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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 25 February 2014 |
| **Meeting venue:** | Terrace Conference Centre, 114 The Terrace, Wellington |

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| **Time** | **Item of business** |
| 12noon | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 30 January 2014 |
| 12.30pm | New applications (see over for details) |
|  | i 14/CEN/11  ii 14/CEN/13  iii 14/CEN/15  iv 14/CEN/16  v 14/CEN/17 |
| 2.45pm | General business:   * Noting section |
| 3.00pm | 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 |
| Mr Paul Barnett | Lay (the law) | 01/07/2012 | 01/07/2014 | Present |
| Mrs Gael Donoghue | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2014 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2014 | 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 |

## Welcome

The Chair opened the meeting at 12 noon 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 30 January 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/CEN/11** |
|  | Title: | COG AEPI10N5:Genetic Epidemiology of Ewing Sarcoma |
|  | Principal Investigator: | Dr Mark Winstanley |
|  | Sponsor: | Children's Oncology Group |
|  | Clock Start Date: | 13 February 2014 |

Dr Mark Winstanley and Dr Sarah Hunter 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 it had reviewed previously submitted studies from the researchers and had some similar questions to those asked previously. The Committee asked whether there is a Bio bank in USA. Dr Hunter confirmed that the samples collected in this study would be batched and sent to a bio bank in the USA. Once the analyses start the samples can’t be used and will be destroyed.
* Dr Hunter clarified for the Committee that batches would potentially be sent to USA twice a year. The Committee asked that the researchers state in the consent form that potentially the samples will not be able to be destroyed up to six months after being collected.
* The Committee asked the researchers to clarify under what circumstances they would intend to approach a sibling to participate in this study. Dr Hunter advised that they would do so in cases where only one biological parent is available noting that their ideal is to be able to approach both biological parents.
* Dr Hunter advised that if there was no consent from one of the biological parents then the sibling would not be approached to consent for the study.
* The Committee asked that the researchers include the word ‘OPTIONAL’ under consenting for samples to be sent to the bio bank in all of the relevant participant information sheets and consent forms.
* In the interests of fully informed consent, the Committee asked that inclusion and exclusion criteria listed at question f.2.1 on page 28 of the application form also be included in the participant information sheet. Dr Hunter advised that they are aware of the Committee’s requirement for inclusion of the criteria and will also start putting it in their information sheets for future applications.

Decision

This application was *approved* by consensus.

Although the Committee has approved the application, the Secretariat will check that the updated participant information sheet and consent forms are uploaded and that the changes have been made as requested above.

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| **2** | **Ethics ref:** | **14/CEN/13** |
|  | Title: | COG ACNS1123 |
|  | Principal Investigator: | Dr Stephen Laughton |
|  | Sponsor: | Children's Oncology Group |
|  | Clock Start Date: | 13 February 2014 |

Dr Stephen Laughton and Ms Paula Murray 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.

Summary of ethical issues

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

* This study involves using a different radiation therapy regimen for nervous system germ cell tumours in patients who have responded well to induction chemotherapy. The rationale is that conventional radiation therapy regimens have severe long lasting side effects and with this new regimen these side effects are hopefully less severe.
* The Committee commended the researchers on a well completed application and clear participant information sheets for stratum 1 and stratum 2 but noted that some of the information sheets were not included with the application when originally submitted. The Committee asked the researchers to submit a participant information sheet for adolescents and young adults for stratum 2, and a re-consent information sheet for stratum 1.
* The Committee asked the researchers to revise the content of the parent consent forms to reflect that consent is on behalf of their child and not themselves. For example, “I understand that my participation in this study […]” to “I understand that my child’s participation in this study […]”.
* Please clearly state in lay language the inclusion and exclusion criteria listed at question f.2.1 on page 27 of the application form in the participant information sheets. It is important that participants understand who can and cannot be involved as part of the fully informed consent process.
* The Committee requested a certificate of indemnity (medical insurance), for the study’s CI Dr Stephen Laughton.
* The Committee noted that it would expect to see a summary of the CI’s expertise at question b.3.1 on page 15 of the application form and asked that in subsequent applications that the question be answered in this way.
* The Committee noted that for future applications it would be helpful if the time that participants will have to consider the information before consenting is included in the answer at question p.2.1 on page 23 of the application form. Dr Laughton advised that in this study, participants will have up to 30 days to consider the information.
* The Committee noted that question r.3 on page 20 of the application form about the risks associated with the use of human tissue was not enabled on the form but that the researchers will be taking blood samples. Dr Laughton advised that blood samples would be taken for monitoring disease recurrence or response to therapy, that the samples will not be sent to the USA and that samples will be collected in accordance with good clinical practice. The Committee noted that answers given earlier in the application form (‘No’ to the use of Human Tissue at question E) may have predetermined question r.3 not being enabled. The Committee noted that the researchers still need to acknowledge that tissue is being used even though it will be used as part of good clinical practice.
* The Committee noted the answer given at question p.4.2 on page 26 of the application form and advised that a cultural issue for some Māori will be the use of human tissue (in this case blood). For future reference, the Committee asked that such issues be stated in this question along with information that shows the researchers understand such issues and how they will plan to manage them in a culturally sensitive way.
* The Committee noted that the answer given at question f.1.2 about reducing inequalities in health outcomes for different populations on page 27 of the application form would have been a good statement to include at question p.1.4 on page 26.

Decision

This application was *approved* by consensus.

Although the Committee has approved the application, the Secretariat will check that all participant information sheets and consent forms are uploaded and that the changes have been made as requested above.

* Please submit evidence that the CI is professionally indemnified, for example through membership of the Medical Protection Society (MPS).
* Please submit the requested information sheet and consent form, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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| **3** | **Ethics ref:** | **14/CEN/15** |
|  | Title: | CRAIn II |
|  | Principal Investigator: | Ms Molly Kallesen |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 February 2014 |

Ms Kallesen 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.

Summary of ethical issues

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

* This study will validate the use of a Cough Reflex Test (CRT) in ICU patients who have recently had an intubation tube removed to see whether they are more likely to inhale liquid and food which can lead to pneumonia and other lung problems. The researchers will use a nebulizer in a face mask on consenting patents to induce a coughing reflex and compare the results of this test with the gold standard video endoscopy method which introduces a camera through the nose to visualise swallowing and coughing reflexes.
* The Committee noted that the video endoscopy camera will be placed in participants’ noses and that it was not clear what the size of the camera is. Ms Kallesen confirmed that the camera is 2.9 ml in diameter and is the smallest camera available. The Committee suggested that the researchers put a picture of the camera in the participant information sheet next to a contrasting image, for instance a thumb, so that participants can get an idea of the size of camera.
* The Committee noted the researchers’ comment that there can be “moderately severe” reactions when introducing the camera. Ms Kallesen advised that this may have been too strong a term to have used and noted that there were very few mild adverse reactions in a previous study that looked at this test in patients undergoing coronary artery bypass surgery. With endoscopy there was a 6 percent chance of a nose bleed and very rarely laryngospasm. The camera used in this study is routinely used for other procedures.
* The Committee noted that the scientific peer review submitted did not quite fulfil the requirement of objective review but advised it would consider evidence of scientific review from the Dean of Postgraduate research, Prof Lucy Johnston.
* The Committee note the NEAC guideline requirement that in order for peer review to be considered free of bias, equitable and fair, that appropriate peer reviewers will not be materially connected to the researcher(s) in a way that might undermine objectivity.
* The Committee highlighted some aspects of the application for the researchers to consider in future applications –
  + Question r.5.4, page 16. The Committee noted that this question was answered ‘yes’ when it did not think that the lead investigator would also be the health and disability support provider. Ms Kallesen advised that she had misinterpreted the question and would not be the usual health and disability health provider for participants in this study.
  + Question p.4.1, page 21. The researchers aptly pointed out that Māori are disproportionately overrepresented in surgical, respiratory and neurological patient groups and suggested inclusion of available statistics as support.
  + Question p.4.2, page 21. The Committee advised that in this question it is looking to see that researchers have an understanding of the issues for Māori. The researchers had stated the issues but had not clearly demonstrated an understanding in the answer.
  + Question p.2.1, page 19. The Committee asked how long patients will have to think about consenting to the study after the information is given. Ms Kallesen advised that this could be variable depending on the situation but in cases where patients were unconscious, their family would get information as soon as possible and patients as soon as they gained consciousness. In any case, the researchers will endeavour to get information to patients as soon as possible.
  + Question a.5.2, page 8. The Committee requested a contact name for the sponsor and agreed that the dean of the faculty can be named.
* The Committee noted that the study protocol was clear and detailed but that the participant information sheet and consent form were a bit light on detail and therefore inadequate for patients to be fully informed before consenting. For example, the Committee noted that the information sheet states that the researcher will try three citric acid solutions at most during the CRT but the protocol suggests that this is likely to be more so is misleading.
* The Committee suggested that the researchers use the HDEC template as a guide to help ensure that enough information is provided to help participants make an informed decision. Ms Kallesen said she will relay the Committee’s comments to ICU who provided the submitted form template. The HDEC secretariat will send Ms Kallesen a copy of the HDEC participant information sheet template.
* The Committee noted the importance of not understating the risks on the participant information sheet as risks need to be well stated so that the patient is fully informed before making a decision. For instance, the video endoscopy was described as being “mildly uncomfortable”. While from a clinical perspective that may be apt, the protocol states that 32 percent found the procedure (including choking sensation and momentary chest tightness) “moderately uncomfortable” which is quite different from “mild” discomfort.
* The Committee noted that both inclusion criteria and exclusion criteria should be clearly set out in the participant information sheet and asked that the researchers include exclusion criteria.
* Ms Kallesen clarified for the Committee that records will be securely stored in the ICU office and the Committee asked that this be clearly stated in the participant information sheet.
* The Committee asked that contact details on the participant information sheet include the name and details of Ms Kallesen’s supervisor and also the Māori contact person’s details.
* The Committee discussed the use of the term ‘whānau’. Ms Kallesen advised that a patient can identify anyone who they feel is appropriate to represent them and it was agreed that ‘whānau member’ would be the most appropriate tem to use.
* Please state that the Central Health and Disability Ethics Committee has given approval for this study on pages 5 and 6.
* Question p.1.7.1, page 19. The Committee noted the final sentence in this answer that if a patient does not regain competence that permission will be sought from the HDEC to use the data. The Committee noted that family/whanau consent would be sought prior so re-consent would not be needed. Subsequent to the meeting the HDEC secretariat received legal advice that another person cannot give proxy consent for participants who cannot consent for themselves for research that is not conducted to save a person’s life. The HDEC’s cannot approve proxy consent and the Committee suggests that this research only include people who are competent to consent for themselves.

Decision

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

* Please amend the information sheet, 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, Mr Paul Barnett and Dr Patries Herst.

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| **4** | **Ethics ref:** | **14/CEN/16 – CLOSED MEETING** |
|  | Title: | Children's modified onset of sleep study |
|  | Principal Investigator: | Dr Nicholas Reid |
|  | Sponsor: | University of Otago Wellington |
|  | Clock Start Date: | 13 February 2014 |

Decision

This application was *provisionally approved* by consensus.

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| **5** | **Ethics ref:** | **14/CEN/17** |
|  | Title: | Te Waka Oranga; bringing the recovery destination to whānau |
|  | Principal Investigator: | Dr Hinemoa Elder |
|  | Sponsor: | Te Whare Wananga o Awanuiarangi |
|  | Clock Start Date: | 13 February 2014 |

Dr Elder 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.

Summary of ethical issues

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

* The Committee gave a brief overview of its understanding of this research. It is an assessment of a questionnaire and how well it works. The researchers will work with three to five groups of whānau who have a child or young person with a head injury. Dr Elder confirmed that this will be the case; she intends to test out the questionnaire and to use it as a base tool when working with whanau and professional care teams.
* The Committee noted that some participants in this study will be urban Māori who will be taken back home to their marae or whānau but who do not speak Te reo or know Tikanga Māori. It may be that the young person is reluctant to take part but his or her whānau are keen. The Committee asked how the researchers would deal with such cases. Dr Elder advised that this would likely be addressed in the consenting process. The research team will have discussed with whānau as a group what is involved and will also talk to the child or young person themselves. If they do not want to participate they will not be included regardless of the wishes of any other party. If people are reluctant to take part they can choose not to do so. Dr Elder said that she hopes that there will be a spread along Māori identity: that there will be some for who this research resonates and some who will not be feeling so sure but in the context of a brain injury that no matter where they are in the spread, they will be curious and bring the best of both worlds to serve the young person’s recovery.
* Dr Elder further advised that a process of negotiation will be involved. Based on discussions with partners in the community, there is a sense that in the context of whanau relationships that the young person with the traumatic brain injury will on balance decide to give this a go.
* The Committee commended the researchers’ recognition of whakama noting that this will be one of the main “brick walls” to address in the study. Dr Elder noted that she sees whakama as a dimensional imperative. With different circumstances and different people, this element will be powerful tool or able to be ameliorated. Dr Elder’s sense is that this external tool (questionnaire), will enable people to talk about how whakama might be getting in the way and to explore what grief issues are and are not related to the traumatic brain injury.
* The Committee noted that there may be situations where the young person is reluctant but the whānau is pushing for participation and trying to hide the young person’s reluctance and asked how the researcher’s would ensure that the young person’s rights and safety are protected. Dr Elder noted that one of the things the micro protocol would need to address is first encounters with whānau. The young person would have some one on one time with the Dr Elder to allow space so that the voice of the individual is honoured. They could explore nuances in some of “no go” issues initially then work with Dr Elder on how they can communicate these issues to wider whānau.
* Traditional and urban norms will clash at times with what the researcher hopes to achieve.
* Dr Elder acknowledged that there may be a mismatch at times. The Committee noted that a young person may have a completely different idea about what would happen but be expected to conform and asked how the researchers will ensure that doesn’t happen. Dr Elder advised that she can’t guarantee that this won’t happen. Her experience is that anti-traditional young people have a right to access the healing processes within their culture. If there is an injury to wairua and the injury is not attended to then they don’t get the chance to heal even if they are not open initially. The Committee noted that Dr Elder was aware of this and that is the important aspect for consideration.
* The Committee commended the study protocol noting that they had seen a similar concept work in prisons.
* The Committee asked whether people who are not able to give consent would be included in this study. Dr Elder advised that this would not be the case. When looking that the feasibility of getting results that might be helpful to whānau it was decided that young people who no longer have language skills won’t be included in the study. There will potentially be infants in this study who are developing language skills and they will be included. The Committee advised that they would need to see assent forms for participants who are under the age of 16. Children aged 7-15 years can give assent and the Committee would like to see a participant information sheet and assent form for this group.
* The Committee requested the following change to the participant information sheet:
  + Please add the inclusion criteria stated at question f.2.1 on page 21 of the application form that participants will be: “A young person who identifies as Māori with a history of traumatic brain injury, under the age of 24, with a traumatic brain injury having occurred more than 6 months prior to the study, who lives with whanau or is in the process of moving back to live at home”.

Decision

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

* Please amend the information sheet, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide a participant information sheet and assent form that is age appropriate for participants who are 7-15 years old (*Ethical Guidelines for Intervention Studies para 5.32*).

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

## 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:** | 25 March 2014 |
| **Meeting venue:** | Deloitte House, 10 Brandon Street |

No members tendered apologies for this meeting.

The meeting closed at 3pm.