: | Professor Dirk De Ridder |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 September 2014 |

Professor Dirk De Ridder and Mr Patrick Manning were present by teleconference for discussion of this application.

Potential conflicts of interest

Dr Nicola Swain declared a potential conflict of interest. The Committee discussed the conflict and decided it was appropriate for Dr Swain to participate in discussion of the application and the decision.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

* This is a feasibility study.
* The study involves an electrode device (neurostimulator) that is implanted on the surface of the brain (requiring a craniotomy procedure). The signals from the electrode are hypothesized to reduce cravings to drink alcohol.
* The Researchers confirmed the study procedure had occurred in one human, two years ago.
* The Researchers explained that there is a very recent publication where the target of the brain was the same, though the treatment goal was to suppress pain, and involved a different technique to place the electrodes (wires through the brain, rather than placing on top of the brain).
* The Researchers confirmed the operative risk is fairly low, adding this is because the study procedure does not go through the brain; rather it goes along the midline. The electrodes go on the surface of the brain which decreases the risk of haemorrhage. This also reduces risk of infection. The Researchers added there is still a small risk of haemorrhage: this is approximately 1-2%.
* The Committee asked about the risk of infection. The Researcher explained that because the whole system is implanted is all at once, it reduces the risk of infection – it is not zero but it is decreased.
* The Researchers confirmed the pacemaker is placed either in the abdomen or the buttocks, where ever the participant prefers. The wire is tunnelled from the back of the head, down to the pacemaker, subcutaneously.
* This technique is the same as brain implants which treat Parkinson’s disease, but it is a different target area in the brain.
* The Committee asked the researchers to clarify the composition and operating procedures of the data safety monitoring committee (DSMC). The Researchers explained that the DSMC will be independent, but the composition was not finalised. The Researchers explained that a co-investigator, Professor Glue, has expertise in DSMC.
* The Committee stated that the composition and operating guidelines of the DSMC will need to be submitted to HDEC before the study commences.
* The Researchers confirmed they will submit any SAE occurring during the study to MEDSAFE, through the voluntary reporting mechanism at <http://www.medsafe.govt.nz/regulatory/devicesnew/9adverseevent.asp>
* The Committee requested a separate PIS/CF for the genetic sample analysis. The Researchers acknowledged this was required.
* The Committee noted this PIS will need specific information on how the tissue will be stored, as well as outlining cultural considerations for tissue use, storage and genetic testing.
* The Committee suggested that information for the support person mentioned should be submitted, as this is a requirement to participate in the study. Please also request contact information for the support person. The Researchers agreed this was a good idea.
* Please outline, in a cover letter, what will happen with the genetic sampling, where it goes and how long it is stored for.
* The Committee asked what process is in place if a participant withdraws from the study, and what will happen for the implant? The Researchers stated that if a request to remove the implant is received in a clinical context they will advise that there is a surgical risk related to removing the implant, compared with little risk leaving it in. Furthermore if it is left in, then if in future a new stimulation design is discovered or created then the participant may have access to this without additional surgery. The Committee requested the Researchers include more information about this. The PIS is currently lacking in content with regard to withdrawing from the study and regarding future applications of the implanted device.
* The Committee queried what the Researchers response was to the peer review statement on timeframes, suggesting extending the study duration to include a 1 year follow up, rather than 12 weeks. The Researcher confirmed they think this is a good idea and will submit a protocol amendment after initial approval is received.
* The Committee discussed the inclusion criteria.
* The Committee suggested simplifying the terminology in the introduction of the PIS, but noted this was not a requirement.
* The Committee queried if recruitment would be feasible. The Researchers explained that they were aware of a few potential participants, but noted that it would be an on-going process (2 years), adding that they want to be very careful about who they recruit.
* The Committee queried if it was safe to leave the device in indefinitely, noting the wording on the PIS indicated that it was ‘perfectly’ (implying 100%) safe. The Researchers explained that it depended on ‘what you considered long term’, adding there is evidence of implanted devices being safe, but not this particular place in the brain combined with this procedure. There is currently insufficient evidence to state that the device is perfectly safe in long term use. The Committee suggested rewording the PIS to reflect this – perhaps state that there is limited information on this technique for this condition. Currently is misleading; implying it is well known to be safe.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please include lay title, page numbers and remove interpreter box, instead have a sentence saying that interpreters may be available on request.
* Include information on withdrawing and options available for device removal and or future applications or uses of device.
* Add area for support person to sign on existing PIS.
* For optional genetic samples PIS: include information on use, storage, cultural issues and explain what testing will occur.

Decision

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

* Provide details of the Data Safety Monitoring Committee’s composition and monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*
* Please provide a separate OPTIONAL Participant Information Sheet and Consent Form for the use of tissue for genetic testing (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This following information will be reviewed, and a final decision made on the application, by Ms Raewyn Idoine and Dr Sarah Gunningham.

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| **2** | **Ethics ref:** | **14/STH/128** |
|  | Title: | Human papilloma virus (HPV) associated oropharyngeal cell carcinoma (OPSCC): Case prevalence, diagnosis, and the potential for screening in New Zealand |
|  | Principal Investigator: | Ms Rebecca Lucas-Roxburgh |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 September 2014 |

Ms Rebecca Lucas-Roxburgh and Ms Laryssa Howe 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

The main ethical issues considered by the Committee were as follows.

* The Committee noted that use of tissue without consent was the main issue.
* Ms Lucas-Roxburgh explained their study is looking at HPV in relation to OPSCC, to estimate the New Zealand prevalence, with the aim of guiding future research.
* The Committee noted the reasons given for not seeking consent were the potential difficulty of knowing correct contact information (for some cases it may be 18 years since the OPSCC biopsy was taken) as well as the likelihood that some participants will have died during this period.
* The Researchers were asked to explain the mortality rate in this group of patients, for example what is the 5 year survival? The Researchers explained it is different for HPV positive or negative participants, which we don’t know as this was not tested for at the time. The Researcher cited that in general about 30-50% patients survive for 5 years.
* The Committee queried where this 30-50% figure came from. The researchers could not provide a specific source. The Committee was concerned that the survival rate was not correct.
* The Researchers clarified that this patient population generally had late onset OPSCC, which affected survival rates. The Committee felt that this may justify not seeking consent for the older samples, but queried whether it was justifiable to not seek consent for the more recent samples.
* The Researchers confirmed they were working with the cancer registry. The Committee queried if the registry included mortality information and contact details which could assist in identifying potential participants who were alive and able to consent. The Researchers confirmed they would have contact details, and Committee members noted that mortality information is available in the NHI datasets.
* The Committee queried why the study could not be prospective, noting the 126 new cases in 2010. The Researchers explained that the study would look at the changes over time (during the last 18 years), and then a prospective study would be conducted after these results were analysed.
* The Committee stated that for the more recent samples, consent should be sought because for patients who were still alive, knowing if they were HPV positive could have an important clinical impact (as detailed in the application).
* The Committee queried what the difference is in treatment is if HPV was present. The Researchers explained that lower doses of radiation could be used if patients were HPV positive, but there is limited evidence on these aspects and it is not currently universal clinical practice.
* The Committee queried if it was possible to cross check contact details with mortality information and to send PIS/CF to those potential participants who were alive. The Researchers stated this would be feasible.
* The Committee explained that tissue samples of deceased participants can be used without consent.
* The Committee noted it was important to not send PIS/CF to deceased participants and asked the researchers to cross check the cancer registry details with NHI data to ensure this does not occur.

Decision

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

* Please create an information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Submit an updated protocol outlining changes made with regard to contacting live potential participants for consent to use tissue (*Ethical Guidelines for Observation Studies* *para 5.11*).
* The Committee notes that for those participants who are deceased, tissue may be used without consent.

This following information will be reviewed, and a final decision made on the application, by Dr Nicola Swain and Ms Raewyn Idoine.

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| **3** | **Ethics ref:** | **14/STH/129** |
|  | Title: | TRANSDIAB |
|  | Principal Investigator: | Associate Professor Helen Pilmore |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 September 2014 |

Associate Professor Helen Pilmore was not present for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

* Study involves patients who have had a kidney transplant. Aims to assess development of diabetes post-transplant.
* The study will administer a glucose tolerance test and those who have an abnormal result will then be further randomised to standard practice of care or Metformin.
* The primary outcomes measure will be the incidence of development of diabetes and secondary outcomes are the safety and tolerability of metformin in this renal transplant population
* The Committee discussed the risk profile of Metformin and the chance of renal failure, but noted there were exclusion criteria to mitigate this risk.
* The Committee stated that the proposed follow up of patients is adequate.
* The Committee noted that evidence of peer review was lacking. Please include the comments or evidence of peer review process from A+ grant.
* (R.5.4.1) Explain how conflict of interest will be managed.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* the statement on page 1 of the PIS “metformin has been shown to prevent development of diabetes in the general population’ is incorrect. Please clarify.
* Remove ECFR statement from page 3 of 7.
* The Committee noted that the study population may have a large proportion of Maori and Pacific participants, which the PIS/CF was not tailored for, and in general is not patient friendly. Please revise.
* There are typos, extra words, multiple fonts and sizes, lack of white spacing. Please revise for spelling, grammar and formatting.
* The chance of randomisation (i.e. 50%) must be explained clearly.
* The PIS should explain the symptoms associated with lactic acidosis in lay language, so that patients know when to seek medical help.
* Please separate frequency of various side effects, for instance nausea and vomiting.
* The Committee noted there were errors and inconsistencies regarding the reporting of the frequency of adverse events. Please refer to CIOMS (Council for Information on Organisation of Medical Sciences) guidelines regarding the frequencies defined by the terms ‘common’, ‘uncommon’ ‘rare’ etc.

Decision

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

* Provide evidence of the peer review process for A+ grant (*Ethical Guidelines for Intervention Studies* Appendix 1) and any other peer review obtained.
* Please amend the patient information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Explain how the conflict of interest resulting from care provider being the researcher is addressed *(Ethical Guidelines for Intervention Studies para 4.19)*

This following information will be reviewed, and a final decision made on the application, by Ms Raewyn Idoine and Dr Sarah Gunningham.

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| **4** | **Ethics ref:** | **14/STH/131** |
|  | Title: | The effectiveness of a Community psycho-education group for people who have self-harmed |
|  | Principal Investigator: | Dr David Carlyle |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 September 2014 |

Dr David Carlyle was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

* Dr Carlyle explained that there are many people in the community who would do well to access treatment for deliberate self-harm, at the earliest possible stage. His goal was to offer help to patients not under the care of mental health services and at the earliest possible stage. .
* Dr Carlyle explained that this education group may provide better outcomes, but it is also possible that patients may worsen and enter the mental health system, or be suspended in a neutral state of distress, without cutting.
* Dr Carlyle confirmed GPs will do pre-screening, adding that in some respect they already do this, and will be asked to refer patients to the study.
* The Committee asked if ED would be asked to refer patients to this study. Dr Carlyle explained that it is more likely for GP to be aware of minor cutting or burning, as the participants are not self-harming so badly that they would present at ED. Also, patients presenting to ED are more likely to be referred to mental health services.
* The Committee queried if there is any evidence that early intervention for deliberate self-harm is beneficial. Dr Carlyle acknowledged there is limited evidence on this and explained that this study would address this question.
* The Committee queried the qualification of investigators who would be leading the group sessions. Dr Carlyle confirmed all facilitators have professional registration.
* The Committee asked for more detail about the management of risk in this study: for example, what is the process in place to manage identified distress during the sessions? Dr Carlyle said participants who indicate distress could be removed from the group, followed up within the study, and then the investigators would identify what is required for on-going support – if immediate assistance is needed emergency psychiatric help can be sought, otherwise more time can be spent with the person to assist the person to manage their emotions.
* Please include information in the patient information sheet about agreeing to have GP be informed.
* The Committee queried if there is a risk of grouping participants who start to compare behaviour, resulting in negative social contagion. Dr Carlyle explained that this is very unlikely to occur, and experiences of self-harm would not be discussed in the groups. The focus of this intervention will be on things that bring participants to the level of distress, and learning the process that occurs which leads from ‘zero to stress to cutting’.
* Dr Carlyle explained that there is the risk of participants connecting outside of the study, and that this was unavoidable. The Committee suggested including information on this in the PIS/CF.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Pg.2 of PIS – the Committee stated that study related procedures, including screening, must occur after consent is signed. Pre-screening can occur during consent process but can’t record any information or administer study related procedures.
* ‘Destroy study files’ – please remove this sentence.
* ‘Little risk of harm’ pg.3 – Committee noted this has an area to write participant initials? Dr Carlyle stated this will be amended to state a study number, not participant initials.
* Pg.2 – please state they will participate in a 12 week programme, and explain the programme in more detail.
* Include information in PIS/CF on being able to withdraw anytime.
* Please include agreeing to have GP be informed.
* Committee commended the simplicity and readability of the PIS/CF for this study.

Decision

This application was *approved* by consensus.

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| **5** | **Ethics ref:** | **14/STH/132** |
|  | Title: | Optimising mechanical ventilation in ICU |
|  | Principal Investigator: | Associate Professor Geoffrey Shaw |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 September 2014 |

Associate Professor Geoffrey Shaw, Professor Geoff Chase, and Dr Yeong Shiong Chiew 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 ethical issues

The main ethical issues considered by the Committee were as follows.

* The study aims to assess how best to ventilate patients with injured lungs. Injured lungs are harder to inflate, but once they are inflated they need extra pressure.
* ICU specialists all over the world use a ‘best guess’ process for each individual patient requiring ventilation.
* This Study will measure the stiffness of the lungs in patients with ARDS and use computers to generate suggested ventilation pressures based on this information.
* The aim of this study is to optimise the ventilation of ICU patients.
* Patients are given sedation and muscle relaxant (standard practice). Over time upper and lower pressure limits are increased, and then decreased. This ‘Recruitment Manoeuvre’ is repeated twice – measuring for when the lung is the least stiff.
* The real time assessment in this study is novel.
* The committee queried how often it is measured. The Researchers explained it would be maximum of every 3 hours, but more likely to be every 6 hours. Mini-recruitment will occur every 6 hours 4-8 times a day. This continuous measurement is novel.
* The Researchers explained the pilot study that has occurred prior to this application.
* The Committee noted that this was a formalised standard practice approach.
* The Committee noted that the clinicians were in control of the care at all times during the study.
* The Committee discussed the proxy assent process, and delayed consent, and was satisfied with the processes in place.
* The Committee queried why pregnant women are excluded. The Researchers explained that it was an exclusion criterion in an earlier, related, study. The Researchers were agreeable that pregnant participants should be included, as they are treated in clinical practice. The Committee agreed. The Researcher will discuss with the DMC and submit an amendment if approved.
* The Committee commended the quality of the PIS/CF and application.
* The Committee noted the interpret box could be removed. It would be preferable to have a sentence on the consent form reading ‘I have read this in a language I understand’.

Decision

This application was *approved* by consensus.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Chair informed the Committee that Dr Martin Than’s term had finished and has left the Committee, but would be available in an advisory role.
3. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 14 October 2014, 12:00 PM |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Avenue, Christchurch |

The meeting closed at 2.45pm