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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 13 May 2014 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 1.00pm | Welcome |
| 1.10pm | Confirmation of minutes of meeting of 08 April 2014 |
| 1.30pm | New applications (see over for details) |
|  | i 14/NTA/62  ii 14/NTA/64  iii 14/NTA/65  iv 14/NTA/66  v 14/NTA/67  vi 14/NTA/69 |
| 4.00pm | General business:   * Noting section of agenda |
| 4.10pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Brian Fergus | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Susan Buckland | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Shamim Chagani | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2014 | Present |
| Mr Kerry Hiini | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2014 | Present |
| Ms Michele Stanton | Lay (the law) | 01/07/2012 | 01/07/2014 | Present |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 01/07/2013 | 01/07/2016 | Apologies |
| Dr Christine Crooks | Non-lay (intervention studies) | 01/07/2013 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 1.06pm and welcomed Committee members, noting that apologies had been received from Dr Karen Bartholomew.

Dr Brian Fergus noted that the HDEC Chairs will be meeting with Minister Ryall on 9 June.

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 8 April 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTA/62** |
|  | Title: | Pipelle for Pregnancy (PIP) studies |
|  | Principal Investigator: | Prof Cindy Farquhar |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 May 2014 |

Professor Cindy Farquhar and Miss Sarah Lensen 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.

* Professor Farquhar explained that some published research has shown that if the lining of the uterus is disrupted in women who have had implantation failure, they are twice as likely to conceive in the next implantation. She explained that a pipelle sampler passed through the cervix before IVF disrupts the uterus.
* The Committee expressed some confusion about the three studies. Professor Farquhar explained that there were three groups in the study – women undergoing embryo transfer as part of an IVF cycle, women with unexplained infertility trying to conceive naturally and women with polycystic ovarian syndrome.
* The Committee asked if the study was statistically powered. Professor Farquhar confirmed that it was.
* The Committee asked what other countries would be taking part in the study. Professor Farquhar explained that this study would take place in Auckland, with discussions taking place for Australia, Brazil, the United Kingdom and Canada. She explained that it was easier to recruit in New Zealand as the researchers know the setting and they are part of a network of people interested in fertility trials. Professor Farquhar explained that IVF trials in New Zealand are unique as women only undergo a single embryo transfer. She noted that any group that wants to take part in this study would have to agree to a single embryo transfer. She noted that Australia follows the same process but Brazil does not.
* Professor Farquhar advised that there are 2,000 IVF cycles per year in the Auckland region and she believes that they should be able to recruit the numbers in Auckland.
* The Committee asked about the future use of human tissue (B.4.5.2). Miss Lensen explained that she had been talking to a group in Melbourne about running a microarray on the samples of women who failed to conceive. She explained that this would be a separate study but that they wanted to get consent for future research on the samples. The Committee noted that as this will be a separate application references to this should be removed from the consent form (point 6) and the PIS.
* The Committee noted that the researchers should refer to the Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes at <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> for the future application.
* The Committee asked where the tissue samples would be stored. Professor Farquhar explained that the majority of samples would not be stored but those that would be used for the microarray study would be stored at the University of Auckland.
* The Committee queried how Dr Wihongi’s comments on over sampling Māori had been addressed. Professor Farquhar noted that for various reasons very few Māori end up in fertility clinics. Miss Lensen explained that she wants this study to be representative of the New Zealand fertility population which is different to the general New Zealand population and over sampling Māori would not achieve this.
* The Committee asked if private clinics would be used. Professor Farquhar confirmed that Fertility Plus is a public clinic, while Fertility Associates and Repromed are private clinics. The Committee noted that all would have Māori health strategies and recommended talking with Maui Hudson at Fertility Associates and the Māori representative at Repromed who may be able to advise on Māori recruitment.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please consult with Māori representatives at the fertility clinics and explain how Dr Wihongi’s comments on over sampling of Māori will be addressed *(Ethical Guidelines for Intervention Studies, para 4.7).*

This following information will be reviewed, and a final decision made on the application, by Dr Brian Fergus, Dr Christine Crooks and Ms Michele Stanton.

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| **2** | **Ethics ref:** | **14/NTA/64** |
|  | Title: | Assessing Facial Affect Recognition in People with Intellectual Disability |
|  | Principal Investigator: | Miss Zara Godinovich |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 01 May 2014 |

Miss Zara Godinovich 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.

* The Committee thanked the researcher for attending in person.
* Miss Godinovich explained that the purpose of this study is to assess facial emotion recognition in people with intellectual disabilities. The current literature says that people with intellectual disabilities have deficits in facial emotion recognition which can cause difficulties in social situations. Ms Godinovich believes that there are flaws with the current methodology used. She said that this study may find that facial emotion recognition deficit has been overstated because of the level of cognitive ability required of participants in previous studies.
* The Committee asked how this study will be recruited. Miss Godinovich explained that People with mild or moderate intellectual disabilities will likely be recruited from group homes primarily from IDEA services
* The Committee noted that they were unclear about which group each PIS was for and recommended clearly labelling each PIS. The Committee also recommended simplifying the language for the PIS and ensuring that each PIS is targeted to the relevant audience.
* The Committee asked how the consent process would work. Miss Godinovich explained that it would depend on the individual as some people with an intellectual disability would have to have somebody give consent on their behalf. She noted that every participant’s next of kin would be informed of the study.
* The Committee noted that as per Right 7(4) of the Code of Health and Disability Services Consumers’ Rights, if people are not competent to give consent, then they cannot be included in the study. They advised that the researcher will need to be able to independently verify that participants are able to give consent.
* Miss Godinovich advised that she will sit down with each participant to discuss the study. She will ask the participants to explain the study back to her to ensure that they understand it and to avoid them just agreeing with her. She noted that she will be working with people with mild to moderate intellectual disabilities so they will have good verbal skills.
* The Committee asked if the Massey Kaumatua had suggested any changes to the study. Miss Godinovich said that his comments were about how to approach participants.
* The Committee asked whether the Kaumatua had raised the possibility of the potential for any bias or stigmatisation based on where the study would take place. Miss Godinovich explained that the testing of children without intellectual disability will probably take place at schools as this is not a mental health study and they do not want to give the impression that there is anything wrong with the participants. She noted that for adults with an intellectual disability, the testing would take place at the facility at which the researcher is based.
* The Committee asked for clarification on whether there would be any interaction with the participants before the study. Miss Godinovich confirmed that there will be no interaction with the participants before testing unless the school principal wants her to give a presentation on intellectual disability.
* The Committee were concerned that the peer review was not from an objective reviewer. They asked for a letter from the researcher’s supervisor explaining the peer review process.
* The Committee noted that access to participants’ medical information should only be that which is directly relevant to this study.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Observational Studies, para 6.10).*
* Please provide a letter from the study supervisor explaining the peer review process *(Ethical Guidelines for Observational Studies, para 5.8).*

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

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| **3** | **Ethics ref:** | **14/NTA/65** |
|  | Title: | COMBINE II - Optical Coherence Tomography Aboard Informing Atherectomy II |
|  | Principal Investigator: | Associate Professor Andrew Holden |
|  | Sponsor: | Avinger, Inc. |
|  | Clock Start Date: | 01 May 2014 |

Mr Andrew Hill and Ms Anna Zhou 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.

Dr Christine Crooks declared a minor potential conflict of interest, and the Committee decided that she would take part in the discussion and voting.

Summary of ethical issues

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

* Mr Hill explained that this device is a combination of two technologies – an imaging technology called OCT and an atherectomy device which cuts plaque from blood vessels. The combination of the two devices allows for closer control of where the blood vessel is being cut.
* The Committee asked if the atherectomy device has been used in other surgeries. Mr Hill confirmed that it has but the main limitation is the guidance of the device.
* The Committee noted the number of trials coming through the researchers’ department and asked how it was decided which participants would take place in each trial. Mr Hill explained that the department carefully manages which devices it trials to avoid testing similar devices at the same time. The Committee asked if the researchers had any problems recruiting participants. Mr Hill advised that they sometimes struggle to get enough participants due to the exclusion and inclusion criteria being much tighter than clinical criteria.
* The Committee queried the data safety monitoring arrangements for this study. Ms Zhou confirmed that there is an internal data safety monitoring committee for the trial.
* The Committee asked for confirmation on what would happen to the tissue samples. Ms Zhou explained that the tissue samples will be sent to the United States and will be destroyed after seven years. If a participant asks for them to be destroyed before the samples have been tested, they will be destroyed immediately. If the participant withdraws consent after the sample has been tested, the sample will be destroyed but the data will be used. The Committee noted that this information needs to be included in the PIS and it needs to be clear that this is standard histopathological testing.
* Ms Zhou confirmed that Māori review was pending.
* The Committee asked if the images being sent overseas were x-ray or optical. Mr Hill confirmed that they would be both.
* The Committee asked what can be seen on OCT images that cannot be seen on x-ray. Mr Hill explained that an OCT image shows the whole circumference of the blood vessel.
* Ms Zhou confirmed that the insurance is currently being renewed and that she has asked for the liability amount to be raised from $2M to $5M
* Ms Zhou explained that another similar trial is currently being run in Latin American countries. The COMBINE II trial has not yet been approved in other countries but it is planned to be a multi-centre study.
* The Committee suggested surveying participants on this study and other similar studies on their views of the participant information sheets, for example the length and readability. Ms Zhou agreed to look at whether it was possible to condense the PIS.
* The Committee requested the following changes to the PIS and consent form:
  + Please include a statement in the first paragraph of the PIS to the effect of “although this is a first in human trial using the particular combination of components for this particular application, the components being used for this study are currently being used for other treatments”.
  + Please include the clinical trials register number in the PIS.
  + Please include information on tissue samples in the PIS.

Decision

This application was *approved* by consensus subject to the following non-standard conditions

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

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| **4** | **Ethics ref:** | **14/NTA/66** |
|  | Title: | EYE-SPY: Examining Young Eyes for Signs of PrematuritY |
|  | Principal Investigator: | Ms Myra Pui-Sum Leung |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 02 May 2014 |

Ms Myra Pui-Sum Leung and Dr Jane Alsweiler 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.

* Dr Alsweiler, a neonatologist, explained that preterm babies are at a higher risk of an eye disease called retinopathy of prematurity. This can be treated with laser treatment in the neonatal ward. She advised that there are questions about how this affects their eyesight as they get older. This study will look at the eyesight of eight to ten year olds to see how well they see and to see if there is any scarring at the back of their eyes.
* The Committee asked how participants would be recruited to the study. Dr Alsweiler advised that the neonatal unit has a database of preterm babies, with information taken until the children are four. Potential participants will be identified from this database and contacted. The preterm children will be asked if they have any friends of the same age who would like to take part in the trial as a control group.
* The Committee asked how old the children would now be. Dr Alsweiler confirmed that they would be between eight and ten. The Committee noted that this should be included in the PIS.
* The Committee asked about the Māori review process. Dr Alsweiler explained that it was going through the ADHB process at the moment. The Committee noted that the researchers should ensure that any feedback from the review is included in the PIS.
* The Committee asked about data retention for the study. Dr Alsweiler advised that data would be kept for 20 years after the project is complete and then destroyed. She noted that it was important to keep the data for this long as it is health information that will not be stored anywhere else in the health system.
* The Committee noted that the researchers had labelled this an observational study. The Committee explained that this is deemed an intervention as clinicians will be giving participants eye drops. The Committee noted that this distinction is significant from an ACC perspective as this could result in a treatment injury. The standard ACC clause needs to be included in the PIS.
* The Committee asked about the accessing the B4 School data. Dr Alsweiler explained that before children start school, they are given tests, for example growth and vision tests. The researchers would like to be able to view the vision tests to see if they can be used to identify vision problems. Dr Alsweiler explained that they will get the data from the Ministry of Health through a child’s NHI number. Once the researcher has the data, they would be given a separate study ID number and the NHI would be removed and stored separately and securely.
* The Committee asked how Māori preterm birth rates compared to other ethnicities. Dr Alsweiler advised that at about 16%, they were higher than the European and Asian populations. Māori also had higher rates of astigmatism, which is often seen in preterm children.
* The Committee asked if the researchers envisaged any problems with the length of the testing (three hours). The researchers gave an example of a recent study in which seven year olds coped with a six hour test. Ms Leung noted that most of the tests are interactive so the children will think of these as games.
* The Committee asked whether a child needed to go to more than one location for testing. Ms Leung explained that most of the testing would take place at the Grafton campus of the University of Auckland but as they do not have a camera which takes a wide angle image of the inside of the eye, they will have to use a machine at Greenlane Hospital or a local optometry practice. Ms Leung will accompany the children for this test.
* Dr Alsweiler confirmed that the funding covers the use of the camera at a local optometry practice. She advised that they are currently deciding where this will be but as the Greenlane camera cannot be used during the day, it is likely to be a local optometry practice.
* The Committee commended the researcher on the PIS.
* The Committee requested the following changes to the PIS and consent form:
  + Please include the following statement in the PIS “If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.”
  + Please include the following statement in the consent form “I understand the compensation provisions in case of injury during the study.”

Decision

This application was *approved* by consensus subject to the following non-standard conditions to the Secretariat.

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please ensure that any feedback from the Māori Research Review Committee is included in the PIS *(Ethical Guidelines for Intervention Studies, para 4.7).*

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| **5** | **Ethics ref:** | **14/NTA/67** |
|  | Title: | PET 1 |
|  | Principal Investigator: | Associate Professor Simon Mitchell |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 01 May 2014 |

Dr Cornelius Kruger, Dr Owen Hodges and Dr Jacqueline Hannam 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.

* Dr Kruger explained that this is a preliminary study comparing propofol and etomidate as induction agents for anaesthetic. The results of this study will be used in a second part study which will compare the 28 day mortality rate in those who have received either of these two drugs as their induction agents.
* The Committee asked about the use of etomidate in New Zealand as it is a Section 29 drug. Dr Kruger explained that in New Zealand it is common use in cardiac anaesthesia, used in about 50% of cases and separate consent is not obtained. In other types of surgery this is not common. Dr Kruger explained that it is the clinicians’ choice of which one they use, with a 50/50 split among anaesthetists in his team.
* The Committee asked if there was a difference in price between the drugs. Dr Kruger advised that etomidate was more expensive but not significantly so.
* The researchers explained that non-clinical members of the research team who have had training in aseptic techniques will be involved in drawing up the drug. Safety procedures include drawing the drug up immediately prior to administering it, the use of a date and time stamp and having a second person check.
* The Committee asked who will be blinded in the study. Dr Kruger confirmed that anaesthetists will not be blinded in the first part of the study but in the second part of the study anaesthetists, patients and other clinical staff will be blinded. The Committee asked if the same volume of induction agent is used. Dr Kruger advised that 10ml of etomidate equates to 20ml of propofol. He explained that the drugs are not given as a fixed dose and that anaesthetists will inject the drug until a patient loses consciousness. The amount given will differ depending on the patient. The end point for both of the drugs is the patient becoming unconscious. Dr Kruger advised that was a general agreement among the anaesthetists they could use the drug safely while being blinded and they would not take part if they felt uncomfortable at any stage. He noted that anaesthetists would assume that they are giving patients the most potent drug.
* The Committee noted that a lot of the information on the generic PIS booklet is not relevant to this study and may confuse participants. They advised that the information on ACC, HDC advocates and independent advice services should be copied to the PIS.

Decision

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

* Please amend the PIS 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 Michele Stanton and Ms Shamim Chagani.

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| **6** | **Ethics ref:** | **14/NTA/69** |
|  | Title: | LUNG SAFE |
|  | Principal Investigator: | Dr Paul Young |
|  | Sponsor: | ESICM - European Society of Intensive Care Medicine |
|  | Clock Start Date: | 01 May 2014 |

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 ethical issues

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

* The Committee noted that this appeared to be a worthwhile study.
* Being an observational this would normally be considered under the expedited process and be reviewed by the Chair and one other. However, because it involves vulnerable patients it was appropriate for it to be reviewed by full committee.
* The Committee noted that this was an ICU audit study, with consent not being obtained during or after the study.
* The study will be over a month, reviewing hospital records, abstracting data and the data would be sent overseas for a combined analysis from all sites. The data is de-identified.
* The Committee asked what the expected outcome of the audit would be for New Zealand hospital care and what the benefit would be for New Zealand patients. Dr Young explained that at the moment there is not a lot of understanding about how international practice varies and how patients are managed when on life support. He noted that understanding the variance is the first step in promoting optimal care. He advised that it is important for New Zealand to be involved in this study as researchers are moving toward international collaborative trials. Dr Young noted that if New Zealand is involved in the initial observational study, it helps support them being involved in future intervention studies.
* The Committee asked if participants will only be recruited by CCDHB. Dr Young advised that the New Zealand and Australian part of the study is primarily being coordinated by a researcher in Australia. He explained that they are hoping to get a representative sample from as many ICUs as possible. Dr Young confirmed that four DHBs have currently expressed an interest and that he will have the lead site.
* The Committee noted that Form 2A has space for a study ID number and a patient ID number and asked if NHI numbers would be collected. Dr Young advised that as far as he is aware, there is no intention to collect NHI numbers. Dr Young confirmed patients would remain completely de-identified.

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 reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 10 June 2014, 01:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

No members tendered apologies for this meeting.

The meeting closed at 4.01pm.