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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 23 February 2016 |
| **Meeting venue:** | Room G.04, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 28 January 2016 |
| 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 | i 16/CEN/11  ii 16/CEN/17  iii 16/CEN/19  iv 16/CEN/21  v 16/CEN/22 |
| 2.35-3.00 | Substantial amendments (see over for details) |
|  | i MEC/07/10/141/AM08 |
| 3.00-3.15 | General business:   * Noting section of agenda |
| 3.15pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 01/07/2015 | 01/07/2018 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Cordelia Thomas | Lay (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Present |
| Dr Melissa Cragg | Non-lay (observational studies) | 01/07/2015 | 01/07/2018 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 01/07/2015 | 01/07/2018 | Apologies |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Dr Peter Gallagher.

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 28 January 2016 were confirmed. Change on page 15 of 28 – remove Code of Rights 7(4) and replace with clause 4.

## New applications

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| **1** | **Ethics ref:** | **16/CEN/11** |
|  | Title: | Wellington Asthma Research Group Tissue Bank |
|  | Principal Investigator: | Professor Julian Crane |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 January 2016 |

Prof Crane 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 (resolved)

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

* The establishment of a tissue bank is not research but the committee is required to focus its review on the governance arrangements for a tissue bank to ensure that robust and appropriate processes are in place for all aspects of tissue management and storage.
* HDEC approval for tissue banks is given for a period of 10 years, subject to the submission of annual progress reports and the progress reports should contain a brief summary of the research projects for which tissue has been made available during the year.
* HDEC approval for a tissue bank does not override the need for any study using tissue from the bank that falls within the scope of the HDEC review to be reviewed by a committee.
* The committee had no significant ethical concerns with this application.
* Prof Crane clarified for the committee that they may collect tissue for ages ranging from birth to death depending on the study. Any future use of tissue will depend upon the study protocol. Each study will include consent/assent forms depending on the nature of the study and applications within HDEC scope of review will be submitted.
* The researchers are looking to consolidate storage facilities used now for 20 years.
* The committee asked who will have access to the stored tissue. Prof Crane explained that a variety of staff currently have access but the plan is to make one person largely responsible for the day to day operation of the tissue bank. This would change over time as and when people leave the organisation or retire. Prof Crane will have overall responsibility for the tissue bank at this time.

Decision

This application was *approved* by consensus.

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| **2** | **Ethics ref:** | **16/CEN/17** |
|  | Title: | Long term follow-up of adolescent and paediatric subjects with Hepatitis C after receiving a Gilead HCV study drug |
|  | Principal Investigator: | Dr Helen Evans |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 11 February 2016 |

Dr Evans and Dr Hu 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 the Study

The primary objective of this observational Registry study is to look at the long term effectiveness and safety of anti-HCV regimens in the paediatric population as determined by assessments of growth and development. Once enrolled, participants will be followed for up to five years where they’ll have bloods taken every 6 months and complete a quality of life study (the exploratory aspect of this study), and growth and pubertal development will be assessed.

Participants enrolled in this study will have previously been enrolled in one of two Gilead sponsored drug trials that looked at different direct acting anti-viral HCV drug combinations.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee were as follows

* For future reference the committee noted that the answer given at question Kb on page 3 of the application form stated among other things that “no participants will be vulnerable” and reminded the researchers that all children are vulnerable.
* Question a.1.6 on page 5 of the application form: the committee noted the statement that all patients are well-informed of the risks involved and sign a consent form acknowledging this prior to the study. The committee noted that it would have been useful to note the risks, i.e the giving of personal information, having bloods taken and some potential discomfort in answering personal questions here.
* Question p.3.1 on page 21 of the application form: the committee noted the use of “parental studies”, was confusing language. The researchers clarified that the parental studies referred to the previous two sponsored trials that are ‘parent’ studies of this study, not parents of the participants.
* For future reference, the committee explained that the intent of question p.4.1 on page 22 of the application form is asking if the research addresses an important health issue for Mãori and if so how this study might benefit Mãori. Researchers can provide any known information/statistics about relative prevalence and prognosis in Mãori to the committee to help demonstrate their case and then how the study might benefit Mãori. If no information is available then the researchers may comment on that. The committee noted the same for question f.1.2 which asks the same question in regard to other population groups in New Zealand.

The committee requested the following changes to the participant information sheet and consent forms:

* Page 2, ‘2.0 Approval by ethics committee’, first sentence: please state “All *health* research…”
* Page 2, ‘3.0 What is the purpose of this study?’: the committee noted that the information noted here is brief and asked that the researchers explain more fully why they are doing this study; i.e that there is concern that the HCV antiviral will affect maturation and that there is concern of a viral breakthrough.
* Page 4, Table 1a, ‘Measurement of your physical development’: states that participants will have a physical assessment that will require them to be examined without clothes on. The committee asked whether the participants will be offered a chaperone or support person to be present during the examination. The researchers confirmed that they will and explained that participants will not be required to remove all their clothing at once and that they will only be asked to partially remove clothing depending on the part of the body being examined. The committee asked that the researchers state in the PIS that participants will be offered a chaperone or support person to be with them during the examination. Please also explain in lay language the term “Physical Development Stage 5”.
* Measurement of maturation stage. The committee asked whether both male and female doctors will assess participants and noted that participants might feel more comfortable if they are assessed by a doctor of the same gender.
* Page 4: ‘6.0 Who do I contact for more information or if I have concerns?’: the committee noted that the HDC does not include Mãori advocates. Please remove the words “including Mãori advocates”.
* Page 5, ‘Questionnaires’: the committee noted that given people will be deciding whether they will consent to taking part in the study, it might be good to have an example of what questions might make them uncomfortable. Please include a couple of examples and please also make clear that if participants were to feel uncomfortable about any of the questions then they don’t have to answer them.
* Page 7: the committee asked whether genetic testing will be part of the New Zealand cohort and noted that if it will then the committee will need to see a separate participant information sheet and consent form that covers this aspect. The researchers explained that participants in the NZ cohort will have bloods taken but they will not process the bloods in NZ. In this case, the participants will need to see a separate information sheet and sign a separate consent form. The committee suggested that the researchers may wish to adapt the parent/caregiver information sheet for this purpose.
* Page 8, second paragraph: the committee noted the sentence that states the study sponsor may communicate information about participants to third parties that are “located in your country, the United States,” Please replace reference to the United States with New Zealand.
* Child Assent Form for 7-15 year olds: the committee noted that the form makes no mention that they will have to remove clothing for a physical examination. Please clearly state this in the form as this is information they should know before they give assent.
* The committee noted for the researchers that if they have any questions about what to put in the information sheet and consent form documents they can contact the secretariat as the committee can only either decline or approve the provisional approval response.

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 submit separate information sheets and consent/assent forms for the optional genetic testing offered as part of this study. *(Ethical Guidelines for Intervention Studies, para 6.22)*

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

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| **3** | **Ethics ref:** | **16/CEN/19** |
|  | Title: | Targeted Testing Project |
|  | Principal Investigator: | Mr Charles Henderson |
|  | Sponsor: | Needle Exchange Services Trust (NEST) |
|  | Clock Start Date: | 11 February 2016 |

Mr Charles Henderson 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 the study

* The researcher noted that this study will look at exposure to the Hepatitis C Virus (HCV) in an at-risk group (people who inject drugs), and will measure rates of testing rather than the rate of incidence of HCV. There is a heightened exposure to HCV in this particular population who aren’t aware of what that exposure means. One of the key outcome objectives of this pilot is to encourage a better understanding of HCV among clients and to get them from a contemplative state to more active state and to improve pathways to treatment in this population.
* The researcher noted that the populations who use the needle exchange are far behind in rapid testing when compared to other marginalised populations, yet HCV is an ongoing issue.

Summary of ethical issues

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

* The committee noted that some of the people who visit the needle exchange will be transient and may not come back. The researcher confirmed that engagement is always an issue but they mitigate this by providing a seamless move on to a blood test arrangement with full clinical oversight. The researcher noted that this issue of engagement is important, especially in a transient population group but they are hoping that this will be minimal and that they will be able to more fully assess this issue in this pilot study.
* The researcher confirmed that most people in this population have a reasonable trust in needle exchanges, which should not be underestimated. An important part of what this project does is to give access and greater awareness about what is on offer at the needle exchange - i.e access to treatment and support services.
* The committee was pleased to see an application that recognises where the risk of stigmatisation in this population group comes from and how the organisation will ensure that this won’t happen (question r.6.1 on page 20 of the application form).
* For future reference, the committee noted that the Health Information Retention Regulations require that health information generated from this study be retained for a period of 10 years. (question r.2.5 on page 17 of the application form).
* For future reference, the committee explained that the intent of question p.4.1 on page 22 of the application form is asking if the research addresses an important health issue for Mãori and if so how this study might benefit Mãori. Researchers can provide any known information/statistics about relative prevalence and prognosis in Mãori to the committee to help demonstrate their case and then how the study might benefit Mãori. If no information is available then the researchers may comment on that. The committee noted the same for question f.1.2 which asks the same question in regard to other population groups in New Zealand.
* The committee noted that the researchers anticipate 350 participants in NZ and that in section O on page 3 of the application form the researchers have answered that this study will involve participants from a vulnerable population. Question p.3.2 on page 23 of the application form however, was answered ‘no’ to vulnerable population although this population will likely have individuals with co-existing mental health issues. The researcher confirmed that this is often the case and that question p.3.2 should have been answered as ‘yes.

The committee requested the following changes to the participant information sheet and consent forms:

* Page 3, ‘What are the possible benefits and risks of this study?’: the committee noted the statement that some of the questions participants might be asked may be sensitive or embarrassing and suggested that it may help to give an example or two here of what the sensitive or embarrassing questions may be.
* Page 4, ‘Who pays for the study?’: the committee noted the information that stated that all participants having the Rapid Test will receive either NEP products such as hirudoid cream and/or equipment or a voucher to the value of $20. The committee asked whether participants will get to choose which of the three things they would like to receive. The researcher confirmed that they will have this choice and the committee asked the researcher to reword this statement to reflect this.
* Page 5, ‘What happens after the study or if I change my mind?’: the committee noted the statement *“If you wish to be referred for treatment you will be asked to authorise sharing of your details with the hospital and laboratory staff, and other health professionals such as your GP.”* The committee noted that this is technically part of the study and asked that it be included as a statement on the participant consent form.

Decision

This application was *approved* by consensus.

Non-standard 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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| **4** | **Ethics ref:** | **16/CEN/21** **CLOSED MEETING** |
|  | Title: | A study assessing the trial drug ISIS 696844, following multiple doses in healthy men and women. |
|  | Principal Investigator: | Dr Richard Robson |
|  | Sponsor: | Ionis Pharmaceuticals, Inc. |
|  | Clock Start Date: | 11 February 2016 |

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| **5** | **Ethics ref:** | **16/CEN/22** |
|  | Title: | ALS-8176-510 |
|  | Principal Investigator: | Dr. James Taylor |
|  | Sponsor: | Quintiles Pty Limited |
|  | Clock Start Date: | 11 February 2016 |

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 (outstanding)

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

* The main ethical concern that the committee had was that it was not clear from the application who the unwell people are and whether they are able to consent for themselves. The committee was therefore unclear as to whether the information sheet and consent forms submitted with the application fit the intended study population. The committee noted that it would have been useful to have a member of the research team attend the meeting to discuss.
* The committee noted that participants will be unwell and will be intubated and queried how they would be able to provide written informed consent and how the researchers will ensure that an intubated person will be able to provide consent.
* The committee agreed that the participant information sheets and consent forms were complicated and could be simplified for patients who are intubated and unwell.
* It was not clear to the committee whether the researchers intend to do future unspecified research on the samples collected. If they are then a separate information sheet and consent form is needed.
* The committee noted the answer stated at question p.2.1 on page 24 of the application form that the study sites research teams will identify potential participants and provide them with an information sheet and answer any questions or concerns the participants or their friends and whanau might have. It was not clear to the committee how the research team intends to identify potential participants. For example, will they access their medical records? The committee agreed that the research team should have a pre-screening consent form in addition to the main consent forms.
* For future reference, the committee explained that the intent of question p.4.1 on page 22 of the application form is asking if the research addresses an important health issue for Mãori and if so how this study might benefit Mãori. Researchers can provide any known information/statistics about relative prevalence and prognosis in Mãori to the committee to help demonstrate their case and then how the study might benefit Mãori. If no information is available then the researchers may comment on that. The committee noted the same for question f.1.2 which asks the same question in regard to other population groups in New Zealand.
* The committee noted that the answer stated at question p.4.1 refers to the wrong article of the Treaty of Waitangi.

The committee requested the following changes to the participant information sheets and consent forms:

* Please include a short lay title.
* The committee noted that the information is complex and that the inclusion of a table that sets out what participants need to do would provide a helpful visual.
* Page 3, ‘Day 1 (Hospital)’ It was not clear to the committee what is meant by the statements in the first sentence. Does it mean that if participants come early in the day they will receive another dose but if not they won’t?
* Page 4, ‘Day 3 to 6 or Discharge (Hospital). The committee noted the statement: “Some subjects later in the study may receive study medication for up to 10 days (up to 20 doses).” and asked that it be explained who these people are and why as it confuses the area of visits. The committee advised that the application does not contain any reference to there being a long term cohort in this study. The committee requested that the researchers remove any reference to the long term cohort in this PIS/CF and that after the safety and efficacy results from the first (short term) cohort are available that the researchers submit an amendment to this study to include the long term cohort and include any supporting documentation such as PIS/CF with the amendment.
* Page 8, ‘Can I have other treatments during this research project?’ Please clarify whether participants will receive standard of care or whether they are just reliant on what they receive in this study.
* Page 8, second paragraph states that participants may need to pay for study medications during or after the research. The committee was concerned that this requirement may be unfair to participants.
* The committee noted that tracked comments in documents e.g, page 11, that are not related to HDEC requests or are not seeking clarification from HDEC should not be included in documents and should not be accepted by the HDEC secretariat.

Decision

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

* The requirement for informed consent. *(Ethical Guidelines for Intervention Studies, paras 6.8, 6.9, 6.13, 6.14, 6.15 and 6.22)*

## Substantial amendments

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| **1** | **Ethics ref:** | **MEC/07/10/141/AM08** |
|  | Title: | New Zealand Youth Tobacco Monitor 2013-2017 |
|  | Principal Investigator: | Dr Rhiannon Newcombe |
|  | Sponsor: |  |
|  | Clock Start Date: | 11 February 2016 |

Jo White, Karen McBride-Henry, Stephanie Serick and Sicily Sunseri were present in person for discussion of this amendment.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The committee reminded the researchers present of the reason that health research ethics committees are in place, namely protection of participants in health research, and noted that one of major drivers is to check that fully informed consent from participants is sought and achieved. The committee noted its deep concern at having received an annual progress report in which ‘Yes’ was answered of the question: “Has the conduct of this study over the past year complied with all relevant ethical standards” was accompanied by a document that advised that the informed consent process was not abided by. The committee noted concern that it had received no notification of this breach of ethical standard until it received the letter with the annual progress report. The committee also noted a further breach of privacy stated in the letter that a field work provider sent information that was meant to be anonymised to a third party. The committee is seeing an increasing number of applications from government departments and it is paramount that they check that the processes for securing data and for seeking informed consent are robust.
* In this case a field worker took saliva samples from children without their assent and without parental/caregiver consent. The committee asked what training the fieldworker had received and how this happened.
* The researchers explained that training is done by direct employee contract. The hiring of fieldworkers and overseeing of the work, quality of work and, that integrity of samples is maintained and done in the way HPA has previously described i.e. three stage process whereby the school principal first and foremost asks parents and then the child has the option to decline taking part. The training was a mix of face to face teleconference with fieldworkers around the country. In terms of reviewing training manual sign off, it was reviewed and mindful of all consent related procedures. Fieldworkers were supplied with the ethics approval and stipulation and as soon as the HPA heard of the breaches it stepped in immediately. The fieldworker in question was stood down and the samples were removed from the study. Measures have been put in place to stop this kind of thing happening again.
* The committee noted again that the annual progress report submitted answered ‘yes’ to the question: “Has the conduct of this study over the past year complied with all relevant ethical standards?” and asked how the lead reviewer ticked the ‘yes’ box and then included the letter that notified the committee of the breaches.
* The researchers noted that there are two different projects under the YTM umbrella and that they have two different numbers. When the researchers talked with someone in the ethics team about the fact that the Cotinine study is a sub-study they were advised that the best way to notify of the breaches was to put them in a covering letter.
* The committee asked the researchers what other research projects they are working on apart from this one. The researchers noted some New Zealand Ethics Committee approved studies, adding that it is currently a challenging environment to get ethics approval for non-health related studies.
* The committee stressed the need for the research team to audit its systems to ensure that data from other protocols is being treated with respect and confidentiality and that there are no other cases of data going to a third person incorrectly. The researchers stated that these incidents had triggered a review of their security systems and what became apparent was that they were carrying a huge amount of risk. Consequently they have reviewed the systems.
* The committee asked what attempts were made to reach the school principal where the breach occurred. The researchers explained that a situation of a personal and tragic nature meant that the principal was not contacted.
* The committee stressed that as an ethics committee it has to place its trust in researchers to follow up the procedures of confidentiality and consent set in place that they signed up to. The researchers in turn must ensure that their subcontractors realise that they are also signing up to the same commitment even though the final responsibility lies with the research team.
* The committee noted that there is a new lead investigator for this study and asked that the research team submit an amendment to via online forms to formally notify and seek approval from the committee for this change.

Decision

This amendment was *approved* by consensus.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 22 March 2016, 12:00 PM |
| **Meeting venue:** | Room G.04, Ground Floor, Ministry of Health, Freyberg Building, 20 Aitken Street, Wellington, 6011 |

No members tendered apologies for this meeting. Mrs Sandy Gill tendered apologies for the June meeting.

The meeting closed at 3.15pm