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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 24 September 2013 |
| **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 27 August 2013 |
|  | New applications (see over for details) |
| 12.30-12.50  12.50-1.10  1.10-1.30  1.30-1.50  1.50-2.10  2.10-2.30  2.30-2.50  2.50-3.10  3.10-3.30  3.30-3.50  3.50-4.10 | i 13/CEN/124  ii 13/CEN/125  iii 13/CEN/135  iv 13/CEN/128  v 13/CEN/129  vi 13/CEN/130  vii 13/CEN/131  viii 13/CEN/132  ix 13/CEN/133  x 13/CEN/134  xi 13/CEN/126 **CLOSED** |
| 4.10pm | General business:   * Noting section of agenda |
| 4.20pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 01/07/2012 | 01/07/2015 | Apologies |
| 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 |
| Dr Lynne Russell | Non-lay (observational studies) | 01/07/2012 | 01/07/2014 | Apologies |

## Welcome

The Chair opened the meeting at 12.14 and welcomed Committee members, noting that apologies had been received from Dr Angela Ballantyne and Dr Lynne Russell.

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 27 August 2013 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **13/CEN/124** |
|  | Title: | CLDK378A2301 |
|  | Principal Investigator: | Associate Professor Mark McKeage |
|  | Sponsor: | Bivartus New Zealand Limited |
|  | Clock Start Date: | 12 September 2013 |

Assoc Prof Mark McKeage 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 it had reviewed similar studies and asked A/Prof McKeage whether he had recently submitted a similar application. A/Prof McKeage has not submitted an application but he explained that he is currently participating in a phase II trial that is different to the study before the committee. This study is a phase III trial.
* A/Prof McKeage confirmed for the committee that SCOTT approval is pending for this study. The committee noted that the study could not begin until SCOTT approval is given.
* The committee noted that question p.4.2 in the application form asks that researchers identify the main cultural issues for Māori and asked A/Prof McKeage what he thought the main issues for Māori in this study are. A/Prof McKeage explained that lung cancer is a major issue of concern to Māori who tend to have higher mortality rates in comparison with non-Māori. This research attempts to improve outcomes for lung cancer. A/Prof McKeage noted another issue may be concerns about tissue and blood samples being taken for testing to determine eligibility to the study. The committee was satisfied that A/Prof McKeage understood the cultural issues involved and noted for furture reference that it would be useful to state the issues at p.4.2. A/Prof McKeage noted that he had consulted further with staff at the ADHB since submitting the application and that the Māori research committee had subsequently approved the study.
* The committee noted that the pre-screening information sheet and consent form did not mention what the likelihood of being consented to this study would be and further noted that the likelihood appeared small based on the information provided in the application (AKL rearrangement a relatively rare event in non-small cell lung cancer, 2-8 per cent). A/Prof McKeage explained that the percentage of 2-8 is of lung cancer overall and that the actual percentage in the target population is higher than 2-8 per cent. The committee asked that the likelihood of being consented to the study is made clear in the information sheet and consent forms.
* The committee asked A/Prof McKeage why the right to withdraw authorisation to release information was set at 50 years in the Pregnancy follow-up information sheet and consent forms. A/Prof McKeage noted the rationale was that if there were any risks to a person exposed to the drug that this would become apparent in 50 years. He further noted that this is a multi-centre study and although his research team has had input into development of the protocol, the policy of following people born for that period of time exposed to the drug is that of the study sponsor.
* The committee asked that the researchers ensure that the insurance cover available to study participants does cover the five essential points that ACC cover would provide if it were available. The committee cautioned that some policies can omit these and recommended that researcher double check this. The committee noted that it is aware that some participants have had difficulty getting insurance, which is why it is raising the importance of researchers double checking insurance cover.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:  
  + Please make it clear in the pre-screening PIS the likelihood of being ALK positive and therefore eligible to potentially participate in the main study.
  + Please make clear what assessments participants will receive in this study are and how they differ to standard treatment.
  + Please delete the phrase “standard medical tests” as the blood tests that will be done are part of a clinical trial and therefore not “standard”.
  + Please specify the timeframe participants will have to consider the information provided before deciding whether or not to take part in the study.
  + Please make the main exclusion criteria e.g surgery or radiotherapy clear to participants.
  + Consent form, page 17: please remove the statement *“I agree to my samples being stored for up to 15 years and used for future research of ALK inhibitors (such as LDK378) in non-small cell lung cancer”* and include it in the Optional Biomarker consent form.
  + Please state that the Central Ethics Committee has approved the study.
* Additional Biomarker Participant Information Sheet:   
  + There is some redundancy in statements and therefore potential for confusion. For example: duplication of sample return. Please review and delete any redundant statements.
  + Please replace “Additional” in the title with “Optional” as additional implies that this sub-study is part of the main study when it is optional.
  + Please state that the Central Ethics Committee has approved the study.
* Additional Extensive ECG and PK sampling Information Sheet and Consent Form:  
  + Please replace “Additional” in the title with “Optional” as additional implies that this sub-study is part of the main study when it is optional.
  + Please state that the Central Ethics Committee has approved the study.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please ensure that compensation for participants will be covered to at least ACC- equivalent standard (*Ethical Guidelines for Intervention Studies* *paras 8.4-8.5*).

This information will be reviewed, and a final decision made on the application, by the Chair, Dr Dean Quinn and Mr Paul Barnett.

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| **2** | **Ethics ref:** | **13/CEN/125** |
|  | Title: | Apollo Phaco System Prototype Field Investigation |
|  | Principal Investigator: | Dr Dean Corbett |
|  | Sponsor: | Abbott Medical Optics |
|  | Clock Start Date: | 12 September 2013 |

Dr Dean Corbett and Mr Henry Heering were present by teleconference and Ms Dale Lambert 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 introduced the study and noted that its purpose is a simple validation of a new piece of equipment, which is a modification of an already used system for removing cataracts. The researchers confirmed this adding that a further study aim is to see whether the Apollo Phaco system will be easier for surgeons to use in comparison with the system already in use.
* The committee noted that the answers given in the application form were succinct and that they had to read the protocol to fully understand the study. The committee suggested that the researchers might provide more detailed information in the application form itself in future.
* The committee also noted the participant information sheet and consent form is succinct and recommended the researchers use the Health and Disability Ethics Committees’ pro-forma as a reference for future applications.
* The committee sought clarification on the study design noting that researchers had stated there are two arms to the study with 100 patients enrolled but that the protocol sets out three stages (1,2 and 3). Dr Corbett confirmed that this application is for stage 2, and aims to assess the system after incorporating resolutions to any issues identified at stage 1, which assessed the first prototype for this system. Stage 3 will involve using the system as it rolls off production line and will involve multiple countries. The committee noted that it would have been useful for the researchers to explain this in the application form.
* The committee sought further clarification on the termination criteria for the study and asked whether termination of the study is something that surgeons will decide. Dr Corbett advised that if the equipment doesn’t perform well for the surgeon then they would stop the study.
* Dr Corbett confirmed for the committee that surgeons decide whether to use the new system to treat patients noting that the equipment has been progressive for some years and has upgrades at regular intervals. AMO wants to validate changes to machines with surgeons and the effects will flow onto patients. For example, the new system may be safer for patients.
* Given that this study aims to assess the use of the new system for surgeons, the Committee questioned why it came to the HDECs for review. Ms Lambert noted this is because the equipment used is classed as a class IIb device. Ms Lambert acknowledged that this study is minimal risk but that it needs to be fully assessed regulatory-wise.
* The committee noted that the study co-investigator names were not provided in the application form. Ms Lambert noted that this was because the co investigators were not confirmed when the application was submitted. They have since been confirmed (5 surgeons), and their details will be provided.
* The committee questioned the retention of health information for this study noting that this information won’t be held by the sponsor. Dr Corbett confirmed information will be stored as part of the hospital system and be governed by hospital protocol.
* The committee noted receipt of evidence of insurance cover for participants in this study. R.1.9 sets out requirements for cover equivalent to ACC. The committee recommended that it would be useful for the researchers to confirm with ACE insurance that cover does is equivalent to that covered by ACC (five types listed at r.1.9 on the application form). The committee further noted that ACC cover is concerned with the “types” of cover rather than quantum. Ms Lambert noted that the cover for this study would likely be similar to cover used in previous studies but that she would follow this up with the sponsor.

Decision

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

* Please ensure that compensation for participants will be covered to at least ACC- equivalent standard.
* Please provide details for the five co-investigators in this study.

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| ***3*** | **Ethics ref:** | **13/CEN/135** |
|  | Title: | Cognitive stimulation using exer-games (Able-X) for people with dementia |
|  | Principal Investigator: | Mrs Jeanette Drury-Ruddlesden |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 September 2013 |

Mrs Drury-Ruddlesden and Dr Kay deVries were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The committee complimented the researchers on a well put together ethics application.
* This study aims to assess cognitive stimulation using the device in people with mild to moderate dementia (MMSE 10 or >/=) who can follow simple instructions and the committee noted that some participants may not be able to do so. Mrs Drury-Ruddlesden explained that this criteria is based on similar studies but that she could review this. She would prefer to keep at this level for now so that participants are included rather than excluded.
* Mrs Drury-Ruddlesden confirmed the study population live in a general scope care facility and demonstrate dementia. The committee asked whether the pool could extend to those in a stable home environment as the current recruitment strategy would effectively exclude most Māori and Pacific Islanders. Mrs Drury-Ruddlesden had considered doing this, but noted it is not viable due to difficulties in recruitment process.
* The committee noted that the researchers had answered no to the risk of clinically significant findings and asked whether there is a process if they are found, for example unexpected severe depression. Mrs Drury-Ruddlesden said that they intended to discuss results with immediate family and carers and pass on results to participants’ GPs. The committee noted that this would be useful information to include in the participant information sheet and consent forms.
* The committee noted that no cultural issues were noted at question p.4.2 of the application form and asked Mrs Drury-Ruddlesden what she sees as main cultural issues may arise. Mrs Drury-Ruddlesden advised that she had sought advice but didn’t think there would be engagement by Māori within this cohort. The committee advised that if Māori do happen to be involved that taonga of knowledge and tapu of head would be cultural issues to consider. Mrs Drury-Ruddlesden said they would seek advice if Māori do become involved with this study.
* Mrs Drury-Ruddlesden confirmed that some of the information from this study will be provided to industry representatives and privacy and confidentiality will be protected. The device is manufactured by the industry representatives’ company. The device uses technology developed for stroke patients and is being given free to the researchers for use in this study.
* The committee noted that the range of participants will vary widely and with this in mind it might be useful to have a more visual participant information sheet and consent form. Mrs Drury-Ruddlesden noted that she had developed an alternative template that is less wordy.
* The committee recommended two participant information sheet and consent forms – a visual one for participants with impaired cognitive function and another for caregivers so that participants could play more of a part of the consenting process.
* The Committee requested the following changes to the Participant Information Sheet:  
  + Please change “person with dementia” to “participant”.
  + Recommended ‘surrogate or caregiver’ for the other person.
  + Please provide details for a Māori contact person.
  + Please include the main exclusion criteria in lay language for the participants’ families/caregivers.
  + Please change “verbal explanation” to “oral explanation”.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

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| **4** | **Ethics ref:** | **13/CEN/128** |
|  | Title: | Does free primary health care access reduce secondary care use in a vulnerable patient group? |
|  | Principal Investigator: | Dr Lik Loh |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 September 2013 |

No member of the research team was present for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The committee agreed that while this is necessary research, the issue of main concern is that the methodology does not appear to be sound.
* The committee questioned whether the way researchers intend to approach participants for recruitment to the study, i.e by phone, is the most appropriate way to approach participants. The committee discussed whether a face to face approach may be a more respectful and careful approach. For example, someone from the research team could phone and suggest a face to face meeting to talk about the study. The committee recommended the meeting take place in a neutral environment with support available for the researcher.
* The researchers intend to gain identities of patients who have had a relatively high number of visits to hospital or Servants Health Centre, from Ministry of Health records and then phone these people to ask them to participate in the study. The committee was concerned that this will constitute a breach of privacy and further, the researchers will be dealing with a vulnerable population who may be concerned as to how the researchers got their personal information. The fact that this may expose participants to a breach of privacy is acknowledged in a circumspect way in the participant information sheet. For example, page three of the participant information sheet states: *“Again, the aim is not to point the finger at anyone, but instead to understand your situation better”.* The committee suggested that the researchers may be able to get names of potential participants by checking how many people who visited the free clinic also went to hospital rather than gaining patient identities from health records.
* The committee noted concerns about the participant information sheet and consent form. Namely, that the researchers are addressing a population that is highly likely to have a low literacy rate and the information sheet and consent form does not address that likelihood.

Decision

This application was *declined* by consensus, as the Committee did not consider that the study would meet the following ethical standards.

The committee recommends the researchers reassess the methodology and as a consequence also revise the participant information sheet and consent form so that it is more appropriate and accessible for the population they intend to reach. (*Ethical Guidelines for Observational Studies* *para 5.5 and section 6 Free and informed consent)*.

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| **5** | **Ethics ref:** | **13/CEN/129** |
|  | Title: | Child TBI Genetics Study |
|  | Principal Investigator: | Dr Kelly Jones |
|  | Sponsor: | National Institute for Stroke and Applied Neuroscience |
|  | Clock Start Date: | 12 September 2013 |

Dr Kelly Jones 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 the premise of this study is straightforward. It is based upon a previous Health Research Council funded Brain Injury Outcomes New Zealand in the Community (BIONIC) study and the pool of participants will have agreed to take part in further studies.
* The committee advised that the standard requirements for obtaining samples and the potential for use in future unspecified studies are a consent form for main study and a separate consent form for future unspecified research. DNA to be looked at again for other studies/tests therefore requires an optional consent form. Dr Jones noted the use of a separate clause in participant information that similar studies done in the past. The committee explained that the Ministry of Health guidelines for the *Use of Human Tissue for Future Unspecified Research Purposes* require a separate consent form with ‘optional’ in title. The committee noted that consent both studies can be gained at the same time.
* Dr Jones asked whether researchers could gain consent to store samples and if analyses were anticipated in future request consent from participants then. The committee noted that while such an approach is valid, gaining consent for both studies at the same time may be simpler as the researchers don’t need to try to track participants down again in the future.
* The committee noted that the age of participants for this study is not clear. Dr Jones stated that participants would have been aged 3-7 years when they had an injury and would now be between 6-11 years of age. The committee advised that the study therefore requires an assent form. Assent can be based on a case by case basis depending on the child. The committee noted that Dr Jones may want to have two forms as there is a wide range of understanding between 6 and 11 years age. Dr Jones agreed to provide assent forms to the committee.
* The committee complimented Dr Jones on the way they had completed the cultural section of the application.

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*) and (*Guidelines for the Use of Human Tissue for Future Unspecified Research purposes Part One: Consent, paras 1-4).*

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

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| **6** | **Ethics ref:** | **13/CEN/130** |
|  | Title: | Vascular Anomalies Study |
|  | Principal Investigator: | Professor Swee T Tan |
|  | Sponsor: | Gillies McIndoe Research Institute |
|  | Clock Start Date: | 12 September 2013 |

Dr Tinte Itinteang was present in person for discussion of this application.

Potential conflicts of interest

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

Dr Dean Quinn declared a potential conflict of interest, and the Committee decided that Dr Quinn would not take part in the discussion or decision relating to this application.

Summary of ethical issues

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

* Approval is sought for the use of samples for future unspecified research with a request to use blood or biopsies for tissues already stored for participant currently enrolled in CEN/12/06/023. Dr Itinteang confirmed that CEN/12/06/023 is on-going and noted that the researchers will also potentially use urine samples.
* The committee complimented the researchers on the participant information sheet noting it is clear and includes all relevant information.
* The committee complimented the researchers on the way in which they had covered cultural issues in the application and on their consultation with Māori.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:  
  + The committee noted that the consent form is drafted on the basis that the child is giving consent and asked therefore asked that the researchers tweak the consent form to reflect that the parent or caregiver is consenting on behalf of the child.
  + Please include a footer that states the version number.
  + Please state approval is given by the Central Ethics Committee.
  + Please include exclusion criteria in lay language.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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| **7** | **Ethics ref:** | **13/CEN/131** |
|  | Title: | R3ACT CTL Study |
|  | Principal Investigator: | Dr Nyree Cole |
|  | Sponsor: | Western Sydney Local Health District |
|  | Clock Start Date: | 12 September 2013 |

Dr Nyree Cole and Ms 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.

* This study involves a stem cell transplant (white blood cells) for patients who are immune compromised. The committee was satisfied that patient safety has been taken into account.
* Dr Cole emphasised for the committee that the donation of cells outlined in the study protocol is for the committee’s information only and is not part of the clinical trial in New Zealand at this time. This trial relates to the recipients only. The donors are based in Australia. The researchers will manipulate and use cells at the time of collection. Dr Cole advised that they would apply for most closely matched cells to be sent over and used on recipients here in New Zealand.
* The committee noted that SCOTT approval is pending. Dr Cole advised that they have submitted to SCOTT and are awaiting a response. The study can begin once SCOTT approval is granted.
* The committee noted that an assessment of the quality, safety or efficacy of the product to be used in this study was not covered in the Australian review body’s assessment, but was satisfied that these aspects would be covered by SCOTT.
* The committee noted question p.4.2 asks researchers to identify the main cultural issues that may arise for Māori in this study and advised that the acknowledgment of information as taonga at question p.4.1 would have been better placed at p.4.2. The committee noted that taking bloods is also presents a cultural issue and for future reference this should be identified in p.4.2.
* The Committee requested the following changes to the Participant Information Sheet:
* Please state approval has been given by the Central Ethics Committee.

Decision

This application was *approved* by consensus.

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| **8** | **Ethics ref:** | **13/CEN/132** |
|  | Title: | Stressors and autoregulation |
|  | Principal Investigator: | Dr Shieak YC Tzeng |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 September 2013 |

No member of the research team was present for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* This study aims to look at the physiological difference in responders and non-responders to mental and physical stressors.
* The committee recommended that the researchers might consider offering an orientation visit before coming in to have base-line measurements/assessments done.
* The committee noted the exclusion criteria of very low (<100/60) resting blood pressure and the likelihood of having a young population in this study for whom low blood pressure would be common.
* The committee noted that the researchers intend to conduct further analyses of MicroRNA to look at potential genetic markers linked to stroke. The committee questioned how the researchers intended to link this as participants are in their 20s and information will be held for 16 years. Those participants are potentially not at high risk of stroke.
* The committee noted the protocol was silent on the issue of pregnancy testing. Pregnancy should be an exclusion criterion given that vasoactive substances are being administered. The committee requests the researchers test for pregnancy and note that they will indicate that they will do so in the participant information sheet and consent form.
* The committee complimented the researchers on how they have noted and addressed cultural issues.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:  
  + Please include headache in the side effects profile as headaches may be common when inhaling CO2.
  + Please replace “I understand the **protocol** and risks involved […]” with “I understand the **participant information sheet** and risks involved […]” on the main consent form.
  + Please provide details for the Māori contact person.
  + Please provide the health and disability ethics committees contact number: 0800 4 384 427
  + Please include the exclusion criteria listed at f.2.1 on page 21 of the application form.
  + Please state that participants can withdraw their consent from the study at any time.
  + The committee complimented the researchers on the information provided under ‘Compensation’ but asked that you please update the Injury Prevention Rehabilitation and Compensation Act to the ‘Accident Compensation Act 2001’.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

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| **9** | **Ethics ref:** | **13/CEN/133** |
|  | Title: | Safety study of PF582 versus Lucentis in patients with age-related macular degeneration |
|  | Principal Investigator: | A/Prof Philip Polkinghorne |
|  | Sponsor: | Pfenex Inc |
|  | Clock Start Date: | 12 September 2013 |

Ms May Mendoza 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 application was well executed and provided comprehensive information for the committee to consider.
* The committee confirmed that this study is a bioequivalence study. An equivalent drug is available on the market but it is expensive and inaccessible.
* This is a first in human study and the committee noted a sentinel participant will be followed carefully before the bigger study follows where Pharmaco-dynamic and Pharmaco-kinetic parameters will be assessed.
* The committee noted that compensation cover for a commercial entity is required to be equivalent to ACC cover if applicable. Because the terminology given in the insurance information provided is imprecise, the committee recommends that the researchers check that this cover is ACC equivalent. Ms Mendoza agreed to clarify this with the study sponsor.
* The researchers have acknowledged some cultural issues (for example, face to face) but have not included the fact that taking of samples can be a cultural issue for some Maori. The committee noted that the use of tissue is a cultural issue that could be mentioned in future at p.4.2 on the application form.
* The committee noted the answer of ‘no’ at question p.4.3 on the application form and advised that consultation with Māori must be carried out unless Māori are excluded from the study. Ms Mendoza advised that consultation with Māori has been carried out in consultation with Jamie Ingrams, a team leader at Auckland Hospital. The committee asked to see the letter from Jamie Ingrams and also that Jamie’s contact details, or contact details for an appropriate Maori organisation/person where a participant can discuss any cultural issues that may arise, are stated in the participant information sheet and consent form.
* The committee sought clarification about whether the blood samples to be sent to Pfenex Inc. will be used for future unspecified research. Ms Mendoza confirmed that no further genetic studies will be done. The pharmaco kinetic and pharmaco dynamic tests will be in relation to this study only.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:  
  + The committee noted that it requires principal exclusion and inclusion criteria be included. It would be useful if you could include a statement that advises a medically qualified person would interview participants to identify whether there are any clinically significant illnesses or element that would compromise the safety of the participant thus excluding participation. For example: “You will be interviewed to make sure that the exclusion criteria do not apply to you.”
  + Please include details of the laboratory and institution names that are currently blank on pages 9, 10 and 12.
  + Please clearly state how long participants will have to consider whether or not they will take part in this study.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

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| **10** | **Ethics ref:** | **13/CEN/134** |
|  | Title: | Pesticide Exposure and Neuropsychological Effects in Children |
|  | Principal Investigator: | Prof Jeroen Douwes |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 12 September 2013 |

Prof Jeroen Douwes, Prof Janet Leathem and Ms Naomi Brewer were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The committee noted that this is an overdue and necessary study, which has the committee’s support.
* The foremost issue in this application however, is that a significant part (a questionnaire that will assess neuropsychological and behavioural effects), was not completed when the application was submitted. The committee noted that when a significant part of an application is not provided, it could decline the application but the committee is sympathetic regarding funding timeframes. The committee then questioned why the application was submitted in September when HRC funding was advised at the end of May. Prof Douwes explained that this study is part of an international study and development of the draft questionnaires takes time as they are circulated to co-investigators. Also the funding allows researchers to develop questionnaires but they can’t hire staff unless they have the full funding.
* Prof Douwes noted that previously, provisional approval was granted to allow the questionnaires to be developed. The committee noted the current guidelines differ from the previous guidelines as timeframes now apply. However, the committee would like to assist the researchers forward.
* Prof Douwes confirmed that two of study questionnaires that will be used have been submitted. The committee has reviewed both and noted the protocol also clearly explains their purpose. Prof Douwes noted that two questionnaires (BASC-2 and BRIEF), are commercially available and cover the health effects. The third questionnaire that the team is developing addresses the unique aspects of this study and will look at exposure levels, the proximity of participants’ homes to farms and whether they use pesticides. The committee was given a copy of the questionnaire to review.
* Prof Douwes explained the HRC referee report process which involves external experts who score the study. Several referees provide a report to take into account variation in scoring (conservative vs. positive). This study is one of only four studies funded by HRC so it scored in the top four of 130 applications. Therefore it has been assessed by colleagues as being of high quality and relevance.
* The committee noted that it is good to see consultation with Māori taking place. Prof Douwes explained that they have many Māori researchers working with the team including Lis Ellison-Loschmann who has substantial experience in conducting research with Māori children. They are also working with Prof Cunningham who has extensive history in Māori health research. The committee noted that the researchers have answered cultural questions well but noted that one cultural issue missed was the taking of samples. However, given the number of people the researchers are working with cultural issues will be covered. Prof Douwes advised that they have a system in place to check with Prof Cunningham and Dr Ellison-Loschmann should further issues arise.
* The committee noted the researchers’ intent to store samples for up to 10 years and asked for delineation as to whether they would be used for future research or will be closely linked to this study. Prof Douwes explained that in this study dust samples will be analysed here in New Zealand. They are restricted to how many pesticides they can measure due to cost. The samples can be analysed for other pesticides if further funding can be gained and what the researchers extract from samples will go overseas.
* The committee asked whether there is any provision for abnormal results to be sent to parents. Prof Douwes noted this is a difficult thing to show as the researchers’ currently don’t know what levels are safe. While this study may provide clues, the data won’t be conclusive. The researchers do give summary reports that show average exposure for everyone in study and how an individual child rates in relation to the average. Participants may also ask the researchers for advice regarding the summary reports. The committee asked that the researchers make clear to participants that they can request a summary of their individual results.
* Consent to samples being sent outside country (urine samples are being sent overseas). Prof Douwes explained that there is no laboratory currently in NZ that can perform the analyses. The committee was satisfied that this does not constitute future unspecified research.
* The committee asked why the researchers have provided for someone who does not wish to participate on the consent form. Prof Douwes noted that this is because the researchers would like to assess non-responder bias. He noted that he was previously requested to include this option and would be happy to remove if the committee required. The committee decided that the onus is on Prof Douwes to decide whether to include the option for this study.
* The committee asked the researchers to provide a participant information sheet and assent form for the 6-11 year old age group in this study noting that this allows the child to have some part in the process even though parents still need to give consent.
* The committee noted that the researchers had answered ‘no’ to the risk of unexpected clinically significant findings. The committee noted that the assessments on children may in fact reveal such findings. Prof Douwes thought that abnormal findings would be rare and he didn’t want to class findings as abnormal based on a screen. The committee asked that the researchers state on the consent form that participants can consent to the researchers contacting their GP if abnormal results are found.
* The Committee requested the following changes to the Participant Information Sheet Participant Information Sheet and Consent Form:  
  + Please provide contact details for the Māori support person.
  + Please make clear to participants that at the end of study the samples may be tested for other chemicals.
* Consent Form  
  + Please include “and my own individual results” in the final sentence next to the yes/ no tick box.
  + Please include a sentence stating consent for the researchers to contact GPs if abnormal results are found and a yes/no tick box.

Decision

This application was *provisionally approved* by consensus, subject to the approval of the questionnaire now available to the committee.

This questionnaire will be reviewed, and a final decision made on the application, by the Central Ethics Committee.

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| **11** | **Ethics ref:** | **13/CEN/126** **CLOSED** |
|  | Title: | The EVARREST Liver Study |
|  | Principal Investigator: | A/Prof Jonathan Koea |
|  | Sponsor: | ETHICON, Inc., a Johnson & Johnson Company |
|  | Clock Start Date: | 12 September 2013 |

Assoc Prof Koea 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.

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:

|  |  |
| --- | --- |
| **Meeting date:** | 22 October 2013, 12:00 PM |
| **Meeting venue:** | Clinical Trials Unit, Level 8 Ward Services Block, CCDHB, Wellington, 6011 |

No members tendered apologies for this meeting

The meeting closed at 4.15pm.