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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 25 November 2014 |
| **Meeting venue:** | Deloitte House |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 21 October 2014 |
| 12.30pm | New applications (see over for details) |
| 12.30-12.55  12.55-1.20  1.20-1.45  1.45-2.10  2.10-2.35  2.35-3.00  3.00-3.25  3.25-3.50  3.50-4.15 | i 14/CEN/200  ii 14/CEN/187  iii 14/CEN/188  iv 14/CEN/189  v 14/CEN/190  vi 14/CEN/194  vii 14/CEN/198  viii 14/CEN/199  ix 14/CEN/186 |
| 4.15-4.30pm | General business:  Noting section of agenda |
| 4.35pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mr Paul Barnett | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Gael Donoghue | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Cordelia Thomas | Lay (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Present |
| Dr Kay de Vries | Non-lay (observational studies) | 19/05/2014 | 19/05/2017 | Present |

## Welcome

The Chair opened the meeting at 12.13pm and welcomed Committee members, noting that no apologies were received.

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 21 October 2014 were confirmed.

## New applications

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| **1.** | **Ethics ref:** | **14/CEN/200** |
|  | Title: | HBV-001: A study of INO-1800 alone or in combination with INO-9112 for Chronic Hepatitis B patients to evaluate safety, tolerability, and immunogenicity. |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Inovio Pharmaceuticals, Inc. |
|  | Clock Start Date: | 13 November 2014 |

Professor Gane, Jane Biddulph and Faye Manu were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

* This study is an immunotherapy trial studying two experimental drugs; one drug is an immune system stimulant and the other is a DNA plasmid which contains a number of viral genes. The drug will be injected into the muscle of patients with chronic Hepatitis B infection using a new delivery system. The hope is that the muscle cells will produce viral protein, which alerts and activates the immune system to kill the virus and affect a cure rather than decrease viral load as all previous drugs do.
* This is a Phase I, first in human study which aims to enrol 126 participants who will be assigned to one of 8 groups – an active control group or one of seven treatment arms. The researchers will look to recruit 10 patients in New Zealand. Participants will have up to 26 weeks of treatment (depending on which group they have been allocated to) with a year follow up. Treatment will follow a dose escalation regime, increasing the dose after ensuring the previous dose is safe.

Summary of ethical issues (resolved)

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

* The committee noted the information in paragraph 4 on page 15 of the participant information sheet, which stated that because of the new nature of these study drugs and study device that it is possible that the media may exhibit interest in the study and its participants. The committee queried why and how this would happen. Prof Gane explained that because the study drug is a therapeutic vaccine there may be some interest in the outcome. The main interest may come from countries where other parties are developing new drugs and medical breakthroughs. They might be trying to access patients to talk about safety and tolerability. Prof Gane noted that he had not experienced this in New Zealand to date and assured the committee that any interest from third parties wouldn’t lead to the media knowing who individual participants in the study are.
* The committee noted a statement in the participant information sheet that participants’ blood will be tested for expression of specific genes involved in the immune response against the virus that may affect the way in which individual patients react to these drugs. Prof Gane confirmed that they will not do any genomic DNA sequencing in this study. This is a secondary endpoint of the study and is not optional.
* The committee noted the section of the application form that asks researchers about how their research might reduce health inequalities and queried the prevalence of HBV quoted in Māori and non-Māori. Prof Gane confirmed that HBV affects Māori more than non- Māori. The committee queried the prevalence of HBV in Pacific Island peoples. Prof Gane explained that the rates are variable noting that they tend to be high in Tongan people but some other peoples including Samoan people have a lower incidence of the disease than Māori. The committee noted that this information should be noted for questions p.4.2 and f.1.2 on the application form.
* The committee thanked the researchers for spelling out compensation issues in the participant information sheet.

Summary of ethical issues (outstanding)

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

* There are no outstanding ethical issues.

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

* Page 15: please change Northern A Health and Disability Ethics Committee to Central Health and Disability Ethics Committee.
* Page 15: please include name and contact details of the Māori support person
* Page 17 of the optional consent form for use of photos: the committee queried why photos will be taken and Prof Gane explained that they will be taken to grade the size of the swelling and get data. They will not be published. Please articulate this clearly in the participant information sheet.
* The committee noted that if the photos will be taken to grade the swelling then it is not ‘optional’ for participants. Please include information under in the side effects about the possibility that there will be an ‘injection site’ reaction.

Decision

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

* Please amend the New Zealand participant 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 and Dr Patries Herst.

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| **2** | **Ethics ref:** | **14/CEN/187** |
|  | Title: | Infection prophylaxis in central venous access devices – a randomized controlled trial comparing monthly tissue Plasminogen Activator with heparin locks in children with a CVAD |
|  | Principal Investigator: | Dr Peter Bradbeer |
|  | Sponsor: | Auckland District Health Board |
|  | Clock Start Date: | 13 November 2014 |

Dr Peter Bradbeer and Christine Rawlings 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 (resolved)

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

* The committee did not have any concerns about the safety of this study and noted that it will be a very worthwhile study should a decrease in infection rates be shown.
* Dr Bradbeer noted that it is a worthwhile thing to look at. He explained how recent studies have shown that the plasminogen activator(Alteplase) being trialled in this study can cause disruption to the biofilm that forms inside the lumen of a central venous access device and has been shown to reduce infection rates in children with haemophilia.
* The committee noted that participation in this study is restricted to patients in the Auckland region. Dr Bradbeer explained that aspects of care for patients who live outside of the Auckland region happen at shared care centres closer to their homes. The researchers are not looking at sending the Alteplase to shared care centres at this stage. However, if children from other centres have a planned stay in Auckland for 2-3 months then they will be eligible to be part of this study. There is no simplified protocol for people who are not domiciled in Auckland. At this stage the researchers intend to see whether they can demonstrate feasibility in this study and do not expect that it will be the definitive study. If feasibility is demonstrated, they will look to use a more robust methodology to answer the question and conduct a Phase II study to see whether Alteplase shows efficacy.
* If magnitude of reduction in this study population is the same as has been shown with the haemophilia patients then there is the statistical power to show it works.
* Dr Bradbeer confirmed that a universal trial number is pending and he will chase this up. The committee confirmed that the study cannot begin until a universal trial number is given.
* The committee queried whether there are statistics about rate of infection in Māori. The researchers explained that they don’t keep statistics on infection rates by ethnicity. They could pull such information out of this study but it is not a primary aim at this stage.
* For future reference, the committee noted that a possible cultural issue for question p.4.2 on the application form would be the taking of blood or tissue. Dr Bradbeer noted that this is their first time with the HDEC review process and they may not have appreciated some to the complexities when completing the application form. He noted that every patient will be offered the opportunity to enter the study regardless of ethnicity, that no body fluids will be collected as part of the study and treatment is part of standard of care treatment as part of the line care process. The committee noted that it didn’t see the need for consultation in this study but for future reference if the researchers intend to take blood, consultation would be needed.
* The committee queried where exclusion criteria of patients with a history of allergy to Gentimicin or Alteplase be included in the participant information sheet in the interests of informed consent. Dr Bradbeer explained that virtually every patient in this study will neither have had Gentimicin nor Alteplase prior to being diagnosed so in practice people are unlikely to have been challenged.

Summary of ethical issues (outstanding)

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

* There are no outstanding ethical issues.

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

* The committee noted that there are no assent forms for children in the age groups 7-12 and 12-15. Please provide these assent forms.
* Page 2: please state that the study has been reviewed by the Central Health and Disability Ethics Committee.
* Page 4, under the heading ‘What if something goes wrong?’: please change “would” to “may” be eligible for compensation.
* Page 5: Please provide name and contact details for a Māori support person.
* Page 4: please change “five” to “10” years after the study has finished. (length of time study data will be stored).

Decision

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

* Please amend the New Zealand participant 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, Mrs Gael Donoghue and Mrs Sandy Gill

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| **3** | **Ethics ref:** | **14/CEN/188** |
|  | Title: | Pediatric Vasculitis Initiative or PedVas |
|  | Principal Investigator: | Dr. Arno Ebner |
|  | Sponsor: | University of British Columbia |
|  | Clock Start Date: | 13 November 2014 |

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 Study

* This is an observational longitudinal cohort study aiming to find better ways of diagnosing and treating chronic vasculitis in children. This disease is rare in children and may not respond the same way as in adults. The study is sponsored by Canadian Institute of Health Research.
* A Canadian team has already set up a large clinician responsive database system that provides clinicians with the latest information about diagnosis and treatment of chronic vasculitis in children. This large international Canadian initiative aims to link clinical information with biomarkers from a blood, urine or saliva. The NZ part will only involve gathering clinical information and a saliva sample from 5 patients.
* Left over saliva samples will be stored in a tissue bank under optional future research for which there is a separate PIS/CF.

Summary of ethical issues (outstanding)

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

* The committee noted this is an important study. The main issue of concern for the committee is that the information given in the participant information sheets and consent forms does not give a clear indication of what this research involves, and lacks clarity about the use of any tissue collected. Therefore the committee feels participants are able to give fully informed consent.
* The committee suggested that the researcher consults with someone at the clinical trial unit who might review the application and associated documentation before a new application is made.

Specific comments

* The parent/guardian information sheet should be written using non-medical terminology where possible. For instance remove the names and abbreviations of the different forms of chronic vasculitis.
* The committee queried whether some of the information had been cut and pasted from other documents as there is inconsistency in the information given in the participant information sheet and some of the headings do not match their content. One example of this is on page 2 under ‘What will my participation in the study involve?’ which has information about why participants are eligible to enter the study but no detail about what participants will be asked to do.
* The participant information sheet doesn’t read from a parent or New Zealand perspective; it uses “you” statements rather than “your child” statements in many but not all places. There are several references to the study being conducted in Canada. There is no information about what will happen to the samples in the participant information sheet.
* It was not clear to the committee what the study population age range is. The committee noted that question a.1.5 on page 5 of the application form stated 0-19, the main participant information sheet states 2-20 years old and question f.2.1 on page 20 of the application form states 0-18 years old.
* The parent/guardian information sheet states that children diagnosed with vasculitis after the age of 18 are not eligible to take part in the study. It does not make clear at what stage of disease the participants will be eligible to enter the study (at diagnosis or when they are coming for follow up or both?).
* The language in the participant information sheets, consent and assent forms needs to be revised and rewritten in age appropriate language. 8-15 year old participants will need to give assent rather than consent and these participants must be given full information about the research in a form that they can readily understand.
* Optional participant information sheet for the use of tissue for future unspecified research: The committee noted that it would be clearer to state up front that the parent/guardian had already consented their child to providing a saliva sample and that this optional sub study is asking whether there is consent to use any of the remaining sample for future unspecified research. A clear explanation of what will happen to the samples is needed. The committee noted that this was stated in the protocol but was not clear in the information sheet.
* The committee queried the answer given at p.4.1 on page 21 of the application form that this question was not applicable as the identified patient is European. The committee queried whether Māori are excluded from the study and if so what the rationale for this is.
* If Māori are to be included in this study the researcher will also need to address the issue of tissue collection and storage from a Māori cultural perspective.
* The committee noted the researcher is the treating clinician and also will recruit participants to the study. The committee noted this as a potential conflict of interest and queried whether the researcher could get another member of staff to initially approach participants as some parents may feel obliged to participate in the study because he is their treating clinician (there is the potential for coercion).

The Central committee requests that any new application be assigned to it for review

Decision

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

National Ethics Advisory Committee (NEAC) *Ethical Guidelines for Observational Studies, Free and informed consent, paras 6.10-6.21*

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| **4** | **Ethics ref:** | **14/CEN/189** |
|  | Title: | Prevalence of cognitive impairment and mood disorders in patients with Type 2 Diabetes in the Older Person in the Middlemore Area |
|  | Principal Investigator: | Mr Aik Haw Tan |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 November 2014 |

Mr Tan was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of study

* The researcher wants to determine the prevalence of cognitive impairment and mood disorder in adults over 65 years of age who have Type 2 diabetes and to see whether there is a correlation between glycaemic control and worsening cognitive impairment and mood disorders. The researcher will test two assessment tools, the Montreal Cognitive Assessment (MOCA) and the Rowland Universal Dementia Assessment (RUDA) for co-equivalence.

Summary of ethical issues (resolved)

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

* Mr Tan explained that there is paucity of data about whether MOCA and RUDA are co equivalent in in the diagnosis of cognitive impairment in older people for whom English is not their first language.
* Mr Tan clarified for the committee that he intends to recruit up to 200 people for whom English is not their first language. He will use the RUDA for participants who do not have strong English language skills, MOCA for people whose English language skills are strong and he will look to select 50 or 60 participants in the study population(eg second generation New Zealanders) who can complete both the MOCA and RUDA assessment to see whether the results correlate.
* The committee queried the timeframe for this research and Mr Tan advised that he currently has a six month time frame and could expect to recruit about 6 participants a day through the clinic. If he can’t reach the number in that time frame he expects that the timeframe can be extended.
* The committee queried whether Mr Tan intended to recruit participants who may not be able to consent for themselves. Mr Tan explained that he will only recruit participants who can consent for themselves – if potential participants are deemed to be at a stage of dementia where they can no longer consent then they will be excluded from the study.
* The committee noted an answer given in question r.2.5 on the application form that data will be stored for a “few more years” after the study is completed. The committee reminded Mr Tan that health information must be kept for 10 years.
* The committee queried whether the Mr Tan has any statistics concerning Māori or Pacific Peoples and Mr Tan explained that this is a poorly studied area and currently the only pacific group studied to date is in Hawaii. Mr Tan said that diabetes statistics are available however and the committee noted for future reference that such information would be useful to include at question p.4.1 on the application form.
* The committee reminded Mr Tan that formal consultation with Māori is a requirement and that the guidelines provide that consultation with Māori is done in conjunction in conjunction with the locality assessment process through the DHB. Mr Tan agreed to follow up on this.
* The committee noted the answer given at question f.1.2 about reducing inequalities in health in New Zealand. The committee advised that it is helpful to include known statistical information about Pacific Island and other population groups in New Zealand. The committee reminded Mr Tan that even though this study is an observational study he will be working with people getting them to answer questionnaires.

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

* Please proof read the document as there are a few grammatical errors.
* The committee suggested that the title be reworded to: ‘the prevalence of cognitive and mood disorders in patients over 65.’
* Please be specific about the data you will collect about diabetes.
* Please state clearly in the information sheet and consent form that you will refer participants to their GP and specialist geriatric services if the results suggest an active mood disorder
* Please include a title on the consent form that clearly states it is a consent form. The committee suggested that you may wish to refer to the pro forma consent form that is on the HDEC website: http://ethics.health.govt.nz/
* Please include the name and contact details of a Māori support person.
* Please clearly state that participants who have had head injuries or recent seizures will not be eligible to enter the study. Neither will the MOCA group who are unable to converse in English be eligible.

Decision

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

* Please amend the New Zealand participant information sheet, taking into account the suggestions made by the committee (*Ethical Guidelines for Observational Studies* *paras 6.10, 6.11*).

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

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| **5** | **Ethics ref:** | **14/CEN/190** |
|  | Title: | Prevalence of VTEC and toxigenic C. dif in the Auckland community |
|  | Principal Investigator: | Dr Arlo Upton |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 November 2014 |

Dr Upton was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of study

* The researchers wish to test stool specimens that are provided to them for testing. The specific tests will be for vero-toxin producing E.coli or toxigenic C difficile to see whether it is justifiable to not regularly conduct this test.

Summary of ethical issues (resolved)

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

* The committee noted that this is an important and overdue study and it is looking forward to receiving the results.
* Although the researchers will do the additional tests without consent, the committee was satisfied that this is a low risk study, the samples that will be tested are already sent to lab for standard tests, and the researchers will dispose of the samples within a week.
* The committee queried what process is in place if a sample tests positive for VTEC or toxigenic C. A positive test may not mean that is what is causing their symptoms. The committee queried whether it would appropriate to contact individuals’ GPs prior to doing the tests so that they know. This would not be practically possible. It was suggested that during the period of time that the researchers are doing the enhanced testing they could state this on the report and that an individual can contact their GP. The committee agreed that they do not need to see this before approving the study.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **14/CEN/194** |
|  | Title: | Protein supplementation and glucose tolerance |
|  | Principal Investigator: | Dr Lee Stoner |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 13 November 2014 |

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 study

* This study will look at whether protein supplementation can improve glycaemic control in people with Type 2 diabetes. The protein used in this study is an edible form of wool derived protein and the committee noted that it would have been interested to know some background information about the protein.

Summary of ethical issues (resolved)

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

* The committee noted that the nature of the research was discussed with Prof Chris Cunningham at the Research Centre for Māori Health and Development at Massey University and queried whether that was sufficient to amount to consultation given that diabetes is prevalent in Māori. The committee agreed that this consultation process is sufficient.

Summary of ethical issues (outstanding)

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

* The committee noted that answers given in the application form about future use of human tissue indicated that genetic research is intended. The committee would like to see an optional participant information sheet and consent form for future unspecified research. Please refer to the Ministry of Health Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes for guidance on the information needed in this type of information sheet. http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0

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

* Please include a confidentiality clause on the consent form: *I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.*
* Page 2 and page 8: please change that approval has been given by the Northern B Health and Disability Ethics Committee to the Central Health and Disability Ethics committee.
* The committee noted that the researcher could explain in more detail what participants will be expected to do in the study on page 3 of 8 under the heading ‘Treatment’. For example, it isn’t clear whether participants need to eat the health bar every day for 10 weeks.
* Page 5: Please include the name and contact details for a Māori support person.
* Page 8: the committee noted the first paragraph stated the possibility that the biopsy could damage a small motor nerve branch of the muscle on the lateral aspect of the thigh and partially weaken the lower aspect of the muscle. The committee would like this risk to be stated more clearly earlier in the form.

Decision

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

* Please amend the New Zealand participant information sheet, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please submit an optional participant information sheet and consent form for future unspecified research.

This information will be reviewed, and a final decision made on the application, by the Chair, Mrs Gael Donoghue and Dr Cordelia Thomas.

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| **7** | **Ethics ref:** | **14/CEN/198** |
|  | Title: | Development of a tool for protein counting on a restricted carbohydrate diet |
|  | Principal Investigator: | Dr Amber Parry Strong |
|  | Sponsor: |  |
|  | Clock Start Date: | 13 November 2014 |

Dr Parry Strong 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 considered.

* The committee congratulated Dr Parry Strong on an excellent scientific peer review document.

Summary of ethical issues (outstanding)

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

* The committee queried whether the storage unit where the extra blood sample will be stored is part of an established tissue bank. Dr Parry Strong confirmed that the samples will be stored in a secure research freezer. The committee noted the Standard Operating Procedures definition of a tissue bank, as *“A collection of human tissue or other biological material derived from humans that is stored for potential use in research beyond the life of a specific research project.”* Establishment of a tissue bank requires HDEC review as set out in section 13 of the Standard Operating Procedures.
* The committee agreed that it would not approve the future unspecified research aspect of this study before an application for a tissue bank is reviewed and decided. The committee suggested that Dr Parry Strong make a separate application for a tissue bank for review by the Central HDEC. Once an application is decided Dr Parry Strong could submit the future unspecified research documents for this study as a substantial amendment.

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

* The committee noted that the participant information sheet was brief and would like to see more information included about what is involved in the study: study assessments, meal tests, how many blood tests and the volume of blood that will be taken and if fasted.
* Please include information as to whether participants will be reimbursed for their travel costs and have their parking costs paid.
* Please proofread the section on ACC compensation on page 3 as there is a double up on some information. Please refer to the Act as the Accident Compensation Act 2001.
* Please include the contact details for support people and services.
* Please include a confidentiality clause in the consent form. *“I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study”.*
* Please state what will happen to participants’ data if they withdraw from study.
* Please state how participants will be informed about any new information that comes to light during the study.
* Page 2 under the heading Benefits, Risk and Safety: please include the exclusion criteria from question f.2.1 on page 23 of the application form in lay language.

Decision

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

* Please amend the New Zealand participant 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, Dr Dean Quinn and Mr Paul Barnett.

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| **8** | **Ethics ref:** | **14/CEN/199** **CLOSED MEETING** |
|  | Title: | Vulnerable Children Predictive Modeling: Initial Testing and Trialing |
|  | Principal Investigator: | Ms Moira Wilson |
|  | Sponsor: | Ministry of Social Development |
|  | Clock Start Date: | 13 November 2014 |

Ms Wilson was present in person with MSD colleagues 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 researchers have contacted the Health and Disability Ethics Committee Secretariat to advise that they wish to withdraw their application as one of the planned studies in the initial phase has been deferred.

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| **1** | **Ethics ref:** | **14/CEN/186** |
|  | Title: | Roche RO6864018 treatment in Hepatitis B participants |
|  | Principal Investigator: | Prof Ed Gane |
|  | Sponsor: | Quintiles Pty Limited |
|  | Clock Start Date: | 13 November 2014 |

Professor Gane and Kerry Walker 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 are as follows.

* The committee queried whether the study drug will be kept in participants’ fridges. The researched confirmed that it will and that patients will be given a freezer pack to take home with them and the study drug container is “child proof”.
* The researchers confirmed that a clinical trial registry number is pending. The committee noted that the study cannot begin until a number is allocated.
* The committee queried the answer given at question r.3.11 that tissue would be disposed of at the end of the study or if participants wish to withdraw from the study. The researchers clarified that tissue will be transported to another tissue bank and disposed of at the end of the main study. In the optional study tissue will be stored for longer but is disposed of and there is no option to return. The committee noted for future reference that the researchers can tick more than one option at this question on the application form.
* The committee noted the information given at question r.4.1.1 of the application form about how participants might be informed of any unexpected clinically significant findings. The committee noted that any unexpected test results will be followed up with access to post-test counselling. In the interests of informed consent the committee would like to see this information stated. Prof Gane noted that some participants may not make an appointment if they are referred. Prof Gane will inform GPs of referral in writing and discuss any significant results with participants.

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

* Page 2 under the heading ‘What will happen during the study?’ Please reword the second to last sentence to read *‘you will know whether you are taking the study medication once per week or every other day’.*
* Page 5 under the heading ‘Expenses and payment’: The committee noted that the amount of remuneration that participants may receive was left blank. The researchers explained that the amount can vary and that at the time the application was submitted the budget for the second site was not signed so they couldn’t be sure that the payment was the same. The committee asked the researchers to clarify and to state this information for both sites.
* Page 12: Please state that the study has been approved by the Central Health and Disability Ethics Committee.
* In the optional information sheet for future unspecified research please state which country the tissue will be sent to.
* Please make it clear that when a tissue sample is sent overseas, unless it is sent in conjunction with a New Zealand research project, future research is likely to be considered by an overseas ethics committee without New Zealand representation.

Please state whether the donor may be contacted in the future regarding their tissue sample. Whether or not, and under what circumstances, information about future unspecified will be made available to the donor.

* Please include a confidentiality statement in the consent form.

Decision

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

* Please amend the participant information sheets and consent forms, 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, the Chair, Dr Dean Quinn and Dr Cordelia Thomas

## 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:** | Thursday, 29 January 2015 |
| **Meeting venue:** | Ground Floor, Freyberg Building, 20 Aitken Street, Wellington |

The meeting closed at 5pm.