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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 24 February 2015 |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 20 Aitken Street, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.15pm | Confirmation of minutes of meeting of 29 January 2015 |
|  | New applications (see over for details) |
| 12.30pm | i 15/CEN/19  ii 15/CEN/3  iii 15/CEN/10  iv 15/CEN/13  v 15/CEN/14  vi 15/CEN/15  vii 15/CEN/16  viii 15/CEN/18  ix 15/CEN/22 |
| 4.30-4.45pm | Substantial amendments (see over for details) |
|  | i MEC/05/09/121/AM07 |
| 5.15pm | General business:   * Noting section of agenda |
| 5.30pm | 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 |
| Mr Paul Barnett | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Gael Donoghue | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Cordelia Thomas | Lay (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Present |

## Welcome

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

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 29 January 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/CEN/19** |
|  | Title: | IntReALL SR 2010 |
|  | Principal Investigator: | Dr Siobhan Cross |
|  | Sponsor: | ANZCHOG |
|  | Clock Start Date: | 15 January 2015 |

Mrs Meredith Woodhouse 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

* Study involves 20 countries.
* The study will compare standard practice treatments which differ across countries to see which international protocol is the best treatment.

Summary of ethical issues (resolved)

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

* The study involves children and adolescents under the age of consent. The Committee noted there was a range of assent and consent forms.
* The Committee asked about tissue bank that is being used for this study. Mrs Woodhouse explained that the tissue bank is established in Australia (Children’s Cancer Institute Australia (CCIA) and the Westmead Millennium Institute, both in Sydney, Australia.) The Committee noted the current PIS and CF include information about banking of tissue.

Summary of ethical issues (outstanding)

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

* The Committee suggested only referring to the separate optional sub study and removing the information about it from the main PIS. It is currently confusing for participants and duplicates information.

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

* Adolescence PIS page 10 - add information for Central HDEC as approving committee.

Decision

This application was *approved* by consensus.

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| **2** | **Ethics ref:** | **15/CEN/3** |
|  | Title: | AOST1322: Eribulin in Recurrent or Refractory Osteosarcoma |
|  | Principal Investigator: | Dr Mark Winstanley |
|  | Sponsor: | Children's Oncology Group |
|  | Clock Start Date: | 12 February 2015 |

Dr Mark Winstanley and Mrs Jenny Harrison 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

* The study assesses the effectiveness and side effects of Eribulin in recurrent or refractory osteosarcoma.
* The patient population generally have a poor prognosis and have few treatment options. The researchers want to assess a treatment which has not been used in this type of cancer before.
* The study will conduct several tests at different intervals to see what happens to the tumour, for instance whether it progresses, regresses and will observe any side effects.
* There will be 19 participants initially; if the treatment is shown to be ineffective then researchers will stop study, if demonstrates efficacy then they will enrol a further 10 participants.

Summary of ethical issues (resolved)

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

* The Committee noted the patient population ranged from 12-50 year olds. The Committee queried if there was an adult PIS. Researchers explained that the young adults were for all adults. The Committee requested that the title reflects this.
* The researchers confirmed a SCOTT application had been submitted.
* The Committee noted that information about GPs being informed of study participation should be included in the PIS, under ‘who has access to my data’. The researchers agreed.
* The Committee made comments for future reference on P.4.1 and P.4.2 of the application. For P.4.2, this includes relevant statistics however this should be on question P.4.1. On F.1.2 the Committee noted this was not just asking about Maori, but other minority groups (Chinese, pacific island etc.) Use relevant statistics if available. The Committee clarified - information is appropriate, just placement and or answering the right question with said information could be improved.
* Please amend the PIS title ‘re-consent once of age’ to explicitly state ‘once 16 years old’.
* A.1.6 states the researchers will ‘Adolescents aged 16 and over will have the opportunity to consent on their own behalf but we may also seek consent from their parents/guardians if the patient is systemically unwell.’ The Committee noted that if a participant is over 16, or has been assessed to be competent to provide legally valid consent, they cannot have consent provided by any other adult.
* Committee suggests the researchers seek their own legal advice for cases where researchers may have sought consent for treatment of those participants over 16 or those assessed to be competent to provide informed consent.
* Please explain ‘accepting all eligible participants’. The researchers explained that there will likely be very few participants, clarifying that while all were accepted, there must be ‘slots’ available on the trial. The Committee noted this may be misleading as inclusion was dependent upon the slots available.
* The Committee asked whether there are opportunities for potential participants to store sperm or eggs, due to infertility being a potential side effect. Researchers stated yes, as well as counselling options.
* The Committee and researchers discussed fertility options available to participants.

Summary of ethical issues (outstanding)

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

* F.2.1 on inclusion and exclusion criteria. Please include some of the most important inclusion and exclusion criteria, perhaps on pg. 2 of PIS (who could take part). The Committee noted it is important for informed consent for the participant to understand why they are part of the study.
* The researchers responded that they screen for the exclusion criteria and did not want to confuse the participants by including this information.
* The Committee acknowledged that the researchers would screen but thought it was important to add the main criteria to let the participants know what kind of participants are being approached.

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

* Please add “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.” To the ACC statement.

Decision

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

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| **3** | **Ethics ref:** | **15/CEN/10** |
|  | Title: | Nitrate supplementation on health in TIA patients |
|  | Principal Investigator: | Dr Shieak YC Tzeng |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 February 2015 |

Dr Shieak YC Tzeng and Mr Terry O'Donnell 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.

Dr Patries Herst declared a potential conflict of interest, and the Committee decided to have Dr Herst remain in the room but not take part in the discussion or the decision of the application.

Summary of Study

* The Committee asked for clarification around any future unspecified storage of tissue. The researchers stated that there would be no storage of tissue samples beyond the length of the study, nor would there be any additional testing on the samples. Only health information would be stored and use beyond the study.
* The researchers stated that tissue will be destroyed after study analysis.

Summary of ethical issues (resolved)

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

* The Committee noted that the protocol has had significant amendments made to it since the NTB HDEC declined it. Has this protocol had further peer review since these changes have been made? The researchers stated no, and clarified that the comments that came back from NTB were more related to inconsistencies, rather than the protocol requiring change.
* The Committee noted that the treatment arms had changed, by dropping the healthy control group. The researchers explained that this healthy control arm was removed, clarifying that the placebo arm and treatment arm are unchanged. The healthy person arm does not impact the validity of the trial; rather it just means less data is collected.
* The Committee asked about the time between TIA and hyperventilation challenge. Researchers stated varied between 1-2 days.
* The researchers explained there had been no adverse events in prior study with 47 participants.
* The researchers explained the monitoring of participants during these procedures, noting that it was an open air mask which could be removed at any point. The researchers added that stress levels are gauged during the tests.
* Please explain how ‘capsules’ are created. Capsules will be provided by a pharmacy. Researcher has consulted with Wellington hospital pharmacy and confirmed creation of capsules and their effectiveness.
* The Committee queried why the 10mg dose was selected for this study. The researchers explained the prior study evidence in healthy participants. 10mg has been shown to have an effect on blood pressure, based on previous research.

Summary of ethical issues (outstanding)

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

* Add information about randomisation ratios in the protocol.
* The Committee noted that the study protocol should exclude those with allergy to nitrates.
* Please explain why study stores information for 16 years. Please note that health data derived from the study must be stored for a minimum of 10 years according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html).
* The committee queried whether it was safe to conduct the CO2 reactivity test for those who have had a TIA (cerebral event). The researchers explained that they have done these tests in a prior trial that has recently completed. The prior trial involved breathing a slightly than higher level of CO2.
* The Committee noted that the CO2 concentration in protocol is 8%, in atmosphere it is 0.3% which is not ‘slightly higher’. The researcher explained that it evaporates, so it is not 8% that goes into the body. This is the equivalent of holding your breath for 10-15 seconds. The participant is breathing through an open mask so the participant can take it off and the effects will dissipate quickly. Researcher noted there were no comfort issues or tolerability issues reported in the prior studies that included this procedure.
* Committee requested evidence of safety with this patient population in relation to this particular study procedure.
* Pg.2 in protocol states that participants are oxygen dependent – please reword to require supplementary oxygen.

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

* Please remove the ‘very few treatment options for TIA’ statement as this is not true.
* The Committee requested the researchers add ‘moderately increase the blood level of CO2.’
* The committee requested more potential side effects from the CO2 (headache etc.) be included in the PIS.
* Pg.5 possible benefits and risks. ‘May lead to following benefits’. Reword to ‘no guarantee of benefit for participating in the following study, but may lead to’.
* Please change ‘would’ to ‘may’ be eligible for ACC (pg.6).
* Please add Maori contact and support details, confidentially clause relating to study data and information on the approving committee: the Central Health and Disability Ethics Committee.
* The Committee queried why wearing gloves will minimise the pain. The researchers clarified that wearing gloves reduces chance of infection. The Committee noted that as it stands it was misleading, please amend.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide further safety information on study procedure with this particular patient population.
* Update study protocol with committee suggestions. (*Ethical Guidelines for Intervention Studies* *para* 5.41).

This following information will be reviewed, and a final decision made on the application, by Dr Dean Quinn and Mrs Helen Walker

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| **4** | **Ethics ref:** | **15/CEN/13** |
|  | Title: | Christchurch Heart Institute Tissue Bank |
|  | Principal Investigator: | Professor Mark Richards |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 February 2015 |

Professor Mark Richards 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

* The Committee noted that the questions on the tissue bank application form had been answered well.

Summary of ethical issues (resolved)

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

* The Committee queried what peer review process occurs to assess scientific validity of the studies who are using tissue stored at the bank. Professor Richards explained that most frequently the studies are funded by either HRC or NHF, which requires a peer review to unlock funding. The peer review is organised through the funders.
* Professor Richards added that internal, semi-formal, peer review occurs during regular catch ups with the governance group Christchurch Heart Institute (CHI).
* Q5 - Professor Richards confirmed that samples are de-identified if sent overseas.
* The Committee queried what process is followed for those who have withdrawn consent, asking if it was possible to have a karakia and or returning of leftover samples? Professor Richards confirmed that it is always possible and is outlined in the PIS for each study that this is an option.
* The Committee asked for information about governance arrangements, noting that the application covered the IT side of governance. Professor Richards explained that governance and decision making lies with Christchurch Heart Institute (CHI) which involves about 45 people and is a diverse group. There are 5 core/lead members consisting of, myself and Professor Vicky Cameron, Research Associate Professor Chris Pemberton, Research Professor Chris Charles and Research Associate Professor Miriam Rademaker. These five members are the core decision makers and studies require consensus to use any tissue samples. This group meets weekly covering Molecular, Immunology and Biochemistry issues.
* Q6 The Committee queried how the bank will maintain ability to contact people about incidental findings, over time. Professor Richards explained that incidental findings usually apply to direct findings after standard or screening tests. For example any bloods or scans will sometimes turn up unexpected findings. These are sent to the patients or their GP immediately for follow-up and these are quick. The other work the bank is involved in, looking at biomarkers, take a long time to determine whether a finding is significant or relevant to the patient. These findings are unlikely to be relayed back to the patient.
* Professor Richards added that his experience over last 25-30 years suggests that it is uncommon for any future tests to be relevant to the participants who initially donated tissue.

Decision

This application was *approved* by consensus.

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| **5** | **Ethics ref:** | **15/CEN/14** |
|  | Title: | The Intensive Care Unit Randomised Trial Comparing Two Approaches to OXygen therapy (The ICU-ROX trial) |
|  | Principal Investigator: | Dr Paul Young |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 February 2015 |

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

* The study will assess two different oxygen treatments. The treatments are similar in that they have the same lower levels of oxygen but the top levels will differ (one higher than other). There is currently no consensus or evidence to show which one is better, or rather which one is less toxic.
* The treatment is time dependent, falling under emergency care and patients are unconscious.

Summary of ethical issues (resolved)

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

* The Committee noted that the primary ethical issue was that none of the participants can provide informed consent.
* The Committee clarified with Dr Young that the oxygen any participant receives is enough, but high oxygen has been pushed as the norm without knowing whether this is actually required, and with high oxygen comes potential toxicity.
* Dr Young confirmed that some doctors use one approach, some doctors use the other.
* The Committee queried how the researchers were going to try and seek the wishes of the patient, and if this involved talking to family. Dr Young explained that process is a delayed assent approach as exposure to oxygen that occurs in mechanically ventilated patients must occur very early in treatment. This means there is a very narrow enrolment window, meaning patients must be enrolled first, then after this the researchers will seek the patient wishes when clinically possible.
* Dr Young confirmed this is an emergency situation and that oxygen is an emergency therapy. The hypothesis driving this study is exposure to abnormally high oxygen is potentially harmful.
* The Committee noted that right 7(4) does not apply to emergency treatment. HDEC explained that in emergency then requirements for right 7(4) are not applicable, as the clinician will need to make a decision about best interests and subsequent treatment.
* Dr Young explained that the clinician must believe that enrolment in the study is in the patient’s best interest. Dr Young added that reasonable measures to determine family and friends views on patient wishes will be sought, and if they believe the participant would not want to participate they will be removed from the study, however this relates to data collection rather than the oxygen which will have already been supplied.
* Dr Young explained that if a support person is there we can check with their relatives, if they object they will not enrol a patient at all.
* HDEC suggests that the PIS should and could emphasise the emergency features of this study.
* The Committee discussed that while oxygen is certainly in best interests, is the enrolment into the research study (with randomisation) in the best interests? Dr Young responded that the clinician is required to determine whether participation is actually in the best interest of the individual. This can still apply after the fact of randomisation, as opposed to not participating, which is the sense of which the treating clinician to consider best interest.
* The Committee asked why study participation is in the best interests. Dr Young explained that, in relation to this study, and was true of all intensive care studies, is that participation provides the patients with additional follow up that they otherwise would not receive. 180 days after a study is enrolled they will be contacted and from experience the researchers have found this additional contact will result in new, sometimes clinically relevant, information being detected. This is a benefit, on top of what is comparative effectiveness of standard treatment.
* Dr Young explained that as far as we know there are many hypothetical reasons as to why one treatment is better than the other. There should be a ‘sweet spot’ with respect to good levels of oxygen, not to low, not too high. The levels in this study are within the realms of standard care. After the study we may know which one is better.
* Committee noted researcher must comply with the law.
* The Committee asked if the clinical view at this stage was that both forms (arms) of treatment are standard of care, with no known difference between them. Dr Young confirmed.
* The Committee asked if the study was reliant upon funding from HRC. Dr Young explained that an HRC application would be made, but had not been submitted yet. Dr Young added that a 1500 patient trial can’t be conducted without HRC funding, but could seek MHRC funding, and that the pilot phase is the initial 100 patients which can occur regardless of funding. The Committee requested that information about funding arrangements is included in PIS.
* Dr Young explained consent is for use of data, not providing of oxygen or the randomisation.
* The Committee asked if a doctor personal view that higher level of oxygen is better, would they then enrol them? Dr Young noted that exclusion criteria has a condition to not enrol if not in best interest, either high or low oxygen.
* Committee suggested changing the statement at start of PIS to be about the oxygen, which means consent is given about data collection rather than use of the oxygen. Dr Young explained this statement was the result from legal advice. The Committee noted this, and stated it was just a suggestion.
* R.5.5 Dr Young confirmed that this answer is a mistake.
* The Committee noted that revocation of consent form should not be mandatory, adding that participants could withdraw verbally. Dr Young acknowledged this, adding that the form was just in case they did want to withdraw in writing. The Committee added that it should be clear that the participant doesn’t need to ‘revoke’ consent for the procedure, only for data use, if they initially consented for use of data.
* For future applications: p.4.2 a major cultural issue is dealing with the head. The head is Tapu.
* Any changes that are made to the PIS need to be submitted to HDEC for approval.

The committee was satisfied that mechanisms in place protected patients who will not be enrolled unless in best interests. The Committee is satisfied with legal consultation that researcher has sought.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **15/CEN/15** |
|  | Title: | The IDENTAKIT-HF Study |
|  | Principal Investigator: | Professor Zoltan H Endre |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 February 2015 |

Prof Mark Richards 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 main ethical issues considered by the Committee and addressed by the Researcher as follows.

* R.3.1.2 withdrawal of samples information. The Committee stated that usually there is a statement that explains that ‘tissues can be destroyed but any data analysis until point of withdrawal is retained in the study’. Professor Richards explained that in this study all data could be removed. The Committee stated that if researchers are willing to do then the current statement is fine.
* Committee asked for clarification between information on tissue in main PIS and the optional PIS.
* Please clarify – for main study, will this involve sending tissue to Australia for analysis. Professor Richards confirmed, explaining that they thought it was important to acknowledge the chance of sending tissue to other contractors due to assay analysis cost etc.
* Please clarify – for optional PIS, this relates to the 10 year storage? Professor Richards confirmed it was, after which we can anonymise it and continue to store.
* Pg.2 information sheet – confused about idea that samples will be sent overseas but can also ask to have them back. How does this work? Please clarify what actually happens for participants. Professor Richards explained this relates to any retained samples that can be given back.
* Professor Richards confirmed that there is a screening process involved.
* Professor Richards confirmed HRC funding has been granted.
* The Committee queried the HRC comments relating to needing 450 participants. Professor Richards explained this figure relates to getting better results from peri-discharge management trial which does not apply to this particular study.

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

* The Committee noted that in R.1.1 and P.1.1, there are clinical assessments which ‘might’ occur in clinical practice but if participating in this study they would be mandatory. The Committee suggested that the optional consent form covers off the requirement of informing patients that samples will be used by other researchers which may involve international collaboration, which means it does not need to be in the main PIS.

Decision

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

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| **7** | **Ethics ref:** | **15/CEN/16** |
|  | Title: | Can we avoid unnecessary hospital admissions for COPD? |
|  | Principal Investigator: | Associate Professor Robert Hancox |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 February 2015 |

Associate Professor Robert Hancox 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

* The study is assessing people admitted to hospital with COPD who may have been able to be treated at home. Ass Prof Hancox explained that what we currently know about people admitting to hospital with COPD is that they usually have a good prognosis (low risk of death). We think we know how to predict why these people have a good prognosis, and want to work out why they are coming to hospital. The study aims to generate information to answer questions such as would providing better nursing care at home prevent the need for these people to get to hospital.
* The researchers will be assessing severity of people presenting at hospital.
* Current reasons why low risk COPD patients are presenting are unknown. It may be because they have severe symptoms but no risk of death but still need hospital care, or they may not actually need hospital care.

Summary of ethical issues (resolved)

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

* The Committee asked if the study information can be sought once ‘confusion’ has subsided. Ass Prof Hancox explained that the kind of information we would want is why admitting doctor made the decision to admit to hospital. If we wait 3-4 days when person is able to give informed consent the doctor may not be able to remember.
* Ass Prof Hancox explained that doctor may not write why patient was admitted in their clinical notes.
* The Committee asked if there are there regular presenters with COPD? Ass Prof Hancox stated yes, some have multiple visits in a year, with some only 1 per year or 1 ever.
* Ass Prof Hancox explained that there is a sub study involved to assess patient’s views as to why they are admitted. This will assess whether reasons for calling doctor or ambulance are the same as doctors reasoning for admitting.
* Ass Prof Hancox explained this may identify medical reasons for admitting verses patient views that may not be of a medical nature.
* Ass Prof Hancox explained the questionnaire will not be given to family members. Only patients themselves in sub study and the admitting team. Ass Prof Hancox added family members may provide input from the patient’s experience. The Committee noted that if family is involved they too should provide informed consent.
* The Committee noted that the confusion can be either acute or long term, which may also impact the accuracy of reporting of reasons for admitting by the patients.
* Ass Prof Hancox explained that the patients may be low risk from other points of review. A risk profile is being created, covering cardiac blood tests and blood urea, respiratory rates, blood pressure etc. Chronic confusion may occurring while in other aspects the patient is very low risk and could be reasonably well looked after at the rest home. Rest homes may call ambulance because they are uncomfortable or are not resourced to manage persons in this state.

Summary of ethical issues (outstanding)

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

* Please explain consent processes, noting you stated that participants may not be able to provide informed consent. Ass Prof Hancox explained that people may present with confusion, which is temporary. Some patients may be chronically confused. Ass Prof Hancox explained that getting information (measure blood tests etc) is easier seeking ‘consent’ from next of kin. The Committee noted that it was not possible for any adult to provide consent for medical research for another adult.
* The Committee requires information on the procedure for consenting participants.
* The Committee noted that the application states that these patients can’t consent for themselves. Ass Prof Hancox noted that this isn’t an interventional trial. Committee noted that there will be additional study procedures, which may be problematic insofar as participants not providing informed consent.
* The Committee noted next of kin cannot provide consent on another’s behalf.
* The Committee noted right 7 of the code states that assessment is required to determine a consumer as not being able to be consented. Until assessed they are assumed competent. What assessment is occurring and by who? Please provide more information on consenting process.
* Committee asked if it is possible for participants to provide consent? It is not clear that the participants are not able to provide consent adding the study is very low risk.
* The Committee suggested seeking informed consent from all participants and not recruiting those who could not provide informed consent.
* The Committee asked when the questionnaire be administered? Ass Prof Hancox explained that the information will likely be gathered in the hospital. The questions will be for the respiratory registrar. The Committee noted this means that the registrars are participant and should be provided a participant information sheet. Consent is implied by completing the questionnaire, however the Committee suggests having the researcher submit a consent form to be completed by doctors participating in the study.

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

* Add information on the approving committee: Central Health and Disability Ethics Committee.
* Add confidentiality clauses in PIS.
* Add referral phone numbers.
* Add OPTIONAL heading on future unspecified research.
* Pg.3 of PIS – in relation to keeping ‘information of participation of patients’. The Committee queried if this is a condition of participation? Ass Prof Hancox explained that they wanted to know how many withdrawals they had. Committee noted this isn’t health information so it can be collected. The Committee suggests rewording this statement to be clear that retained data is purely administrative and is not health information.

Please view the following information on future unspecified research:

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| **Future Unspecified Research (FUR) and Biobanking**  **\*note these are requirements for FUR** |
| an indication of the type and nature of the research to be carried out and its implications for the donor, where possible, and an explanation of why the potential donor is being approached for their tissue and specifically what tissue is being sought. |
| known possible researchers or institutions that might use the tissue sample, if possible. |
| whether the donor’s sample is going to be, or is likely to be sent overseas, and where possible, to what country or countries. |
| acknowledgement that all future unspecified research in New Zealand will be subject to ethical review. However, when a tissue sample is sent overseas, unless it is sent in conjunction with a New Zealand research project, future research is likely to be considered by an overseas ethics committee without New Zealand representation. |
| whether the donor’s identity and details will remain linked with the sample or whether the sample will be de-linked. |
| a statement that if a donor consents to a tissue sample being unidentified or de-linked, they relinquish their right to withdraw consent in the future. |
| whether the donor may be contacted in the future regarding their tissue sample. Whether or not, and under what circumstances, information about the future unspecified research will be made available to the donor and/or (where relevant) their clinician. |
| acknowledgement that the donor will not own any intellectual  property that may arise from any future research. |
| whether there is provision to withdraw consent for the use of human tissue samples in the future. Where there is provision to withdraw consent, only tissue samples remaining at the time of a request to withdraw and any information held for future unspecified research may practically be withdrawn. Tissue samples or information used in research before the request to withdraw is received is unlikely to be able to be returned or  destroyed. |
| acknowledgement that the donor’s decision regarding the consent for use of their tissue sample for unspecified future research will in no way affect the quality of a donor’s current or future clinical care. |
| where and for how long a tissue sample will be stored, how it will be disposed of and whether there is a cultural protocol for its disposal. For example, information about the institution holding the tissue sample: its aims, research procedures and research governance. |
| whether or not tissue samples could be provided to other researchers and institutions, and whether or not such provision could include sending samples to other countries |
| whether or not collected samples will be provided to commercial biomedical companies or will be used in commercial research collaborations, if known. |
| what provisions will be made to ensure patient confidentiality. |
| that different cultural views may inform choice about donation of tissue; for example, for some Maori, human tissue contains genetic material that is considered to be collectively owned by whanau, hapu and iwi. |
| that cultural concerns may arise when tissue samples are sent overseas, including how tissue samples are stored and disposed of. Processes for monitoring and tracking what happens to samples may not be acceptable to donors. |
| that donors may want to discuss the issue of donation with those close to them, for example; family, whanau, hapu and iwi. |

**Note:** FUR must be listed as OPTIONAL and must be **distinct** from the main study – this can either be a separate PIS (if there is substantial information that warrants it) or it can be a separate consent area on the consent form (if the additional tests are optional but not that different from the primary study).

**HDEC has a preference for separate PIS/CF for optional sub studies, FUR or bio banking as the information required is often different to the main study.**

For more information see the Guidelines for Future Unspecified Research <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>

Decision

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

* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*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*).
* Provide details on what processes are in place to accommodate the highly vulnerable context of recruitment *(Ethical Guidelines for Intervention Studies para 6.2).*
* Confirm that all of the participants will be able to give informed consent, and elaborate on the vulnerability of the participant group *(Ethical Guidelines for Intervention Studies para 5.28*)

This following information will be reviewed, and a final decision made on the application, by Ms Sandy Gill and Dr Dean Quinn

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| **8** | **Ethics ref:** | **15/CEN/18** |
|  | Title: | A CIDI (3.0) assessment of the mental health of newly sentenced prisoners in NZ prisons. |
|  | Principal Investigator: | Dr P Johnston |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 February 2015 |

Dr P Johnston and Mr Andy Heinemann 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 (resolved)

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

* The Committee thanked the researchers for providing the protocol and the peer review. The researchers acknowledged this.
* The Committee queried why ’reasons for non-participation’ would be kept. The Committee felt that if a participant does not want to participate it is their right to not provide any further information. The researchers acknowledged this, and explained that there was no requirement to give information. The Committee noted that there was no obligation to provide a response but understood the researchers desire to have reasons for non-participation.
* Researchers explained reason for collecting reason for nonparticipation is because they would like to compare the completed sample size compared to the full cohort of potential participants. This allows us to interpret the findings better, understanding their generalizability and representation.
* The Committee queried what additional populations would be involved, such as those who had been in prison for a longer period of time. The researchers explained that they are looking for 1250 respondents all together. If we are short we want to open it up from those who are presenting to those who have been in the prison for a short period of time (3 months). The researchers explained it was only if they couldn’t reach their target (newly sentenced, but 3-4 weeks in prison).
* Committee noted that informed consent require time to consider and have family or whanau consultation. How long will people have to determine participation? The researchers explained that participants may take part after the first 15 minutes of having the study explained to them.
* Committee noted that informed consent needs some time to consider participation.
* Researcher noted that participants may be lost due to the participants being transferred around while giving them time to consider participation.
* Researcher explained that they felt the questionnaire was only able to be reflected upon once it began. The researchers asked what the Committee wanted. Committee responded that participants must have the opportunity of reflection of 24 hours, but it was acceptable for prisoners to take part immediately after being informed, if they want to.
* The Committee was satisfied with participants being given the option of 24 hours to consider participation.
* Researchers explained that this consent process will not happen in first few days of arrival, rather only after a few weeks of being in prison.
* Researcher noted prisoners are often quite interested in participation because of the boredom experienced while awaiting sentencing. Researchers explained they have the option of stopping any time, even right at the start.
* The Committee queried whether there had been consideration of identifying and managing Whakama, and how this will be dealt with in terms of the relationships with offenders. The Committee noted this was raised at the last meeting. The Committee asked where the interviewers are coming from. Researchers explained the interviewers are social science researchers who are not prison officers and have no relationship with the prison.
* Researchers consulted with internal prison Maori groups who did not raise any concerns regarding the approach the interviewers were to take.
* The researchers explained the skillset and experience that the interviewers have, particularly with a Maori population.
* The researchers acknowledged the vast array of dynamic experiences, such as paranoia, anger and emotional distress that could be caused by the experience and that the staff are well trained to work and manage the potential for this.
* The Committee asked about the training the interviewers have. The researchers explained that the person who provided training was a mental health practitioner from Australia.
* The Committee expressed concern about Whakama and how it may impact the way participants answer the questions which may skew the study data. The Committee also noted that Whakama can have devastating consequences for the participants, posing a risk to their health and wellbeing.
* The Committee felt it was a good plan to have interviewers that were coming from outside of the prison.
* Researchers clarified that future use of data will be de-identified, with no identifying information passed on to others.
* Please note that health data derived from the study must be stored for a minimum of 10 years according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html).
* Committee noted that a 2 hour interview was very long.
* The Committee asked whether limiting the study to English speakers would impact study data. Researchers explained that nearly all prisoners can speak English.

Summary of ethical issues (outstanding)

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

* The Committee suggested contacting Kaumatua at state services who could provide some training on Whakama so that interviewers can identify it and manage it. The researchers felt this would be appropriate.

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

* Add footer to PIS.
* Add information about what participants can do if they have concerns or complaints, such as advocacy groups, Maori support contact information, HDC contact information and ethics information – for example:

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050  
Fax: 0800 2 SUPPORT (0800 2787 7678)  
Email: [advocacy@hdc.org.nz](mailto:advocacy@hdc.org.nz)

* For Maori health support please contact :

*Name, position*

*Telephone number*

*Email*

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS

Email: [hdecs@moh.govt.nz](mailto:hdecs@moh.govt.nz)

* Consent form, 3rd bullet point. Can participants truly contact prison health staff at all hours? Researchers stated no, this was not possible. Please amend to accurately provide times that they can contact health staff.
* The Committee noted that the PIS – 4th point – can participants actually be referred to health staff without consent, or do they have to provide consent? Please make it clear that participants may be referred to health staff without consent. Currently conflicting between patient information sheet and application.

Decision

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

* Issues relating to Māori cultural and ethical values should be addressed, in this case by providing the interviewers with relevant training (*Ethical Guidelines for Observation Studies* 4.4)
* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).

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

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| **9** | **Ethics ref:** | **15/CEN/22** |
|  | Title: | Assessment of haemodynamic changes following stroke |
|  | Principal Investigator: | Dr Shieak Tzeng |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 February 2015 |

Dr Shieak Tzeng and Phil Allen\* 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.

Dr Patries Herst has declared a potential conflict of interest, and the Committee decided to have Dr Herst remain in the room but not take part in the discussion of the application or the decision.

Summary of Study

* Commended the explanation of the aims of the study in application.
* Peer review has been submitted.

Summary of ethical issues (resolved)

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

* The Committee queried the involvement of patients who can’t consent, adding that this treatment is not beneficial to the participant. Dr Tzeng explained that no one who can’t provide informed consent will be recruited; only moderate and low risk participants who can provide consent will be recruited.
* Dr Tzeng explained that all clinical treatment is routine, and that the study is to observe further information by adding sensors to record more information, there are no additional procedures, the study is observational. The Committee noted there are additional procedures and that is why it is research.
* Neurologist will individually assess each patient. Only those deemed to be able to provide informed consent will be enrolled in the study. Committee confirmed this was a requirement for the study to be approved.
* Committee confirmed that the study involves no future unspecified research, no storage of tissue, only use of data.

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

* Consider simplifying / lay language for PIS (currently taken from protocol). Explain jargon.

Decision

This application was *approved* with non-standard conditions by consensus. Secretariat to review PIS.

## Substantial amendments

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **MEC/05/09/121/AM07** |
|  | Title: | IBIS II Prevention |
|  | Principal Investigator: | Dr Andrew Simpson |
|  | Sponsor: |  |
|  | Clock Start Date: | 17 February 2015 |

Dr Andrew Simpson was not present for discussion of this amendment.

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

* The Committee noted that the update was appropriate.
* The study is generating good results.
* The placebo arm will cross over to the treatment arm.

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

* Maori contact details were missing from the PIS.
* Consent form should have confidentiality clause / information.
* Add Maori contact details for the consent extension PIS.

Decision

This amendment was *approved* by consensus.

## 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:

|  |  |
| --- | --- |
| **Meeting date:** | 24 March 2015, 12.00 PM |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 20 Aitken Street, Wellington , 6011 |

The following members tendered apologies for this meeting.

* Ms Sandy Gill apologies for April meeting.
* Dr Quinn apologies for March meeting.

1. **Problem with Last Minutes**

The minutes of the previous meeting were agreed as a true record.

The meeting closed at 4.45pm